Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur

Syllabus and Scheme of

Degree of Pharmacy

(Semester, Credit & Grade system)

2013-14

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Appendix-I

Scheme of Teaching for B. Pharm. (Semester wise)
First to Eight Semesters
(Hours per week)

Sub. Code	Subject	Scheme of Teaching Hrs/week	
		Theory	Practical
Semester – I			
1.1	Pharmaceutics-I (General and Dispensing)	03	03
1.2	Pharmaceutical Chemistry-I (Inorganic)	03	03
1.3	Human Anatomy and Physiology-I	03	03
1.4	Pharmaceutical Biochemistry	03	03
1.5	Pharmacognosy and Phytochemistry-I	03	03
1.6	Hospital Pharmacy	03	-
Semester – II			
2.1	Pharmaceutics-II (General and Dispensing)	03	03
2.2	Pharmaceutical Chemistry-II (Organic)	03	03
2.3	Human Anatomy and Physiology-II	03	03
2.4	Pharmaceutical Analysis-I	03	03
2.5	Pharmacognosy and Phytochemistry-II	03	03
2.6	Statistics and Computer Application in Pharmacy	03	-
Semester – III			
3.1	Pharmaceutics-III (Unit operations)	03	03
3.2	Pharmaceutical Chemistry-III (Organic)	03	03
3.3	Pathophysiology and Clinical Biochemistry (Pathophysiology of common diseases)	03	03
3.4	Pharmacology-I	03	03
3.5	Pharmaceutical Microbiology and Immunology-I	03	03
3.6	Pharmaceutical Jurisprudence and ethics	03	-
Semester – IV			
4.1	Pharmaceutics-IV(Unit operations)	03	03
4.2	Pharmaceutical chemistry-IV(Heterocyclic and Macromolecules)	03	03
4.3	Pharmaceutical Analysis-II (Electroanalytical and Physical methods)	03	03
4.4	Pharmacology-II	03	03
4.5	Pharmaceutical Microbiology and Immunology-II	03	03
4.6	Pharmaceutical Management	03	-
Semester – V			
5.1	Pharmaceutics-V (Physical Pharmacy)	03	03
5.2	Pharmaceutical Medicinal chemistry-I	03	03
5.3	Pharmacology-III	03	03
5.4	Pharmacognosy and Phytochemistry-III (Chemistry of Natural Products)	03	03
5.5	Clinical Pharmacy	03	03
5.6	Regulatory Affairs and Intellectual Property Right	03	-
Semester – VI			
6.1	Pharmaceutics-VI (Physical Pharmacy)	03	03
6.2	Pharmaceutical Medicinal Chemistry-II	03	03
6.3	Pharmacology-IV	03	03
6.4	Pharmacognosy and Phytochemistry-IV(Recent Advances in Phytochemistry)	03	03

6.5	Clinical Pharmacotherapeutics-I	03	03
6.6	Pharmaceutical Validation	03	-
Semester – VII			
7.1	Pharmaceutics (DFT-I) (Conventional)	03	03
7.2	Pharmaceutical Medicinal chemistry-III	03	03
7.3	Pharmaceutical Analysis-III (Separation Techniques)	03	03
7.4	Clinical Pharmacotherapeutics-II	03	03
7.5	Pharmacognosy and Phytochemistry-V (Phytopharmaceutical /Herbal Technology)	03	03
7.6	Biopharmaceutics and Pharmacokinetics	03	-
Semester – VIII			
8.1	Pharmaceutics (DFT-II) (NDDS)	03	03
8.2	Pharmaceutical Biotechnology and Molecular Biology	03	03
8.3	Pharmaceutical Analysis-IV (Spectroscopy)	03	03
8.4	Pharmacognosy and Phytochemistry-VI(Industrial Pharmacognosy)	03	03
8.5	Pharmacovigilence (Drug safety)	03	-
8.6	Industrial Pharmacy	03	-
8.7	Project	-	03

Appendix-II

Scheme of Examination for B. Pharm. (Semester wise)
First to Eight Semesters

Sub. Code	Subject	Scheme of Examination						Minimum Marks for passing		Total Marks in Theory / practical (Credits)
		Theory		Practical		Theory Int. Marks	Pract. Int. Marks	Theory	Practical	
		Hrs	Marks	Hrs	Marks					
Semester – I										
1.1	Pharmaceutics-I (General and Dispensing)	3	80	4	80	20	20	45	45	3 + 2 = 5
1.2	Pharmaceutical Chemistry-I (Inorganic)	3	80	4	80	20	20	45	45	3 + 2 = 5
1.3	Human Anatomy and Physiology-I	3	80	4	80	20	20	45	45	3 + 2 = 5
1.4	Pharmaceutical Biochemistry	3	80	4	80	20	20	45	45	3 + 2 = 5
1.5	Pharmacognosy and Phytochemistry-I	3	80	4	80	20	20	45	45	3 + 2 = 5
1.6	Hospital Pharmacy	3	80	-	-	20	-	45	-	3
		Total Marks (credits) for the Semester								**28**
Semester – II										
2.1	Pharmaceutics-II (General and Dispensing)	3	80	4	80	20	20	45	45	3 + 2 = 5
2.2	Pharmaceutical Chemistry-II (Organic)	3	80	4	80	20	20	45	45	3 + 2 = 5
2.3	Human Anatomy and Physiology-II	3	80	4	80	20	20	45	45	3 + 2 = 5
2.4	Pharmaceutical Analysis-I	3	80	4	80	20	20	45	45	3 + 2 = 5
2.5	Pharmacognosy and Phytochemistry-II	3	80	4	80	20	20	45	45	3 + 2 = 5
2.6	Statistics and Computer Application in Pharmacy	3	80	-	-	20	-	45	-	3
		Total Marks (credits) for the Semester								**28**
Semester – III										
3.1	Pharmaceutics-III (Unit operations)	3	80	4	80	20	20	45	45	3 + 2 = 5
3.2	Pharmaceutical Chemistry-III (Organic)	3	80	4	80	20	20	45	45	3 + 2 = 5
3.3	Pathophysiology and Clinical Biochemistry (Pathophysiology of common diseases)	3	80	4	80	20	20	45	45	3 + 2 = 5
3.4	Pharmacology-I	3	80	4	80	20	20	45	45	3 + 2 = 5
3.5	Pharmaceutical Microbiology and Immunology-I	3	80	8*	80	20	20	45	45	3 + 2 = 5
3.6	Pharmaceutical Jurisprudence and ethics	3	80	-	-	20	-	45	-	3
		Total Marks (credits) for the Semester								**28**

Sub. Code	Subject	Scheme of Examination						Minimum Marks for passing		Total Marks in Theory / practical (Credits)
		Theory		Practical		Theory Int. Marks	Pract. Int. Marks	Theory	Practical	
		Hrs	Marks	Hrs	Marks					
Semester – IV										
4.1	Pharmaceutics-IV (Unit operations)	3	80	4	80	20	20	45	45	3 + 2 = 5
4.2	Pharmaceutical chemistry-IV (Heterocyclic and Macromolecules)	3	80	6	80	20	20	45	45	3 + 2 = 5
4.3	Pharmaceutical Analysis-II (Electroanalytical and Physical methods)	3	80	6	80	20	20	45	45	3 + 2 = 5
4.4	Pharmacology-II	3	80	4	80	20	20	45	45	3 + 2 = 5
4.5	Pharmaceutical Microbiology and Immunology-II	3	80	8*	80	20	20	45	45	3 + 2 = 5
4.6	Pharmaceutical Management	3	80	-	-	20	-	45	-	3
		Total Marks (credits) for the Semester								**28**
Semester – V										
5.1	Pharmaceutics-V (Physical Pharmacy)	3	80	6	80	20	20	45	45	3 + 2 = 5
5.2	Pharmaceutical Medicinal chemistry-I	3	80	6	80	20	20	45	45	3 + 2 = 5
5.3	Pharmacology-III	3	80	6	80	20	20	45	45	3 + 2 = 5
5.4	Pharmacognosy and Phytochemistry-III (Chemistry of Natural Products)	3	80	6	80	20	20	45	45	3 + 2 = 5
5.5	Clinical Pharmacy	3	80	6	80	20	20	45	45	3 + 2 = 5
5.6	Regulatory Affairs and Intellectual Property Right	3	80	-	-	20	-	45	-	3
		Total Marks (credits) for the Semester								**28**
Semester – VI										
6.1	Pharmaceutics-VI (Physical Pharmacy)	3	80	6	80	20	20	45	45	3 + 2 = 5
6.2	Pharmaceutical Medicinal Chemistry-II	3	80	6	80	20	20	45	45	3 + 2 = 5
6.3	Pharmacology-IV	3	80	6	80	20	20	45	45	3 + 2 = 5
6.4	Pharmacognosy and Phytochemistry-IV (Recent Advances in Phytochemistry)	3	80	6	80	20	20	45	45	3 + 2 = 5
6.5	Clinical Pharmacotherapeutics-I	3	80	6	80	20	20	45	45	3 + 2 = 5
6.6	Pharmaceutical Validation	3	80	-	-	20	-	45	-	3

Total Marks (credits) for the Semester **28**

Sub. Code	Subject	Scheme of Examination						Minimum Marks for passing		Total Marks in Theory / practical (Credits)
		Theory		Practical		Theory Int. Marks	Pract. Int. Marks	Theory	Practical	
		Hrs	Marks	Hrs	Marks					
Semester – VII										
7.1	Pharmaceutics (DFT-I) (Conventional)	3	80	6	80	20	20	45	45	3 + 2 = 5
7.2	Pharmaceutical Medicinal chemistry-III	3	80	6	80	20	20	45	45	3 + 2 = 5
7.3	Pharmaceutical Analysis-III (Separation Techniques)	3	80	6	80	20	20	45	45	3 + 2 = 5
7.4	Clinical Pharmacotherapeutics-II	3	80	6	80	20	20	45	45	3 + 2 = 5
7.5	Pharmacognosy and Phytochemistry-V (Phytopharmaceutical /Herbal Technology)	3	80	6	80	20	20	45	45	3 + 2 = 5
7.6	Biopharmaceutics and Pharmacokinetics	3	80	-	-	20	-	45	-	3
		Total Marks (credits) for the Semester								**28**
Semester – VIII										
8.1	Pharmaceutics (DFT-II) (NDDS)	3	80	12*	80	20	20	45	45	3 + 2 = 5
8.2	Pharmaceutical Biotechnology and Molecular Biology	3	80	8*	80	20	20	45	45	3 + 2 = 5
8.3	Pharmaceutical Analysis-IV (Spectroscopy)	3	80	6	80	20	20	45	45	3 + 2 = 5
8.4	Pharmacognosy and Phytochemistry-VI (Industrial Pharmacognosy)	3	80	6	80	20	20	45	45	3 + 2 = 5
8.5	Pharmacovigilence (Drug safety)	3	80	-	-	20	-	45	-	3
8.6	Industrial Pharmacy	3	80	-	-	20	-	45	-	3
8.7	Project[#]	-	-	-	100	-	-	-	45	2
	* hrs in two days	Total Marks (credits) for the Semester								**28**

Credits : 28 x 8 = 224

Marks : Theory : 600 x 8 = 4800

Practical : 500 x 8 = 4000

8800

[#]Project Report:-

The topic for the project shall be based on the practical work/theoretical/review oriented/any topic from current Pharmaceutical development and shall be assigned to him/her by the respective guide from faculty member (Maximum eight students per teacher) immediate from the date of the commencement of the eighth semester

Report to be submitted in the institute and examination (seminars on the project report) shall be conducted on the college level.

Examination/Evaluation of the project shall be based on introduction and information retrieval systems, organization of material and references in the project report, representation, skill in oral presentation, questioning and defending and finally on the report.

The project report shall be compulsory for each and every student of Semester VIII.

Appendix-III

Distribution of Marks & Credits

Subject Code	Subject	Maximum Marks (Credits)		Total Marks (Credits)
		Theory	**Practical**	
Semester – I				
1.1	Pharmaceutics-I (General and Dispensing)	100 (3)	100 (2)	200 (5)
1.2	Pharmaceutical Chemistry-I (Inorganic)	100 (3)	100 (2)	200 (5)
1.3	Human Anatomy and Physiology-I	100 (3)	100 (2)	200 (5)
1.4	Pharmaceutical Biochemistry	100 (3)	100 (2)	200 (5)
1.5	Pharmacognosy and Phytochemistry-I	100 (3)	100 (2)	200 (5)
1.6	Hospital Pharmacy	100 (3)	-	100 (3)
	Total			**1100 (28)**
Note - Students having Diploma in Pharmacy and admitted to First year have to appear one theory paper of Semester II viz. 2T-6 Statistics and Computer applications in pharmacy				
Semester – II				
2.1	Pharmaceutics-II (General and Dispensing)	100 (3)	100 (2)	200 (5)
2.2	Pharmaceutical Chemistry-II (Organic)	100 (3)	100 (2)	200 (5)
2.3	Human Anatomy and Physiology-II	100 (3)	100 (2)	200 (5)
2.4	Pharmaceutical Analysis-I	100 (3)	100 (2)	200 (5)
2.5	Pharmacognosy and Phytochemistry-II	100 (3)	100 (2)	200 (5)
2.6	Statistics and Computer Application in Pharmacy	100 (3)	-	100 (3)
	Total			**1100 (28)**
Semester – III				
3.1	Pharmaceutics-III (Unit operations)	100 (3)	100 (2)	200 (5)
3.2	Pharmaceutical Chemistry-III (Organic)	100 (3)	100 (2)	200 (5)
3.3	Pathophysiology and Clinical Biochemistry (Pathophysiology of common diseases)	100 (3)	100 (2)	200 (5)
3.4	Pharmacology-I	100 (3)	100 (2)	200 (5)
3.5	Pharmaceutical Microbiology and Immunology-I	100 (3)	100 (2)	200 (5)
3.6	Pharmaceutical Jurisprudence and ethics	100 (3)	-	100 (3)
	Total			**1100 (28)**
Note-Students admitted on the basis of Diploma in Pharmacy directly to to Second year (Third semester) have to appear one theory paper of Semester II viz. 2T-6 Statistics and Computer applications in pharmacy				
Semester – IV				
4.1	Pharmaceutics-IV (Unit operations)	100 (3)	100 (2)	200 (5)
4.2	Pharmaceutical chemistry-IV (Heterocyclic and Macromolecules)	100 (3)	100 (2)	200 (5)

4.3	Pharmaceutical Analysis-II (Electroanalytical and Physical methods)	100 (3)	100 (2)	200 (5)
4.4	Pharmacology-II	100 (3)	100 (2)	200 (5)
4.5	Pharmaceutical Microbiology and Immunology-II	100 (3)	100 (2)	200 (5)
4.6	Pharmaceutical Management	100 (3)	-	100 (3)
	Total			**1100 (28)**
Semester – V				
5.1	Pharmaceutics-V (Physical Pharmacy)	100 (3)	100 (2)	200 (5)
5.2	Pharmaceutical Medicinal chemistry-I	100 (3)	100 (2)	200 (5)
5.3	Pharmacology-III	100 (3)	100 (2)	200 (5)
5.4	Pharmacognosy and Phytochemistry-III (Chemistry of Natural Products)	100 (3)	100 (2)	200 (5)
5.5	Clinical Pharmacy	100 (3)	100 (2)	200 (5)
5.6	Regulatory Affairs and Intellectual Property Right	100 (3)	-	100 (3)
	Total			**1100 (28)**
Semester – VI				
6.1	Pharmaceutics-VI (Physical Pharmacy)	100 (3)	100 (2)	200 (5)
6.2	Pharmaceutical Medicinal Chemistry-II	100 (3)	100 (2)	200 (5)
6.3	Pharmacology-IV	100 (3)	100 (2)	200 (5)
6.4	Pharmacognosy and Phytochemistry-IV (Recent Advances in Phytochemistry)	100 (3)	100 (2)	200 (5)
6.5	Clinical Pharmacotherapeutics-I	100 (3)	100 (2)	200 (5)
6.6	Pharmaceutical Validation	100 (3)	-	100 (3)
	Total			**1100 (28)**
Semester – VII				
7.1	Pharmaceutics (DFT-I) (Conventional)	100 (3)	100 (2)	200 (5)
7.2	Pharmaceutical Medicinal chemistry-III	100 (3)	100 (2)	200 (5)
7.3	Pharmaceutical Analysis-III (Separation Techniques)	100 (3)	100 (2)	200 (5)
7.4	Clinical Pharmacotherapeutics-II	100 (3)	100 (2)	200 (5)
7.5	Pharmacognosy and Phytochemistry-V (Phytopharmaceutical /Herbal Technology)	100 (3)	100 (2)	200 (5)
7.6	Biopharmaceutics and Pharmacokinetics	100 (3)	-	100 (3)
	Total			**1100 (28)**
Semester – VIII				
8.1	Pharmaceutics (DFT-II) (NDDS)	100 (3)	100 (2)	200 (5)
8.2	Pharmaceutical Biotechnology and Molecular Biology	100 (3)	100 (2)	200 (5)
8.3	Pharmaceutical Analysis-IV (Spectroscopy)	100 (3)	100 (2)	200 (5)
8.4	Pharmacognosy and Phytochemistry-VI (Industrial Pharmacognosy)	100 (3)	100 (2)	200 (5)
8.5	Pharmacovigilence (Drug safety)	100 (3)	-	100 (3)
8.6	Industrial Pharmacy	100 (3)	-	100 (3)
8.7	Project	-	100 (2)	100 (2)

	Total	**1100 (28)**

Year	**Semester**	**Total Marks (Credits)**
First year	Semester-I	1100 (28)
	Semester-II	1100 (28)
Second year	Semester-III	1100 (28)
	Semester-IV	1100 (28)
Third year	Semester-V	1100 (28)
	Semester-VI	1100 (28)
Fourth year	Semester-VII	1100 (28)
	Semester-VIII	1100 (28)
	Total Marks (Credits)	**8800 (224)**

APPENDIX IV

Scheme of Practical Examination

Duration of each practical examination : As presented in the syllabus.

Maximum marks allotted to each practical : 80

Suggested distribution of marks -

Question Number 1 : Synopsis	10
Question Number 2 : Major Experiments	30
Question Number 3: Minor Experiments	20
Question Number 4 : Viva voce	20

Note: The major and minor experiments are set by the examiners considering the scope of subject as described in the syllabus.

Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur
B. Pharm. Syllabus
Credit-grade based performance and assessment system (CGPA)
Features of the Credit System
With effect from Academic Session 2013- 2014

1. Features of the Credit System:-

- Graduate Programme in Pharmaceutical Sciences would be of credits prescribed by the Board of Studies in Pharmaceutical Sciences.
- One credit course of theory will be of one clock hour per week running for 15 weeks.
- One credit course of practical will consist of 1.5 hours of laboratory exercise for 15 weeks.
- Credit system offer more options to students and has more flexibility.
- Students can get requisite credits from the concerned colleges where she/he is mutually permitted on terms mutually agreed to complete the same and be eligible to appear for term end examination.
- The term end examination, however, shall be conducted by the RTM Nagpur University, Nagpur in the allotted centres.

2. FIRST YEAR MAY DIVIDE INTO TOTAL TWO SEMESTERS (SEMESTER-I AND SEMESTER-II) AND SHALL HAVE TOTAL 12 THEORY COURSES, 10 PRACTICAL COURSES.

- 12 Theory courses x 3 credits = 36 credits
- 10 Laboratory courses x 2 credits = 20 credits

Total = 56 credits

3. SECOND YEAR MAY DIVIDE INTO TOTAL TWO SEMESTERS (SEMESTER-III AND SEMESTER-IV) AND SHALL HAVE TOTAL 12 THEORY COURSES, 10 PRACTICAL COURSES.

- 12 Theory courses x 3 credits = 36 credits
- 10 Laboratory courses x 2 credits = 20 credits

Total = 56 credits

4. THIRD YEAR MAY DIVIDE INTO TOTAL TWO SEMESTERS (SEMESTER-V AND SEMESTER-VI) AND SHALL HAVE TOTAL 12 THEORY COURSES, 10 PRACTICAL COURSES.

- 12 Theory courses x 3 credits = 36 credits
- 10 Laboratory courses x 2 credits = 20 credits

Total = 56 credits

5. FOURTH YEAR MAY DIVIDE INTO TOTAL TWO SEMESTERS (SEMESTER-VII AND SEMESTER-VIII) AND SHALL HAVE TOTAL 12 THEORY COURSES, 10 PRACTICAL COURSES.

- 12 Theory courses x 3 credits = 36 credits
- 9 Laboratory courses x 2 credits = 18 credits
- 1 Project x 2 credits = 2 credits

Total = 56 credits

6. EVERY STUDENT SHALL COMPLETE 224 CREDITS IN EIGHT SEMESTERS

- First year (semester I and II) = 56 credits
- Second year (semester III and IV) = 56 credits
- Third year (semester V and VI) = 56 credits
- Fourth year (semester VII and VIII) = 56 credits

Eight semester total credits = 224 credits

7. SCHEME OF SYLLABUS AND CREDIT SYSTEM

• Three credits (theory) = 100 marks

Internal Examination	External Examination
(20 marks)	(80 marks)

• Two credits (Practical) = 100 marks

Internal Examination	External Examination
(20 marks)	(80 marks)

The Internal Assessment marks for theory subject should be based on average marks of two Class Tests.

c) The internal assessment marks for practical subject should be based upon actual performance in one class test (10 marks) and Day to day assessment in the practical class test (10 marks).

8. **Grades:-**Marks would be converted to grades as shown in Table 1.

Table 1: Conversion of marks to grades in credit system

Marks Obtained	Grade	Grade Points
100-85	O	10
84-75	A	9
74-65	B	8
64-55	C	7
54-50	D	6
49-45	E	5
44 and less	F	0-Failed (Clear course)

a. A student failed to score minimum 45% marks in each head of passing and in aggregate shall be given F grade.
b. A student who passes the internal tests but fails in Term End Examination of a course shall be given F grade.
c. Student with F grade in a course would be granted credit for that course but not the grade for that course.

9. The computation of Semester Grade Point Average (SGPA) and Cumulative Grade Point Average (CGPA) of an examinee shall be as given below:-

i. The marks will be given in all examinations which will include college assessment marks and the total marks for each Theory /Practical shall be converted into Grades as per Table 1. SGPA shall be calculated based on Grade Points corresponding to Grade as given in Table 1 and the Credits allotted to respective Theory / Practical shown in the scheme for respective semester.

ii. SGPA shall be computed for every semester and CGPA shall be computed only in VIII semester. The CGPA in VIII semester shall be calculated based on SGPA of last four semesters as per following computation :-

$$\text{SGPA} = \frac{C1 \times G1 + C2 \times G2 + \ldots\ldots + Cn\ Gn}{C1 + C2 + \ldots\ldots + Cn}$$

Where C1 = Credit of individual Theory / Practical
G1 = Corresponding Grade Point obtained in the Respective Theory / Practical

$$\text{CGPA} = \frac{(\text{SGPA})\ V \times (\text{Cr})\ V + (\text{SGPA})\ VI \times (\text{Cr})\ VI + (\text{SGPA})\ VII \times (\text{Cr})\ VII + (\text{SGPA})\ VIII \times (\text{Cr})\ VIII}{(\text{Cr})\ V + (\text{Cr})\ VI + (\text{Cr})\ VII + (\text{Cr})\ VIII}$$

Where, (SGPA) V = SGPA of V Semester
(Cr) V = Total Credits for V Semester
(SGPA) VI = SGPA of VI Semester
(Cr) VI = Total Credits for VI Semester
(SGPA) VII = SGPA of VII Semester
(Cr) VII = Total Credits for VII Semester
(SGPA) VIII = SGPA of VIII Semester

(Cr) VIII = Total Credits for VIII Semester

CGPA	**Final Grade**
9.0 – 10	O
8.0 – 8.9	A
7.0 – 7.9	B
6.0 – 6.9	C
5.5 – 5.9	D
5.0 – 5.4	E
4.9 and less	F

Final Mark List will only show the grade and grade points and not the marks.

10. CGPA equal to 6.75 and above shall be considered as equivalent to First Class which shall be mentioned on Grade Card of VIII Semester as a foot note.

11. CGPA equal to 7.00 and above shall be considered as distinction in that particular subject

12. **ACADEMIC CALENDAR AND TERMS**

The terms and academic activities of the college affiliated to RTM, Nagpur University under CGPA shall be as prescribed by the University for respective academic session.
Beginning of First Term (Semester I, III, V and VII) : As per University academic calendar
Beginning of Second Term (Semester II, IV, VI and VIII) : As per University academic calendar
Vacation : As per University academic calendar

Syllabus
SEMESTER-I

Subject code: 1T1
Subject: Pharmaceutics-I (General and Dispensing)
THEORY: **45 Hours (3 Hrs. /week)**

1. **Pharmaceutical literature** **4 Hrs**
   Historical background to the profession of Pharmacy in India in brief. Brief overview of status of Pharmaceutical industry in India. Introduction to Pharmacopoeias. Development of Indian Pharmacopoeia and other Compendia including B.P.,U.S.P., N.F., Ph Eur., International pharmacopoeia and B.P.C.

2. **Introduction to pharmacological terms & Dosage forms** **6 Hrs**
   Introduction to important pharmacological terms. Definition of drug and dosage form. The desirable properties of a dosage form, the need of dosage form

3. **Routes of administration** **3 Hrs**
   Introduction and Classification on the basis of nature, routes of administration with respect to dosage form design

4. **Prescription** **3 Hrs**
   Prescription and its parts, handling of prescription, labeling and packing, prescription containers and closure, pricing the prescription

5. **Posology** **5 Hrs**
   Meaning, factors affecting dose, calculation of doses for infants and children.

6. **Liquid dosage forms for internal administration** **8 Hrs**
   Aromatic water, syrups, elixirs, spirits, tinctures

7. **Liquid dosage forms for external administration** **8 Hrs**
   Mouthwash, gargles, linctus, douches, enemas, sprays, throat paint, Inhalation, Lotion, liniment, eye drop, ear drop, nasal drop

8. **Ointment** **4 Hrs**
   Classification of ointment and ointment bases, factors governing selection of ointment base, preparation, packaging, labeling, and storage of Ointments.

9. **Pastes and jellies** **4 Hrs**
   Definition, bases of paste, preparation of paste and storage. Introduction to different types of jellies and their preparation.

Subject code: 1P1
Subject: Pharmaceutics-I (General and Dispensing)
PRACTICAL: **3 Hrs. /week**
Compounding and dispensing of prescriptions:

AROMATIC WATER

1. Prepare and submit Camphor Water I.P. 1966.
2. Prepare and submit Chloroform Water I.P. 1966.
3. Prepare and submit Conc. Cinnamon Water B.P. 1980.

SYRUP

4. Prepare and submit Simple Syrup I.P. 1966.
5. Prepare and submit Orange Syrup B.P. C. 1973
6. Prepare and submit Ferrous sulphate Syrup U.S.P. 1990.

ELIXIR

7. Prepare and submit Simple elixir I.P. 1966.
8. Prepare and submit Piperazine citrate elixir I.P. 1966.

SOLUTION

9. Prepare and submit Weak iodine solution I.P. 1966.
10. Prepare and submit Aqueous iodine solution I.P. 1966

SPIRIT

11. Prepare and submit Chloroform Spirit I.P. 1966

LOTION

12. Prepare and submit Calamine Lotion B.P. 1980
13. Prepare and submit Oily Calamine Lotion B.P. 1980

LINIMENT

15. Prepare and submit Camphor Liniment I.P. 1966
16. Prepare and submit Ammoniated Camphor Liniment I.P. 1966

17. Prepare and submit White Liniment B.P. 1980

GLYCERIDES

18. Prepare and submit Phenol Glycerides I.P. 1966
19. Prepare and submit Borax Glycerides I.P. 1966
20. Prepare and submit Tannic acid Glycerides I.P. 1966

MUCILAGE

21. Prepare and submit Starch Mucilage I.P. 1985

OINTMENT

22. Prepare and submit Simple Ointment I.P. 1966
23. Prepare and submit Sulphur Ointment I.P. 1966
24. Prepare and submit Zinc oxide Ointment I.P. 1966
25. Prepare and submit Nonstaining iodine Ointment B.P.C. 1973
26. Prepare and submit Nonstaining iodine Ointment with methyl salicylate B.P.C. 1973
27. Prepare and submit Emulsifying Ointment I.P. 1966
28. Prepare and submit Hydrous emulsifying Ointment I.P. 1966

CREAMS

29. Prepare and submit Zinc Oxide Cream B.P. 1980
30. Prepare and submit Cold Cream
31. Prepare and submit Vanishing Cream

PASTE

32. Prepare and submit Zinc oxide and gelatin Paste
33. Prepare and submit Bentonite and glycerine Paste

Subject code: 1T2
Subject: Pharmaceutical Chemistry-I (Inorganic)
THEORY: 45 Hours (3 Hrs. /week)

An outline of methods of preparation, uses, sources of impurities, tests for purity and identity, including limit tests for iron, arsenic, lead, heavy metals, chloride, sulphate and special tests if any of the following classes of inorganic pharmaceuticals included in Indian Pharmacopoeia.

1. Pharmaceutical aids and necessities **8 Hrs**

- Acids and bases
- Buffers
- Antioxidant
- Water

2. Major Intra and Extra-cellular Electrolytes **8 Hrs**

- Electrolytes used in replacement therapy
- Physiological acid base balance
- Electrolytes used in acid base therapy
- Electrolytes combination therapy

3. Gastrointestinal Agents **7 Hrs**

- Acidifying agents
- Antacids
- Protective and Adsorbents
- Saline Cathartic

4. Topical Agents **6 Hrs**

- Protective
- Antimicrobial
- Astringents

5. Dental Products **3 Hrs**

- Dentifrices
- Anti-caries agents.

6. Inorganic Radio Pharmaceuticals: **8 Hrs**

- Measurement of radioactivity
- Artificial radioactivity
- Radio-opaque contrast media
- Application of radiopharmaceuticals

7. Miscellaneous Agents **5 Hrs**

- Poisons and antidotes
- Respiratory stimulants

- Expectorants and emetics
- Tableting aids and Suspending agents

Subject code: 1P2
Subject: Pharmaceutical Chemistry-I (Inorganic)
PRACTICAL: **3 Hrs. /week**

1. Limit test (As Per I. P.)
   - Chloride
   - Sulphate
   - Iron
   - Heavy Metals
   - Lead and Arsenic
2. Preparation of following inorganic pharmaceuticals and perform Identification tests
   - Aluminium hydroxide
   - Barium Sulphate
   - Calcium carbonate
   - Ferrous Sulphate
   - Potassium citrate
   - Boric acid
3. To check swelling power of Bentonite
4. To check acid neutralising capacity of aluminium hydroxide gel
5. To determine percentage of iodine in potassium iodide
6. To determine percentage of ammonium salts in potash alum
7. To study adsorption property of heavy kaolin

Subject code: 1T3
Subject: Human Anatomy and Physiology-I
THEORY: **45 Hours (3 Hrs. /week)**

1. Basic terminologies used in anatomy and physiology, levels of structural organization, body cavities and their membrane, planes and sections. **3 Hrs**
2. Cell physiology: cell membrane (structure, functions, transport of substances and membrane potentials), cell organelles (structure and functions), and cell cycle. **8 Hrs**
3. Elementary tissues of human body: epithelial, connective, muscular and nervous tissues. Their subtypes and characteristics. **4 Hrs**
4. Haempoitic system: blood-composition and functions, plasma proteins, RBC-genesis and fate, anaemia, WBC-types and physiological role, platelets, mechanism of blood coagulation and blood groups. **9 Hrs**
5. Cardiovascular system: anatomy of heart, action potential & contraction of contractile fibres, conducting system, ECG, cardiac cycle, blood vessels and circulation (pulmonary, coronary, systemic and portal), blood pressure-maintenance and regulation. **9 Hrs**
6. Lymphatic system: lymph-(composition, functions and circulation), lymph node (structure and functions), spleen (structure and function). **4 Hrs**
7. Respiratory system: Anatomy of respiratory organs and their functions, exchange of respiratory gases, transport of respiratory gases, regulation of respiration (nervous and chemical), respiratory volumes and vital capacity. **8 Hrs**

Subject code: 1P3
Subject: Human Anatomy and Physiology-I
PRACTICAL: **3 Hrs. /week**

1. Study of microscope.
2. Determination of bleeding time of own blood.
3. Determination of clotting time of own blood.
4. Determination of haemoglobin content of own blood.

5. Determination of RBC count of own blood.
6. Determination of WBC count of own blood.
7. Determination of differential count of own blood (DLC).
8. Determination of blood group.
9. Recording of pulse rate and blood pressure.
10. Recording of ECG.
11. Recording of breathing rate.
12. Determination of vital capacity.
13. Study of gross anatomy & physiology of various organs/system by models/charts/specimens:
    i) Circulatory system
    ii) Lymphatic system
    iii) Respiratory system
14. Histology: Microscopic study of different types of primary tissues and organs from permanent slides.

Subject code: 1T4
Subject: Pharmaceutical Biochemistry
THEORY: **45 Hours (3 Hrs. /week)**

1. Carbohydrates **12 Hrs**

Introduction, biological roles, classification and reactions of carbohydrates (oxidation, reduction, hemiacetal/ hemiketal formation, acetate / ketal formation, Osazone formation), Discussion of glycolysis, Glycogenesis, Glycogenolysis, TCA cycle, Amphibolic nature of TCA cycle, HMP shunt, Gluconeogenesis, Uronic acid pathway, Galactose metabolism, Blood glucose regulation.

2. Proteins **11 Hrs**

Introduction to protein and amino acid, biological roles, classification of protein and amino acid, Reactions of amino acids(acid base behavior, isoelectric pH, optical activity, N-acylation, ninhydrin reaction, reaction with flurodinitrobenzene, Dansyl chloride reaction, Edman reaction, Schiff base formation, esterification, side chain reactions), Introduction to primary, secondary, tertiary and quaternary protein structure, General reactions of amino acids (Transamination, Deamination, Decarboxylation), Urea cycle, Porphyrins, Bile pigment, Hyperbilirubinemia.

3. Lipid **10 Hrs**

Introduction, biological roles, classification of lipids and fatty acids, reactions of lipid and fatty acids, Properties of fatty acids (physical properties, formation of esters, acid value, iodine value, ester value, rancidity, hydrolysis of fats, hydrogenation of oils), β-oxidation of fatty acid (saturated acid) formation and breakdown of ketone bodies, Biosynthesis of eicosanoids, phospholipid and sphingolipid and prostaglandin.

4. **Nucleic acids** **7 Hrs**

Definition of DNA and RNA, nitrogenous bases, nucleosides, nucleotides, structure of DNA, Types of RNA, their structure and their biological role, Translocation and Transcription.

5. **Enzyme** **5 Hrs**

Defination and Classification of enzymes, Biological role, ,Properties and chemical tests, Factors affecting enzyme activity, Michaclis – Menten equation and meanings of Km and Vmax, Mechanism of enzyme action, Enzyme inhibition.

Subject code: 1P4
Subject: Pharmaceutical Biochemistry
PRACTICAL: **3 Hrs. /week**

1. Identification of carbohydrates (Glucose, fructose, lactose, maltose,sucrose, starch)
2. Identification of proteins and amino acid (Casein, albumin, gelatin)
3. Identification of lipids (Cholesterol).
4. Estimation of protein (Biuret method).
5. Estimation of glucose in blood (Folin / Glucose-oxidase method).
6. Estimation of creatinine (Alkaline picrate method).

Subject code: 1T5
Subject: Pharmacognosy and Phytochemistry-I
THEORY: **45 Hours (3 Hrs. /week)**

1. **Introduction to Pharmacognosy**
   Origin, scope and history of Pharmacognosy. Classification of crude drugs. **3 Hrs**
2. **Various factors affecting quality and purity of crude drugs**
   (a) Exogenous factors
   (b) Endogenous factors
   (c) Preparation of crude drug for market
   (d) Adulteration and types of adulteration **4 Hrs**
3. Alternative and Complementary systems of medicine – Ayurveda, Unani, Siddha, Homeopathy, Chinese medicine and Aromatherapy **4 Hrs**
4. Introduction to different plant metabolites **14 Hrs**

   Primary metabolites
   a. Brief study of basic metabolic pathways and formation of different primary metabolites through these pathways- Photosynthesis
   b. Correlation of primary and secondary metabolites
   c. Introduction to following primary metabolites- Carbohydrates, Lipids and Proteins

   Secondary metabolites
   a. Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
   b. Introduction to following secondary metabolites - Glycosides, Flavonoids, Saponins, Alkaloids, Tannins, Terpenoids, Steroids.

5. Study of organized crude drugs viz. - Stems, Barks, Woods, Roots, Rhizomes, Leaves, Flowers, Fruits, Seeds. **10 Hrs**
6. Cell differentiation and ergastic cell contents – Cell wall, Parenchymatous tissue, Epidermis, Epidermal trichomes, Stomata, Endodermis, Cork tissue, Collenchymas, Schlereides, Fibers, Xylem, Phloem, Secretary tissues, and Ergastic cell contents. **10 Hrs**

Subject code: 1P5
Subject: Pharmacognosy and Phytochemistry-I
PRACTICAL: **3 Hrs. /week**

1. Study on the laboratory microscope
2. Study of morphology and microscopy of crude drugs
   i. Stems- Kalmegh
   ii. Bark- Arjuna, Ashoka
   iii. Wood- Sandalwood, Quassia
   iv. Roots- Jalap, Ashwagandha
   v. Rhizomes and stolons- Turmeric, Picrrorhiza, Acorus
   vi. Leaves- Tulsi
   vii. Flowers- Saffron
   viii. Fruits- Lemon peel, Bael
   ix. Seeds- Isapghula, Nux vomica
3. To perform preliminary phytochemical screening of crude drugs for the identification of different primary and secondary metabolites i.e. carbohydrates, lipids, proteins, alkaloids, tannins, saponins, flavonoids, steroids.

Subject code: 1T6
Subject: Hospital Pharmacy
THEORY: **45 Hours (3 Hrs. /week)**

1. **Hospital pharmacy – organization and management:** Organisational structure – staff, infrastructure & work load statistics. Organization, Administration and functions. Roles & responsibilities of hospital pharmacist. **5 Hrs**
2. **Hospital drug policy:** Pharmacy and therapeutic committee (PTC), Hospital formulary, Hospital committees: Infection committee, Research and Ethical committee **4 Hrs**
3. **Hospital pharmacy services:** Procurement & warehousing of drugs and pharmaceuticals Inventory control: definition, methods of inventory control, ABC, VED, EOQ, lead time, safety stock. **7 Hrs**
4. **Drug distribution in Hospitals:** Outpatient and inpatient services, unit dose, drug distribution system, Floor wards stock system, satellite pharmacy services, bed side pharmacy, distribution of controlled drugs. **6 Hrs**
5. **Central sterile service:** Advantages, management, plan, location, Sterilization of rubber gloves, syringes, needles, catheters, surgical instruments, powders and other materials. **5 Hrs**
6. **Health accessories:** Wheel chairs, canes, crutches, bedpans, vaporizers, syringes, needles, clinical thermometers. **3 Hrs**
7. **Drug house management:** Selection of site, space layout and legal requirements. Codification, handling of drug store and other hospital supplies. **4 Hrs**
8. **Channels of distributions**: Differnet channels of distribution of drugs. Importance and objectives of purchasing, selection of suppliers. Credit information, tenders, contract and price determination and legal requirements thereto. **5 Hrs**
9. **Community pharmacy:** Concept, development of community pharmacy in India, role of community pharmacist **3 Hrs**
10. **Patient counseling:** Meaning, steps involved in patient counseling, interactions with doctors **3 Hrs**

SEMESTER-II

Subject code: 2T1
Subject: Pharmaceutics-II (General and Dispensing)

THEORY: **45 Hours (3 Hrs. /week)**

1. **Pharmacutical calculation** **9 Hrs**
   Percentage calculation, allegation method, calculation involving preparation of isotonic solutions, proof spirit, weights and measures.
2. **Dispersed system** **8 Hrs**
   Emulsion-Definition, types and identification test, merits and demerits, uses and classification of emulsifying agents, preparation and stability of emulsion
   Suspension- Definition, types, merits and demerits, uses and classification of suspending agents, flocculated and deflocculated suspension, preparation and stability of suspension.
3. **Suppositories and pessaries** **4 Hrs**
   Bases, additives, preparation, displacement value and calculations
4. **Powders** **4 Hrs**
   Definition, advantages, disadvantages, special problems, types of powders – tablet trichurates, granular effervescent powder, cachets,simple and compound powder, dusting powder, insufflations, snuffs, dentifrices, Effervecent granule
5. **Tablets** **4 Hrs**
   Definition, types, processing, excipients, defects, evaluation, tablet coating,
6. **Capsules** **4 Hrs**
   Hard and soft gelatin capsules, processing and their evaluation.
7. **Surgical aids** **3 Hrs**
   Surgical dressing, sutures, ligatures and their standards
8. **Extraction** **5 Hrs**
   Infusion, decoction, maceration and percolation process and preparation involving them
9. **Blood and plasma substitutes** **4 Hrs**

Subject code: 2P1
Subject: Pharmaceutics-II (General and Dispensing)
PRACTICAL: **3 Hrs. /week**
Compounding and dispensing of prescriptions:

EMULSIONS

1. Prepare and submit Olive oil Emulsion(Wet gum method)
2. Prepare and submit Olive oil Emulsion(Dry gum method)
3. Prepare and submit Turpentine oil Emulsion(Wet gum method)
4. Prepare and submit Castor oil Emulsion(Wet gum method)
5. Prepare and submit Olive oil Emulsion(Wet gum method)

MIXTURES

6. Prepare and submit Mixture containing Soluble medicaments.
7. Prepare and submit Mixture containing Indiffusible solids.
8. Prepare and submit Mixture containing Diffusible solids.
9. Prepare and submit Mixture containing Slightly soluble liquid
10. Prepare and submit Mixture containing Small dose of potent medicament.

SUPPOSITORIES

11. Prepare and submit Soap-Glycerine Suppositories.
12. Prepare and submit Glycerol Suppositories
13. Prepare and submit Bismuth subgallate Suppositories.

TINCTURE

14. Prepare and submit Orange tincture.
15. Prepare and submit Lemon tincture.
16. Prepare and submit Ginger tincture.
17. Prepare and submit Compound cardamom tincture.

EYE DROP

18. Prepare and submit Atropine sulphate eye drop.

EAR DROP

19. Prepare and submit Chloramphenicol ear drop.

NASAL DROP

20. Prepare and submit Ephedrine hydrochloride Nasal drop.

POWDERS

21. Prepare and submit Aspirin (Compound Powder)
22. Prepare and submit Phenacetin (Compound Powder)
23. Prepare and submit Sodium bicarbonate (Compound Powder)
24. Prepare and submit Codeine phosphate Powder(containing small dose of potent medicament)
25. Prepare and submit Dizepam Powder(containing small dose of potent medicament)
26. Prepare and submit Dusting Powder (Bulk Powder)

TOOTH POWDER

27. Prepare and submit Tooth Powder

GARGLES

28. Prepare and submit Gargles containing potassium chlorate

MOUTHWASH

29. Prepare and submit zinc Sulphate Mouthwash

INHALATION

30. Prepare and submit Eucalyptus oil Inhalation

THROAT PAINT

31. Prepare and submit Throat paint.

ENEMAS

32. Prepare and submit Magnesium sulphate Enema.

POULTIES

35. Prepare and submit Kaoline Poultics.

CAPSULE

36. Prepare and submit Rifampicin capsule.

DOUCHES

37. Prepare and submit Potassium permanganate Solution (douche)

GRANULES

38. Prepare and submit Citrotartaric acid effervescent granules
39. Prepare and submit Granules ready for compression.

LINCTUS

40. Prepare and submit Codeine Linctus.

Subject code: 2T2
Subject: Pharmaceutical Chemistry-II (Organic)
THEORY: **45 Hours (3 Hrs. /week)**

1.Stucture and Properties

Concept of structural theory, atomic orbitals, electronic configuration, molecular orbital theory, hybridization, intermolecular and intramolecular forces, bonds, polarity of bonds, electronegativity, hydrogen bond and its effects, physical properties of the molecules. **10 Hrs**

Organic compounds their sources and scope. Detection and estimation of elements (C, H, O, N, S, P and Halogens). Empirical and molecular formula. **5 Hrs**

Nomenclature, physical properties, uses and detection of organic compounds of following classes
Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes and Ketones, Amines, Phenols, Alkyl Halides, Carboxylic acids, Cycloalkanes. **10 Hrs**

2.Stereochemistry

Stereoisomerism, various projections of molecules, optical activity, enantiomers, diastereomers, Racemic modification and resolution, Geometrical Isomerism, Nomenclature in stereoisomerism (RS, EZ, DL configurations), sequence rule. Configuration and conformations, Bayer strain theory. **10 Hrs**

Introduction to chemical reactions

Functional Groups, Types of organic reactions, substrate, reagent, hemolytic and heterolytic reactions, factors affecting organic reactions. **10 Hrs**

Subject code: 2P2
Subject: Pharmaceutical Chemistry-II (Organic)
PRACTICAL: **3 Hrs. /week**

1 To study the apparatus used in the organic chemistry laboratory.
2 To determine the melting point of the organic compound.
3 To determine the boiling point of the organic compound.
4 To determine the solubility of the organic compound.
5 To detect the functional groups present in the organic compound.
6 To build the structure of organic compounds by using stereomodels.
7 To synthesize benzamide from ammonia and benzoyl chloride.
8 To synthesize Phenyl Benzoate from benzoyl chloride.
9 To synthesize Benzoic acid from benzamide.
10 To synthesize benzoyl glycine from benzoyl chloride and glycine.

Subject code: 2T3
Subject: Human Anatomy and Physiology-II
THEORY: **45 Hours (3 Hrs. /week)**

1. **Digestive system:** Anatomy and physiology of organs of digestive system. Secretion and functions of – salivary glands, stomach, small intestine, large intestine pancreas and liver. Digestion and absorption of Carbohydrate, Proteins and Fats. **8 Hrs**
2. **Nervous system:** Organization, Neurons – membrane potentials as signals, Cerebrum – functional areas, sensory & motor pathways, anatomy and physiology of other parts of brain (mid brain, pons, medulla oblongata, cerebellum, thalamus and hypothalamus), extra pyramidal system, limbic system, Spinal cord (Structure and reflexes), cranial nerves (Names and functions) Autonomus nervous system (Sympathetic and parasympathetic). **12 Hrs**
3. **Urinary system:** Anatomy and physiology of urinary system, structure of Nephron, formation of urine, micturition, Renin angiotensin system. **7 Hrs**
4. **Endocrine system:** Physiology of hormones of hypothalamus-pituitary gland, adrenal gland, thyroid gland, pancreas and gonads (testis and ovary). **8 Hrs**
5. **Integumentary system:** Structure and functions of skin, regulation of body temperature. **4 Hrs**
6. **Sense organs:** Anatomy and physiology of eye and ear, sense of smell and taste. **6 Hrs**

Subject code: 2P3
Subject: Human Anatomy and Physiology-II
PRACTICAL: **3 Hrs. /week**

1. Recording of body temperature.
2. Study of human skeleton.
3. Study of axial skeleton.
4. Study of appendicular skeleton.
5. Study of joints.
6. Study of gross anatomy & physiology of various organs/system by models/charts/specimens:
    a. Digestive system
    b. Central nervous system
    c. Urinary system
    d. Eye
    e. Ear
7. Histology: Microscopic study of different types of primary tissues and organs from permanent slides.
8. Study of first aid measures.
9. Urine analysis for normal and abnormal constituents.
10. Demonstration of simple muscle curve using computer software.
11. Demonstration of the effect of temperature on muscle contraction using computer software.
12. Demonstration of muscle fatigue curve using computer software.

Subject code: 2T4
Subject: Pharmaceutical Analysis-I
THEORY: **45 Hours (3 Hrs. /week)**

1. **Quantitative Analysis**: **6 Hrs**.
   - Pharmaceutical analysis- Definition and scope
   - Different techniques of analysis
   - Methods of expressing concentration
   - Primary and secondary standards
   - Precision and accuracy
   - Errors-concept, classification and minimization of errors

An outline of theoretical consideration, general methodologies, applications (in drug analysis and quality control), advantages, limitation, standardization and assay procedures of following volumetric techniques.

2. **Acid-Base Titration**: **7 Hrs**
   - Neutralization theory & Neutralization curves
   - Theory of Indicators

3**. Non-aqueous Titrations:** **7 Hrs**
   - Theory, advantages and limitation
   - Non-aqueous solvents
   - Acidimetry and Alkalimetry in non-aqueous solvents

4. **Redox Titrations** **7 Hrs**
   - Redox titration curve and detection of end point/redox indicators
   - Potassium permanganate
   - Ceric Ammonium Sulphate
   - Iodimetry and Iodometry

5. **Gravimetric Analysis** **7 Hrs**
   - Practical aspect of gravimetric analysis-precipitation, digestion, filtration, washing, drying/ignition of precipitate
   - Purity of the precipitate:co-precipitation and post precipitation
   - Thermogravimetry

6. **Precipitation Titrations**: **5 Hrs**
   - Mohr's method
   - Volhard's method
   - Adsorption indicators.

7. **Complexometric Titrations**: **6 Hrs**
   - Types of EDTA - titrations with applications in Pharmaceuticals.
   - Titration of mixtures, selectivity, masking and demasking
   - Metal ion indicators- theory of the visual use of metal ion indicator

Subject code: 2P4
Subject: Pharmaceutical Analysis-I
PRACTICAL: **3 Hrs. /week**

1. Assay of aspirin I.P.
2. Assay of boric acid I.P.
3. Assay of ammonium chloride I.P.
4. Assay of sodium bicarbonate I.P.
5. Preparation and standardization of 0.1 N potassium permangnate solution.
6. Preparation and standardization of 0.1 N iodine solution.
7. Assay of hydrogen peroxide I.P
8. Assay of phenol I.P
9. Preparation and standardization of 0.1 N silver nitrate Solution
10. Assay of sodium chloride I.P.
11. Assay of potassium chloride I.P.
12. Preparation and standardization of EDTA solution.
13. Assay of calcium gluconate I.P.

Subject code: 2T5
Subject: Pharmacognosy and Phytochemistry-II
THEORY: **45 Hours (3 Hrs. /week)**

1. **Carbohydrates and related compounds** **12 Hrs**
   Introduction, Collection, Preparation, Chemistry, Chemical tests and uses of-
   Sugars- Honey, Sorbitol, Mannitol, Carmel, Liquid glucose
   Starches and Modified starches
   Cellulose and their derivatives
   Polysaccharides from marine sources- Agar, Sodium alginate, and Carrageenan
   Other Polysaccharides- Bael, Dextrin, Dextran, Inulin, Pectin
   Gums- Acacia, Tragacanth, Gum Karaya, Guar gum
   Mucilages- Isapghula
2. **Lipids** **9 Hrs**
   Definition, method of extraction, chemistry
   Study of method of production, chemical constituents, tests, uses of the following drugs-
   Fixed Oils: Castor oil, olive oil, Linseed oil, Seasame oil, Soya oil, Cod liver oil, Shark liver oil.
   Fats: Cocoa butter, Kokum butter
   Waxes: Bees wax, Wool fat, Carnauba wax
3. **Natural fibers** **6 Hrs**
   Introduction, Classification, Chemical tests and uses of following fibers- Cotton, Jute, Silk, Wool.
4. **Drugs of mineral and Herbo-mineral origin** **8 Hrs**
   Introduction, Classification, Chemical tests and uses of following drugs- Talc, Chalk, Kaolin, Kieselghur, Bentonite, Calamine and Shilajit
5. **Drugs of animal origin** **5 Hrs**
   Musk, Civet, Cantharides, Shellac, and Gelatin.
6. **Enzymes of Pharmaceutical interest** **5 Hrs**
   Papain, Pancreatin, Pepsin, Hyaluronidase, Streptokinase.

Subject code: 2P5
Subject: Pharmacognosy and Phytochemistry-II
PRACTICAL: **3 hrs. /week**

1. Identification of following crude drugs by morphological study and chemical tests -
   Tragacanth, Acacia, Karaya gum, Guar gum, Sodium alginate, Agar, Starch, Honey and Pectin
2. Evaluate following drugs by their morphological characters and chemical tests -
   Castor oil, Wool fat, Bees wax and Sesame oil
3. Detection of adulteration of fixed oil by chemical tests
4. Identification of mineral drugs chemical tests -
   Talc, Chalk, Kaolin, Kieselguhur and Bentonite
5. Determination of swelling factor of Isapghula seeds
6. Identification of fibers by morphological characters and chemical tests - Cotton, Jute, Silk, Wool
7. Isolation of starch from potato

Subject code: 2T6
Subject: Statistics and Computer Application in Pharmacy
THEORY: **45 Hours (3 Hrs. /week)**

1. **Basic Concepts of Statistics** **7 Hrs**
   Introduction, Statistical data, data graphics, types of variables, collection and classification of data, frequency distribution, measure of central tendency, arithmetic mean, mode and median, measure of data dispersion – range, mean deviation and standard deviation
2. **Linear Regression and Correlation** **7 Hrs**

Concepts and method for studying correlation, significance of testing of correlation coefficient, lines of regression, properties of coefficient, methods to find regression lines, application of linear regression

3. **Analysis of Variance (ANOVA)** **5 Hrs**
   Meaning, techniques, one way and two way ANOVA

4. **Statistical Inferences** **7 Hrs**
   Sampling method, estimation, statistical tests for rejection of discordant data – Q test, Z test, Confidence interval estimation, Testing, testing procedure, 't' test, Chi square test, confidence interval in Bio-assays

5. **Computer Fundamentals** **7 Hrs**
   Introduction, history of computer development, hardware, general components of computer viz, memory, various input-output units, C.P.U., secondary storage units, low and high level languages, unit of capacity, classification of computers on the basis of size and capacity

6. **Internet and Networking** **4 Hrs**
   Introduction and history, connecting to internet, World Wide Web and Browser, e-mail. Need and advantages of networking – Concepts of LAN and WAN

7. **Operating system and MS-OFFICE** **4 Hrs**
   Types and functions of operating systems, overview of DOS and UNIX operating system. Introduction to word, Excel and Power-point

8. **Applications** **4 Hrs**
   Application of computer in Pharmacy viz, drug information, storage and retrieval, pharmacokinetics, drug design, crude drug identification, hospital and clinical pharmacy, pharmaceutical analysis, diagnosis and data analysis, bulk drug and pharmaceutical manufacture

SEMESTER-III

Subject code: 3T1
Subject: Pharmaceutics-III (Unit Operations)
THEORY: **45 Hours (3 Hrs. /week)**

1. **Size reduction** **5 Hrs**
   Theories and objectives of size reduction, Factors affecting size reduction, Mechanisms of size reduction with examples of equipment.
2. **Size separation** **5 Hrs**
   Screens, Air separation methods – cyclone separator, bag filter
3. **Mixing** **5 Hrs**
   Types of mixtures, Equipment's used in mixing of powders, liquids and semi-solids.
4. **Mass Transfer** **6 Hrs**
   Molecular diffusion in gases & liquids, mass transfer in turbulent & laminar flow, theories of interphase mass transfer.
5. **Flow of fluids** **7 Hrs**
   Fluid statics, dynamics, transportation of fluids-reciprocating, rotary and centrifugal pumps, fluid flow rate measuring devices-orifice meter, pitots meter, venturi meter and rotameter.
6. **Transportation of solids** **5 Hrs**
   Belt, screw, bucket and pneumatic conveyer for transportation of solids
7. **Filtration** **7 Hrs**
   Mechanisms and types of filtration, Theories of filtration, factors influencing filtration, filter aids, Study of Filter press, Meta filter, rotary drum filter and disc filter.
8. **Centrifugation** **5 Hrs**
   Principle of centrifugation, study of perforated basket centrifuge, tubular bowl centrifuge, conical disc centrifuge.

Subject code: 3P1
Subject: Pharmaceutics-III (Unit operations)
PRACTICAL: **3 Hrs. /week**

1. Sieve analysis to study particle size distribution.
2. Study of particle sedimentation using Stoke's law.
3. Study of filter aid on rate of filtration.
4. Study of effect of centrifugation speed and time on rate of sedimentation.
5. Study of thickeners area using batch settling method.
6. Study of efficiency of pump.
7. Determination of hardness of water sample.
8. Reduction of particle size using ball mill.
9. Determination of drag coefficient for particles settling method.
10. Study of sedimentation behavior using suspending agents.
11. Engineering Drawing sheets (Minimum 5 Experiments): Alphabets and numbering, and Geometric constructions (minimum 5 per sheet)

Subject code: 3T2
Subject: Pharmaceutical Chemistry-III (Organic)
THEORY: 45 Hours (3 Hrs. /week)

Preparation and reactions of the following groups of compounds. (Including mechanism of reaction wherever necessary)

1. Aliphatic and alicyclic compounds like alkanes alkenes, alkynes, cycloalkanes. **10 Hrs**
2. Alkyl Halides **5 Hrs**
3. Aldehydes and Ketones **7 Hrs**
4. Aliphatic and Aromatic Amines **5 Hrs**
5. Organometallic Compounds, Grignards reagent, organolithium compounds, their preparation and synthetic applications. **7 Hrs**
6. Aromatic Hydrocarbons, Huckel's Rule, Aromatic Character, structure of benzene, resonance, orientation of substitution, Electrophilic aromatic substitution reaction. **5 Hrs**
7. Phenols **3 Hrs**
8. Carboxylic Acids and their derivatives. **3 Hrs**

Subject code: 3P2
Subject: Pharmaceutical Chemistry-III (Organic)
PRACTICAL: 3 Hrs. /week

1 To detect the functional group present in the organic compound.
2 To identify the organic compound and prepare its derivative.
3 To synthesize 2,4,6 trinitrophenol (Picric acid) from Phenol.
4 To synthesize p-iodo nitro benzene from p-nitroaniline.
5 To synthesize 1-phenyl Azo-2- Napthol from aniline and 2- Napthol.
6 To synthesize benzanilide from aniline and benzoyl chloride.

Subject code: 3T3
Subject: Pathophysiology and Clinical Biochemistry (Pathophysiology of common diseases)
THEORY: 45 Hours (3 Hrs. /week)

1. Cell injury, death and adaptations: Causes of cell injury, mechanism of cell injury, forms and morphology of injury. Cellular adaptations of growth and differentiation, cellular ageing. **5 Hrs**
2. **Inflammation:** Basic mechanism involved in the process of inflammation and repair, alteration in vascular permeability and blood flow, migration of WBCs, acute and chronic inflammation, and mediators of inflammation and brief outline of the process of repair. **5 Hrs**
3. **Pathophysiology of common diseases:** Rheumatoid arthritis, gout, epilepsy, parkinsonism, schizophrenia, depression and mania, hypertension, angina, myocardial infraction, congestive heart failure, atherosclerosis, diabetes mellitus, peptic ulcer, hepatitis, cirrhosis, acute and chronic renal failure, asthma, chronic obstructive pulmonary disease, sexually transmitted diseases (syphilis, gonorrhea, AIDS), pneumonia, typhoid, urinary tract infection, tuberculosis, leprosy, malaria, dysentery (bacterial and amoebic), and common types of neoplasm. **20 Hrs**
4. **Clinical Biochemistry:** Analytical, therapeutic and diagnostic use of enzymes. Diseases related to carbohydrate metabolism – Galactosemia, glycogen storage diseases. Diseases related to protein metabolism – disorders associated with urea cycle, disorders associated with metabolism of various amino acids, Kwashiorkar and marasmus. Disorders associated with lipid metabolism – hyperlipidemia, fatty liver and obesity. **10 Hrs**
5. Liver function tests, Renal function tests, Gastric function tests and Pancreatic function tests. **5 Hrs**

Subject code: 3P3

Subject: Pathophysiology and Clinical Biochemistry (Pathophysiology of common diseases)
PRACTICAL: 3 Hrs. /week

1. Different methods for collection of blood.
2. Estimation of Haematocrit
3. Estimation of packed cell volume.
4. Physical examination of urine
5. Chemical examination of urine. (Protein, Albumin)
6. Chemical test of urine sugar, ketone bodies.
7. Test for bile salt and bile pigment in urine.
8. Determination of glucose in serum.
9. Estimation of serum cholesterol.
10. Estimation of serum triglycerides.
11. Estimation of serum proteins.
12. Estimation of SGOT and SGPT in serum
13. Estimation of creatinine in serum and urine
14. Estimation of urea in serum and urine.
15. Estimation of serum acid and alkaline phospatase.
16. Estimation of bilirubin content in blood

Note: Animal blood or discarded blood from pathology lab. or blood bank can be used for above mentioned experiments.

Subject code: 3T4
Subject: Pharmacology-I
THEORY: 45 Hours (3 Hrs. /week)

1. General Pharmacology **20 Hrs**

A. Definition, introduction and scope of pharmacology **2 Hrs**
B. Different routes of drug administration in humans and laboratory animals **2 Hrs**
C. Pharmacokinetics:
   1. Principles and applications of pharmacokinetics. **2 Hrs**
   2. Transport across cell membrane **2 Hrs**
   3. Absorption of drug and factors affecting absorption **3 Hrs**
   4. Drug distribution: physiolological barriers and factors affecting **3 Hrs**
   5. Biotransformation of drugs **4 Hrs**
   6. Excretion of drugs **2 Hrs**
D. Pharmacodynamics: General, molecular & biochemical aspects of drug actions, receptors, drug receptor interactions, factors modifying drug effects. **4 Hrs**

Study of Pharmacological action of following classes of drug with respect to classification of recently available drugs, Mechanism of action, Receptors, Adverse effects, Drug interaction, Contraindication and Therapeutic uses:

2. Pharmacology of drugs acting on ANS **22 Hrs**

A. Introduction- Neurohumoral transmission **2 Hrs**
B. Adrenergic and cholinergic receptors **3 Hrs**
C. Adrenergic drugs **3 Hrs**
D. Adrenergic receptor blockers **3 Hrs**
E. Cholinomimetics, anticholinesterases **3 Hrs**
F. Anti- muscarinic agents **3 Hrs**
G. Ganglionic blockers and stimulants **3 Hrs**
H. Neuromuscular blocking agents **2 Hrs**

3. Bio-Assay **3 Hrs**

Scope, Principle and Design of official bioassays.

Subject code: 3P4
Subject: Pharmacology-I
PRACTICAL: 3 Hrs. /week

1. Introduction to experimental Pharmacology.

2. Study of laboratory animals used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Preparation of various physiological salts solution used in experimental pharmacology.
5. Demonstration of rat dissection in general.
6. To isolate ileum, fundus, trachea, uterus and anacoccygeous muscle and to record concentration response curve using these tissues of rats.
7. Demonstrate the effect of cholinergic agents on rabbit eye.
8. Demonstrate the effect of anticholinergic agents on rabbit eye.
9. Demonstrate the effect of local anesthetic on rabbit eye.

Subject code: 3T5
Subject: Pharmaceutical Microbiology and Immunology-I
THEORY: 45 Hours (3 Hrs. /week)

1. Introduction to Microbiology: 10 Hrs
Scope and applications to Pharmaceuticals, Whittaker's five kingdom concept, classification of microbes into bacteria, rickettsia, actinomycetes, fungi, protozoa, algae and viruses. Historical developments – contributions of Alexander Fleming, Antony Van Leeuwenhoek, Louis Pasteur, Robert Koch and Paul Ehrlich.

2. Microscopy: 6 Hrs
Principle and applications of compound, Dark-field, phase contrast and fluorescence microscope. Different parts of compound microscope, resolving power, magnification power, numerical aperture and working distance. Electron microscopy – SEM and TEM

3. Microbiology of Bacteria: 12 Hrs
Size, shape and arrangement, structure of bacterial cell, reproduction, growth, growth requirements, growth curve, culture media, measurements of bacterial growth, colony characteristics, methods for isolation. Identification and preservation of microbial cultures.
Genetics – DNA, RNA, Protein synthesis, transposons, plasmids. Mutation- Types of mutation, mutagenic agents.

Recombination in bacteria – conjugation, transformation and transduction, Replica plate technique.

4. Microbiology of fungi: 4 Hrs
Introduction, classification, nutrition and reproduction

5. Microbiology of Viruses: 6 Hrs
Introduction, general properties, structure, bacteriophage – lytic growth cycle and lysogeny. Human viruses – cultivation and multiplication, quantitative determination.

6. Microbial diseases (Etiology, pathophysiology, transmission, prevention and treatment) 7 Hrs
Bacterial and viral diseases i.e. Tuberculosis, AIDS, Leprosy, Syphilis, Influenza, Typhoid, Malaria. Cholera. Fungal infections.

Subject code: 3P5
Subject: Pharmaceutical Microbiology and Immunology-I
PRACTICAL: 3 Hrs. /week

1. Study of equipments and apparatus used in experimental microbiology.
2. Preparation and sterilization of culture media.
3. Aseptic transfer techniques.
4. Isolation of pure culture by streak plate method.
5. Isolation of pure culture by pour plate method.
6. Study of cultural characteristics of microorganisms.
7. Total count of micro-organisms by direct microscopy method.
8. Viable count of micro-organisms by plate count method.
9. Viable count of micro-organisms by spread plate method.
10. Smear preparation and fixation.
11. Study of bacterial morphology by simple staining.
12. Study of bacterial morphology by negative staining.
13. Study of bacterial morphology by Gram staining.
14. Motility studies.
15. Biochemical tests (Starch hydrolysis, Lipid hydrolysis, Casein hydrolysis, Oxidase test and Catalase test)

Subject code: 3T6
Subject: Pharmaceutical Jurisprudence and Ethics
THEORY: **45 Hours (3 Hrs. /week)**

1. **Historical background of Drug legislation in India.** **3 Hrs**
   Origin and nature of pharmaceutical legislation in India, Its scope and objective, new drug policy and future trends.
2. **Code of Ethics for Pharmacists.** **2 Hrs**
   Principles and significance of professional ethics, critical study of code of pharmaceutical ethics drafted by PCI regarding to pharmacist in relation to his job, to his trade, and to medical profession.
3. **Pharmacy Act 1948.** **6 Hrs**
   Definition, PCI and State Councils, Composition and Function, Preparation of Registers and qualifications for entry into registers, Educational Regulation and Approval of Courses and Institutions, Offences and Penalties
4. **Medicinal and Toilet Preparations (Excise Duties) Act 1955, Rules 1976.** **4 Hrs**
   Definitions, restricted and unrestricted preparations, Manufacturing in bond and outside bond
5. **Drug Price Control Order** **2 Hrs**
6. **Drugs and Magic Remedies (Objectionable Advertisements) Act 1954.** **2 Hrs**
   Definitions, Prohibited Advertisement, Savings
7. **Drugs and Cosmetics Act 1940, Rules 1945**. **15 Hrs**
   Definitions, Advisor bodies DTAB and DCC Composition and function, Drug Control Laboratories and Government Analysts, Drug inspectors, Licensing Authorities, Controlling Authorities and Customs Collectors Provisions Governing Import, Manufacture and Sale of Drugs. Labeling and Packaging of Drugs. Provisions applicable to manufacture and Sale of Ayurvedic Drugs, Provisions Governing Import, Various offences and corresponding Penalties, Broad content of various Schedules of the Drugs and Cosmetic Act and Rules.
8. **Narcotic Drugs and Psychotropic Substances Act, and Rules there under** **6 Hrs**
   Definition, Prohibited and controlled operation, cultivation of poppy plants, sale of opium, import and export of narcotics as amended to date, Offences and corresponding penalties.
9. **Consumer Protection Act** **3 Hrs**
10. **Medical termination of pregnancy act 1970 and rules 1975** **2 Hrs**

SEMESTER-IV

Subject code: 4T1
Subject: Pharmaceutics-IV (Unit operations)
THEORY: **45 Hours (3 Hrs. /week)**

1. **Flow of heat** **6 Hrs**
   Mechanisms of heat transfer: conduction, convection and radiation, Fourier's law, Stefan Boltzmann's constant, Kirchoff's law, heat transfer- between fluid & solid boundary, boiling liquids, condensing vapor's, heat exchangers and heat interchangers.

2. **Evaporation** **6 Hrs**
   Theory of evaporation, classification of evaporators, study of evaporating pan, short tube (single and multiple effect) and long tube evaporators (forced and natural circulation), economy, capacity and feeding methods of multiple effect evaporators.

3. **Distillation** **9 Hrs**
   Roult's law, Henry's law and Dalton's law, Volatility and relative volatility, Simple distillation, Fractional distillation and columns used in it, Azeotropic distillation, extractive distillation and molecular distillation.

4. **Drying** **7 Hrs**
   Theory of drying, Behavior of solids on drying, Classification of solids based on drying, Tray dryer, Fluidized bed dryer, spray dryer, freeze dryer, flash dryer and drum dryer.

5. **Crystallization** **7 Hrs**
   Theory of crystallization, Mier's theory and its limitations, Nucleation and crystal growth, Study of Agitated batch crystallizer, Swenson Walker crystallizer, Krystal crystallizer, Vacuum crystallizer, Vacuum crystallizer with recirculation and its operating variables, growth type crystallizer.

6. **Environmental control** **6 Hrs**
   Theory of humidification and dehumidification, Study of air conditioning, refrigerants and refrigeration cycle, cooling towers.

7. **Corrosion** **4 Hrs**
   Mechanisms, factors influencing corrosion process, method of combating it.

Subject code: 4P1
Subject: Pharmaceutics-IV (Unit operations)
PRACTICAL: **3 Hrs. /week**

1. Study of effect of pressure on the rate of evaporation.
2. Study of effect of viscosity on the rate of evaporation.
3. Plotting of boiling point curve.
4. Study of rate of drying of solid sample (amorphous and crystalline).
5. Study of drying behavior of solid sample (amorphous and crystalline).
6. Crystallization of sodium chloride.
7. Crystallization of boric acid without seeding.
8. Crystallization of boric acid with seeding.
9. Study of effect of cooling on crystal growth.
10. Engineering Drawing sheets (Minimum 5 Experiments): Orthographic projections

Subject code: 4T2
Subject: Pharmaceutical Chemistry-IV (Heterocyclic and Macromolecules)
THEORY: 45 Hours (3 Hrs. /week)

1. Heterocyclic compounds: 15 Hrs
Structure, nomenclature, synthesis and properties including reaction mechanistic, stereochemical considerations and pharmaceutical uses of the following heterocyclic compounds:
Pyrrole, Furan, Thiophene, Imidazole, Oxazole, Pyridine, Pyrimidine, Quinoline, Isoquinoline, Indole, Purine and Phenothiazine.

2. Polynuclear aromatic compounds: 6 Hrs
Structure, nomenclature, synthesis, properties and stereochemistry of Naphthalene, Anthracene and Phenanthrene.

3. Carbohydrate: 10 Hrs
Classification, structure and reactions of Glucose, configuration of aldoses, cyclic structure of D-glucose, mutarotation and conformations, structure of Maltose, Sucrose, Starch, Simple glycosides like Salicin, and Amygdalin.

4. Amino acids and Proteins: 8 Hrs
classification, isolation, and synthesis, of amino acids; isolation, purification and hydrolysis of peptides leading to amino acid sequence determination and their general synthetic methods; classification, properties and structure of proteins,

5. Lipids: 6 Hrs
Classification and general chemistry of lipids and fats, their properties and characterization, fatty acids and their reactions, waxes, phospholipids, glycolipids, lipoproteins.

Subject code: 4P2
Subject: Pharmaceutical Chemistry-IV (Heterocyclic and Macromolecules)
PRACTICAL: 3 Hrs. /week

1. Synthesis and physico-chemical characterization of following compounds
   - Benzimidazole from o-phenylenedimine and formic acid.
   - Quinoline from Aniline by Skraup method.
   - 2-phenyl indole from acetophenone and phenyl hydrazine.
   - Piperazine-2,5-dione from glycine.
   - Eosin from phthalic anhydride and resorcinol
2. Analysis of oils and fats (I.P. method)
   - Acid value
   - Saponification value
   - Iodine value
3. Quantitative determination of organic compounds via functional groups
   - Carboxyl group by alkalimetry.
   - Phenolic group by bromination method
   - Carbonyl group by hydroxyl amine hydrochloride-pyridine method.
   - Amino group by bromination method

Subject code: 4T3
Subject: Pharmaceutical Analysis-II (Electroanalytical and Physical methods)
THEORY: 45 Hours (3 Hrs. /week)

1. Refractometry 3 Hrs
Introduction, factors affecting refractive index, specific and molar refraction, Instrumentation, Application.

2. Polarimetry
Introduction, factors affecting angle of rotation, Instrumentation, Application. **3 Hrs**

3. Potentiometry 6 Hrs
Electrochemical cell, Standard electrode potential, Mechanism of electrode potentional, Types of electrode (Reference electrode-Hydrogen, calomel, silver/silver chloride electrode and Indicator electrode- Glass, redox, ion-selective electrodes), Method of detecting end point, potentiometric titration(advantages, types, applicaions).

4. Conductometry **6 Hrs**

Introduction, Advantages and disadvantages of conductometry, Some important terms (conductance, specific resistance specific conductance, equivalent and molecular conductance), Factor affecting conductance, Measurement of conductance, Instrumentation of conductivity meter, Principle and types of conductometric titrations, Applications, Introduction of High Frequency Titration (Oscilillometry).

5. Polarography **6 Hrs**

Introduction and theory of polarography, Instrumentation, Ilkovic equation, Current potential relationship, Choice of electrode (Platinum and Dropping mercury with types, advantages and disadvantages), Applications, Derivative or Differential polarography, Pulse polarography (Normal and Differential pulse polarography),Introduction of Recent advantages in polarography (Alternating current polarography, Oscillographic polarography, Chronopotentiometry).

6. Amperometry **5 Hrs**

Introduction and principle of amperometry, Instrumentation, Advantages and disadvantages, Types of electrodes, Types of amperometric titrations, Biamperometric titrations/ Dead stop end point method, Applications.

7. Electrogravimetry **4 Hrs**

Theory, electrode reaction, overpotential, completeness of deposition, instrumentation, application.

8. Coulometry **4 Hrs**

Introduction, coulometry at controlled potential, coulometry at constant current, instrumentation, application.

9. Thermal Analysis Introduction and types of thermal analytical methods **8 Hrs**

a. **Thermogravimetry (TG):-** Introduction of thermogravimetry, Information obtained from TG scurve, Factors affecting TG curve, Instrumentation, Applications.
b. **Differential Thermal Analysis (DTA):-** Introduction, Theories of DTA, Factors affecting DTA curve, Instrumentation, Applications.
c. **Differential Scanning Calorimetry (DSC):-** Introduction, Advantages over DTA, Factors affecting DSC curve, Instrumentation, Applications.

Subject code: 4P3
Subject: Pharmaceutical Analysis-II (Electroanalytical and Physical methods)
PRACTICAL: **3 Hrs. /week**

1. Conductometric titration of strong acid Vs strong base.
2. Conductometric titration of strong acid Vs weak base.
3. Conductometric titration of weak acid Vs strong base.
4. Conductometric titration of weak acid Vs weak base.
5. Conductometric titration of very weak acid Vs strong base.
6. Determination of weak and strong acid in mixture by conductometry.
7. Potentiometric titration of strong acid Vs strong base.
8. Potentiometric titration of weak acid Vs strong base.
9. Determination of concentration and pKa of weak acid using pH meter.
10. Potentiometric assay as specified in IP.(Minimum two)
11. Determination of refractive index of sample.(Minimum three)
12. Demonstration of Karl Fischer Titration.
13. Demonstration of Polarimeter.

Subject code: 4T4
Subject: Pharmacology-II
THEORY: **45 Hours (3 Hrs. /week)**

Study of Pharmacological action of following classes of drug with respect to classification of recently available drugs, Mechanism of action, Receptors, Adverse effects, Drug interaction, Contraindication and Therapeutic uses :

1. Pharmacology of drugs acting on CVS **16 Hrs**

A. Antihypertensive drugs **3 Hrs**
B. Antianginal drugs **3 Hrs**
C. Antiarrythmic drug **3 Hrs**
D. Drugs used for CHF **3 Hrs**
E. Drugs used in Hyperlipidemia **2 Hrs**
F. Drug therapy of shock **2 Hrs**

2. Pharmacology of drugs acting on Renal system **6 Hrs**

A. Diuretics
B. Anti- diuretics

3. Autocoids and their blockers **12 Hrs**

A. Histamine and antihistaminic **3 Hrs**
B. 5- Hydroxytryptamine and its antagonist **3 Hrs**
C. Prostaglandins and non steroidal anti-inflammatory drugs, antipyretic, analgesic **3 Hrs**
D. Leukotrienes and platelet activating factor. **3 Hrs**

4. Pharmacology of drugs acting on Haemopoitic system **11 Hrs**

A. Haematinic **4 Hrs**
B. Coagulants and anticoagulants **4 Hrs**
C. Fibrinolytic and antiplatelet agents. **3 Hrs**

Subject code: 4P4
Subject: Pharmacology-II
PRACTICAL: **3 Hrs. /week**

1. To demonstrate per oral (gavage) route of drug administration in rats and mice.
2. To demonstrate parenteral route of drug administration.
3. To demonstrate blood withdrawal by puncture of retro orbital plexus from rats.
4. To demonstrate blood withdrawal from tail vein of rats.
5. To record cumulative dose response curve (CDRC) using rat ileum.
6. To record CDRC using rat fundus preparation.
7. To demonstrate antihistaminic activity using histamine aerosol model.
8. To find unknown concentration of Ach by matching bioassay using rat ileum.
9. To find unknown concentration of Ach by bracketing bioassay using rat ileum.
10. To find unknown concentration of Ach by interpolation bioassay using rat ileum.

Subject code: 4T5
Subject: Pharmaceutical Microbiology and Immunology-II
THEORY: **45 Hours (3 Hrs. /week)**

1. Sterilization: **7 Hrs**
Different methods – dry heat, moist heat, gaseous, radiation and filtration. Sterilization indicators, D-value, Z-value, Sterility testing of Pharmaceutical products as per I.P.

2. Disinfections: **5 Hrs**
Chemical classification of different disinfectants, dynamics of disinfectant and factors affecting on disinfectant action, Evaluation of disinfectant, Phenol coefficient test.

3. Aseptic Techniques: **5 Hrs**
Designing of aseptic area, sources of contamination in aseptic area, and methods of prevention, laminar air flow.

4. Immunology:
a) Fundamentals of Immunology: **10 Hrs**
Microbial flora of human body, portal of entry of microorganism, microbial pathogenecity, virulence, exotoxins, endotoxins. Defense mechanisms of host – specific and nonspecific. Types of Immunity. Antigens, antibodies, Compliment proteins.
b) Antigen - Antibody reactions: **6 Hrs**
Introduction, precipitation, agglutination, compliment fixation, immunoelectrophoresis, immunofluorescence, ELISA, radioimmunoassay.
c) Hypersensitivity reactions: **4 Hrs**
Introduction, Immediate and delayed hypersensitivity, type I, II, III, IV hypersensitivity.

d) Preparation of vaccines and sera: **8 Hrs**

Introduction, manufacturing and quality control. Preparation of vaccines (BCG, TAB, DPT, Polio, MMR and Rabies), toxoids (Tetanus and Diphtheria) and sera (antibacterial, antiviral, antitoxin and antivenum). Diagnostic agents- Tuberculin, Schick tests.

Subject code: 4P5
Subject: Pharmaceutical Microbiology and Immunology-II
PRACTICAL: 3 Hrs. /week

1. Biochemical tests (IMViC tests).
2. Antimicrobial Sensitivity testing.
3. Determination of MIC.
4. Antimicrobial activity of medicinal plant extracts.
5. Microbiological assay of antibiotics by cup plate method (Minimum two antibiotics).
6. Sterility testing by direct transfer.
7. Sterility testing by membrane filtration methods.
8. Sterility testing for powdered drug sample.
9. Bacteriological examination of air.
10. Bacteriological examination of water and milk.

Subject code: 4T6
Subject: Pharmaceutical Management
THEORY: 45 Hours (3 Hrs. /week)

1. Management: 6 Hrs
Concept of management, principles of management, primary functions of management- planning, organizing, staffing, directing, controlling, motivating, entrepreneurship development, operative management- personnel, materials, production, financial, marketing etc. Secondary functions of management: decision making, leadership, innovation, delegation authority/ responsibility.

2. Materials Management: 5 Hrs
A brief exposure or basic principles of materials management-major areas, scope, purchase, stores, inventory control and evaluation of materials management.

3. Pharmacoeconomics: 5 Hrs
Principles of economics with special reference to the laws of demand and supply, demand schedule, demand curves, labor welfare, general principle of insurance and inland and foreign trade, procedure of importing and exporting of goods.

4. Pharmaceutical Marketing 6 Hrs
Functions, buying, selling, transportation, storage, finance, feedback, information, channels of distribution, wholesale, retail, departmental store, multiple shop and mail order business.

5. Salesmanship: 5 Hrs
Principles of sales promotion, advertising, ethics of sales, merchandising, literature, detailing. Recruitment, training, evaluation, compensation to the pharmacist.

6. Accountancy: 7 Hrs
Principle of accountancy, ledger posting and book entries, preparation of trial balance, columns of cash book, profit and loss account, balance sheet, purchase, keeping and pricing of the stock, treatment of cheques, bills of exchange, promissory note and hundies, documentary bills.

7. Production Management: 6 Hrs
Human resource planning, recruitment, and interviewing, human skills evaluation through various instruments, job description, job evaluation, role clarity, career planning.

8. Human Resource Management: 5 Hrs
Human resource planning, recruitment, and interviewing, human skills evaluation through various instruments, job description, job evaluation, role clarity, career planning.

SEMESTER-V

Subject code: 5T1
Subject: Pharmaceutics-V (Physical Pharmacy)
THEORY: **45 Hours (3 Hrs. /week)**

1. **Micromeritics:** **8 Hrs**
   Particle size, size distribution, shape and surface area and their determination in heterogeneous systems. Porosity, density and packaging arrangements in flow properties and their influence on processing of solid dosage forms, Mechanism of particle bonding and granule formation.

2. **Interfacial Phenomena:** **8 Hrs**
   Cohesion, adhesion and spreading. Adsorption at solid and liquid interfaces, adsorption isotherms, adsorption in Medicine and Pharmacy, Electrical properties of interfaces, origin of charge, electrical double layer, Nernst and Zeta potential, Effect of electrolyte.

3. **Surface active agents:** **6 Hrs**
   Classification based on chemical nature and HLB scale, Factors affecting micelle formation, structure of micelle and liquid crystal, Miceller solubelization and its pharmaceutical significance.

4. **Suspension:** **8 Hrs**
   Theoretic considerations, particle interaction and behavior, flocculation and deflocculation, sedimentation parameters, role of wetting, controlled flocculation and structured vehicle in formulation and manufacture of suspension, evaluation of suspension.

5. **Emulsion:** **7 Hrs**
   Types, detection, Thermodynamic consideration, Mechanism of droplet stabilization, Theories of emulsification. Formulation and manufacturing of emulsions, stability of emulsions, assessment of emulsion shelf life.

6. **Colloidal Dispersions:** **8 Hrs**
   Properties of colloids – Optical, Kinetic and Electrical and their application in determining molecular weight of polymer. Stability of colloidal systems, Mechanism of peptization, coacervation and protective action.

Subject code: 5P1
Subject: Pharmaceutics-V (Physical Pharmacy)
PRACTICAL: **3 Hrs. /week**

1. Determination of interfacial tension between two immiscible liquids and to calculate spreading coefficient.
2. Determination of CMC of a surfactant through interfacial tension measurement method.
3. To study the effect of electrolyte on CMC of surfactant
4. Determination of HLB of surfactant.
5. To plot adsorption isotherm.
6. Formulation and evaluation of emulsion
7. Formulation and evaluation of suspension
8. Measurement of the mean globule diameter of the emulsion.
9. Measurement of the particle size of a suspension by Andreasen pipette method.
10. Study of effect of particle size on angle of repose and flow properties.
11. Study of effect of fines and lubricant on angle of repose and flow properties.
12. Determination of bulk density, True density and Granular density of few pharmaceuticals and to calculate porosity of material

Subject code: 5T2
Subject: Pharmaceutical Medicinal Chemistry-I
THEORY: **45 Hours (3 Hrs. /week)**

1. Basic principles of medicinal chemistry: **5 Hrs**
Structure of biological membrane, physicochemical parameters affecting drug action, drug absorption, distribution and elimination. Stereochemical aspects of drug action, drug receptor interaction including transduction mechanism, blood brain barrier.

2.Drug metabolism: **4 Hrs**
Phase I and phase II reaction, biological factor affecting drug metabolism, inducers and inhibitors of drug metabolism, significance of drug metabolism studies in drug development.

3. Prodrug concept: Principles of prodrug design and applications. **2 Hrs**

Following topics shall be treated covering nomenclature, synthetic procedure of official drugs, uses SAR including physicochemical and steric aspects and mode of action.

Antiasthamatics, bronchodilators, phosphodiestrase inhibitors, expectorants, decongestant and antitussives. **4 Hrs**

General and local anaesthetics, sedative and hypnotics, skeletal muscle relaxants, anticonvulsant, CNS stimulant agents, antipsychotics and antidepressants, hypoglycemic agents and oxytocics **15 Hrs**

Antihistaminics, drugs used in Parkinsonism, Alzheimer's diseases and urinary tract infection. **6 Hrs**

Thyroid hormones and antithyroid drugs, Narcotic analgesics and NSAIDs, prostaglandins and eicosanoids. **9 Hrs**

Subject code: 5P2
Subject: Pharmaceutical Medicinal Chemistry-I
PRACTICAL: **3 Hrs. /week**

1. Pharmacopoeial assay of following solid dosage form
   - Aspirin
   - Thibendazole
   - Tolbutamide
   - Ibuprofen
   - Atenolol
2. Synthesis and physico-chemical characterization of following compounds
   - Sulfanilic acid from aniline
   - Prontosil from m-phenylenediamine and sulfanilamide
   - Benzylideneacetophenone (chalcone) from benzaldehyde and acetophenone
   - Methyl orange from sulfanilic acid and dimethyl aniline
   - Anthranilic acid from phthalic anhydride and urea

Subject code: 5T3
Subject: Pharmacology-III
THEORY: **45 Hours (3 Hrs. /week)**

Study of Pharmacology of following classes of drug with respect to classification of recently available drugs, mechanism of action, receptors, adverse effects, Drug interaction, contraindication and therapeutics uses.

1 Pharmacology of drug acting on CNS **24 Hrs**
- A. Introduction : cell signaling, neurotransmission, central neurotransmitters **2 Hrs**
- B. Alcohol and alcoholism **2 Hrs**
- C. General anesthetics **2 Hrs**
- D. Sedatives and hypnotics **2 Hrs**
- E. Anticonvulsants **2 Hrs**
- F. Antipsychotics, antidepressants and anxiolytics **6 Hrs**
- G. Drug dependence and drug abuse **2 Hrs**
- H. CNS stimulants **2 Hrs**
- I. Drugs for Neurodegenerative disorders **2 Hrs**
- J. Opoid Analgesic. **2 Hrs**

2. Pharmacology of local anaesthetics **2 Hrs**

3. Pharmacology of drugs acting on Respiratory System **6 Hrs**
- A. Drug therapy of asthma
- B. Anti tussives, expectorant and mucolytic agent.

4. Pharmacology of drugs acting on GIT **6 Hrs**
- A. Drugs used in ulcers
- B. Drugs for treatment of diarrheoa and constipation.
- C. Emetic and anti-emetics.

5. Clinical Research: **7 Hrs**

A. Clinical Trials: History, Terminologies, Various phases of clinical research, Role of clinical trial in new drug development. **2 Hrs**

B. Documents in clinical study: Investigator Brochure (IB), Protocol and its amendment, case report form (CRF), Informed consent form (ICF). **2 Hrs**

C. Ethical issues in clinical trial **3 Hrs**

Subject code: 5P3
Subject: Pharmacology-III
PRACTICAL: **3 Hrs. /week**

1. General introduction to CNS experimental pharmacology.
2. To study the analgesic activity of by using tail flick method in rats or mice.
3. To study the analgesic activity of by using hot plate analgesiometer in rats or mice.
4. To study the anti-inflammatory activity by using plethysmometer in rats or mice.
5. To study the anticonvulsant activity by using electroconvulsiometer in mice
6. To study hypnotic activity by using pentobarbital induced loss of righting reflex in mice.
7. To study the antipyretic activity by using telethermometer in rats.
8. To study the antidepressant activity by using forced swim test in rats or mice.
9. To study the anxiolytic activity by using in rats or mice.
10. To study the CNS Stimulant activity by using actophotometer in rats or mice.
11. To study the CNS Depressant activity by using actophotometer in rats or mice.

Subject code: 5T4
Subject: Pharmacognosy and Phytochemistry-III (Chemistry of Natural Products)
THEORY: **45 Hours (3 Hrs. /week)**

1. Extraction, isolation and purification methods for phytopharmaceuticals **10 Hrs**

a. Extraction: Theory of mass transfer, maceration, percolation, Soxhlet extraction and super critical fluid extraction
b. Chromatography isolation and purification: General principles and applications of adsorption, ion-exchange, size-exclusion, affinity. Detailed study of thin layer chromatography, paper chromatography, column chromatography, high performance thin layer chromatography, high pressure liquid chromatography and gas liquid chromatography.

2. Terpenoids and volatile Oils **10 Hrs**

a. Introduction, occurrence, general properties, classification, chemistry, uses, methods of extraction and evaluation, general biogenetic pathway.
b. Pharmacognostic study of following drugs

Hydrocarbon:	Pepper
Alcohol:	Peppermint, Cardamom, Coriander, sandalwood
Aldehyde:	Cinnamon, Lemon Grass, Citronella
Ketone:	Caraway, Camphor, Dill
Phenol:	Clove, Tulsi
Phenolic ether:	Fennel, Nutmeg
Oxide:	Eucalyptus

3. Resins and resin combinations **10 Hrs**

a. Introduction, Biosynthetic pathways, classification, physical and chemical properties, methods of extraction, and uses.
b. Pharmacognostic study of following drugs

Resins:	Colophony, Podophyllum, Benzoin, Tolu Balsam, Peru Balsam, Storax
Gum Resins:	Gamboage
Oleo-Gum Resins:	Asafoetida, Guggul, Boswellia, Myrrh
Oleo-Resins:	Capsicum, Ginger, Turmeric

4. Isolation, purification and chromatographic profiles of following phytoconstituents - Eugenol, cineole, camphor, menthol, citral. **6 Hrs**

5. A study of structural elucidation of following phytoconstituents - Camphor, eugenol, taxol and artemisinin. **9 Hr**

Subject code: 5P4
Subject: Pharmacognosy and Phytochemistry-III (Chemistry of Natural Products)
PRACTICAL: **3 Hrs. /week**

1. Isolation of volatile oil by hydro-distillation method using Clavenger's apparatus
2. Paper chromatography and TLC of natural products.
3. Thin layer chromatography of volatile oils.
4. Demonstration of column chromatography of crude extract
5. Determination of balsamic acids in Tolu or Peru balsam
6. Estimation of citral content from lemon grass oil
7. Estimation of carvone content from Dill oil
8. Estimation of cineole content of Eucalyptus oil
9. Isolation of eugenol from Cinnamon leaf oil
10. Study of morphological and microscopical characters of-
    Coriander, Cardamom, Cinnamon, Caraway, Dill, Clove, Fennel, Eucalyptus, Ginger
11. Identification of following crude drugs by their morphological characters and chemical tests
    Colophony, Benzoin, Balsams, Storax, Asafoetida, Guggul, Boswellia, Myrrh

Subject code: 5T5
Subject: Clinical Pharmacy
THEORY: **45 Hours (3 Hrs. /week)**

1. Introduction to Clinical Pharmacy Practice **2 Hrs**

2. Toxicology
   a) Acute, Sub acute and Chronic toxicity. **2 Hrs**
   b) Poison (Types and Classification) and General treatment of Poisoning. **2 Hrs**
   c) Signs, Symptoms and treatment of acute and chronic poisoning due to
      i) Barbiturates ii) Alcohol iii) Morphine iv) Insecticides v) Snake bites vi) Heavy metals (Lead, Arsenic, Mercury). **4 Hrs**
   d) Drug and Poison information center. **1 Hrs**

3. Drug interactions: Introduction, Reason for increasing number of drug interactions, Factors affecting drug interactions, Types of drug interactions, Pharmacokinetic and Pharmacodynamic mechanism for the drug interactions. Role of Pharmacist in minimizing drug interactions. **7 Hrs**

4. Drug induced diseases: Drug induced cardiovascular diseases, Drug induced liver toxicity, Nephrotoxicity, Diarrhoea, Sexual Dysfunction, Drug induced depression and psychosis. **6 Hrs**

5. Therapeutic Drug Monitoring: Objectives, Applications, Methodology for the monitoring patient during illness. **3 Hrs**

6. Adverse Drug Reaction Monitoring: Introduction, Predisposing factors causing ADRs, Detection and reporting of adverse drug reaction. **3 Hrs**

7. Ambulatory Patient Care, Institutional Patient Care, Role of pharmacist in long term care **2 Hrs**

8. Clinical Laboratory Tests: Significance and Interferences of some diagnostics tests for Cancer, Diabetes mellitus, Liver function test, Kidney/Renal function test and Seizures. **4 Hrs**

9. Pharmacoeconomics **6 Hrs**
   a. History, introduction and importance
   b. Significance of Pharmacoeconomics
   c. Pharmacoeconomic evaluations: introduction, classification and types
   d. Methodologies of Pharmacoeconomic
   e. Drug development and Pharmacoeconomics

10. Computer application in Clinical Pharmacy Services **3 Hrs**

Subject code: 5P5
Subject: Clinical Pharmacy
PRACTICAL: **3 Hrs. /week**

1) Paracetamol/ Carbon tetra Chloride induced hepatotoxicity in rats-Changes in markers like SGOT, SGPT, and Bilirubin, LDH etc.
2) Determination and interpretation of biochemical Data by Urine analysis.
a) Urine Microscopy.
b) Determination of Normal Constituent.
c) Determination of Abnormal Constituent Like Albumin, Blood, Ketone Bodies, Uric Acid, Casts, Microorganisms.
3) Comment on the given prescriptions with reference to case report mentioning possible therapeutic uses, and contraindications, with dose, route of administration, justification of inclusion of each ingredient, and possible Drug interactions.(At least one case of important diseases should be discussed on basis of available evidences from literature and if possible from Hospitals.)
4) Patient Counseling-Interview techniques and advice on some theoretical conditions.
5) ADR Reporting According to the Blue Letter of Asthma and Allergic Diseases Research Centers (AADRC), Australia, Yellow Form of CSM, UK. ADR Reporting Form Developed By KEM, Mumbai.
6) Calculating Cost of Prescription.
7) Histological Studies in Biopsies. (Human permanent slide).
8) Preparation of information material for educating patients about drug usage.
9) Study of Prescription and Case Report on the Some Commonly Occurred Drug Induced Diseases.

Subject code: 5T6
Subject: Regulatory Affairs and Intellectual Property Right
THEORY: 45 Hours (3 Hrs. /week)

1. **Regulatory Affairs** **3 Hrs**
Introduction, Importance of regulatory affairs, Funtions of regulatory affairs, Regulation marketing and Violation and Enforcement.

2. **Drug regulatory strategy** **4 Hrs**
Regulatory strategies for different phases of product development:- Regulatory strategy during the preclinical development phase, Regulatory strategy during the clinical development Phase (Phase I, Phase II, Phase III) and Regulatory strategy for the post approval phase.

3. **Drug regulatory authorities and agencies**: - **4 Hrs**
United states food and drug administration (USFDA), Therpeutic goods administration (TGA), Medicines and healthcare regulatory agency (MHRA), International conference on harmonisation (ICH), World health organization (WHO), Ministry of health, labor and welfare (MHWL) in Japan, Central drugs standard control organization (CDSCO), Indian pharmacopoeia commission (IPC)

4. **Investigational new drug application (INDA)** **3 Hrs**
Introduction, The content and format of an IND application, Maintaining an IND

5. **New drug application (NDA)** **3 Hrs**
Introduction, FDA Guidelines, Assembling applications for submission, NDA contents.

6. **Abbreviated new drug application (ANDA)** **2 Hrs**
Introduction, Requirements for filing ANDA,

7. **Drug master file (DMF)** **2 Hrs**
Introduction, Types of DMF, DMF submission.

INTELLECTUAL PROPERTY RIGHTS

8. **Introduction** **4 Hrs**
Understanding Intellectual property rights (IPR) and review of IPR regime: - Copyrights, Trademarks, Geographical indications, Appellations of origin, Industrial designs, and Intellectual property laws in India.

9. **Patent legislation** **6 Hrs**
Patent Act 1970, Patentability criteria, Patentable subject matter, Patent amendment (1999, 2002, 2005).

10. **Patent procedure, filing, search and licensing**. **3 Hrs**

11. **Patent infringement issues and freedom to operate**. **2 Hrs**
International treaties and conventions on IPR; Trade related Intelletual property rights (TRIPS), Paris convention, World trade organization (WTO), General agreement on trade and tariff (GATT), Patent cooperation treaty (PCT). **3 Hrs**

12. **Other Features**: Hatch-Waxman Act, Compulsory licensing, Laws related to Biosimilars. **6 Hrs**

SEMESTER-VI

Subject code: 6T1
Subject: Pharmaceutics-VI (Physical Pharmacy)
THEORY: 45 Hours (3 Hrs. /week)

1. **Solubility and Distribution Phenomena: 10 Hrs**
   Mechanism of solute solvent interactions. Ideal solubility and Scatchard – Hildebrand equation, solvation and association, Quantitative approach to the factors influencing solubility of drugs. Distribution of solutes between immiscible liquids, ionic dissociation and molecular association influencing partitioning. Application of distribution phenomena in pharmacy, Phase rule and phase equilibria, phase diagram, one and two component, the solid state amorphous, crystalline and polymorphism.

2. **Diffusion and Dissolution 4Hrs**
   Diffusion, Steady state diffusion, diffusion coefficient, determination of diffusion coefficient. Importance of diffusion coefficient. Historical perspective and importance of dissolution, zero-order kinetics, first order kinetics, Hixon crowell and Higuchi equations. USP dissolution apparatus

3. **Rheology: 8 Hrs**
   Types of flow behavior, thixotropy and thixotropic coefficient. Measurement of various rheological properties, factors influencing rheology of dispersed systems.

4. Complexation and Methods of detection of complexes. **7 Hrs**

5. **Kinetics and Drug Stability: 8 Hrs**
   Influence of temperature, light, solvent, catalysts and other factors, Accelerated stability studies.

6. **Polymer Science: 8 Hrs**
   Historical background, Pharmaceutical applications of polymers, definition, Molecular weight, Average molecular weight, Determination from solution viscosity, Conformation of dissolved linear macromolecules, Polymer as thickening agent, Polymer solution overview, Solvent selection, Preparing polymer solution, Mechanical properties, Interchain cohesive forces, Crystallinity, Tacticity, Morphology, Orientation glass – rubber transition, plasticization.

Subject code: 6P1
Subject: Pharmaceutics-VI (Physical Pharmacy)
PRACTICAL: 3 Hrs. /week

1. Determination of heat of solution of Benzoic acid.
2. Determination of heat of solution of boric acid.
3. Determination of relation between dielectric constant of solvent and solubility of drugs.
4. To plot ternary phase diagram.
5. Determination of partition coefficient and distribution of drug between two phases.
6. Study of rheograms of some mucilages.
7. Determination of molecular weight of polymer by viscosity measurement method
8. To determine the distribution coefficient of benzoic acid between water – benzene system.
9. To study the effect of temperature and pH on aspirin hydrolysis.
10. To determine upper consolute temperature of phenol water system

Subject code: 6T2
Subject: Pharmaceutical Medicinal Chemistry-II
THEORY: 45 Hours (3 Hrs. /week)

Following topics shall be treated covering nomenclature, synthetic procedure of official drugs, uses SAR including physicochemical and steric aspects and mode of action.

1.Chemotherapeutic agents: 18 Hrs
Antimalerial, antiamoebic, anthelmentic and sulfonamides, antimycobacterial agents (antitubercular and antileprotic agents), antifungal agents, antiviral (including drugs used in AIDs), antineoplastic agents,

2/Antibiotics and prominent analogues: 15 Hrs
Penicillin, cephalosporin, aminoglycosides, tetracyclines, polypeptides, chloramphenicol, macrolide, lincomycins, lactamase inhibitors

3.Drug design: **7 Hrs**

Objectives, general principles, physicochemical properties and common approaches. Computer aided drug design (CADD), Theoretical consideration of quantitative structure activity relationship (QSAR) and its methods, molecular modeling, simple correlation equation.

Brief introduction to combinatorial chemistry **3 Hrs**

Concept and brief introduction of genetic engineering in medicinal chemistry. **2 Hrs**

Subject code: 6P2
Subject: Pharmaceutical Medicinal Chemistry-II
PRACTICAL: **3 Hrs. /week**

1. Pharmacopoeial assay of following solid dosage form
   - Mebendazole
   - Glipizide
   - Nifedipine
   - Cimetidine
   - Diclofenac
2. Synthesis and physico-chemical characterization of following compounds
   - Orange II from sulfanilic acid and β-naphthol
   - Phenothiazine from diphenyl amine
   - Isoniazid from isonicotinic acid
   - Thiobarbituric acid from diethyl malonate and thiourea
   - Chloramine-T from toluene p-sulphonamide
   - 1-phenylazo 2-naphthol from aniline and 2-naphthol

Subject code: 6T3
Subject: Pharmacology-IV
THEORY: **45 Hours (3 Hrs. /week)**

Study of Pharmacological action of following classes of drug with respect to classification of recently available drugs, mechanism of action, receptors, adverse effects, Drug interaction, contraindication and therapeutics uses:

1. Pharmacology of drug acting on endocrine systems **10 Hrs**

A. Pitutory hormone and regulation of secretion
B. Thyroid hormone, antithyroid agents
C. Parathyroid harmone, calcitonin, vitamin D.
D. Insulin, oral hypoglycemic agents.
E. Adrenocorticoids, anabolic steroids and fertility agents

2. Chemotherapy of microbial infection **24 Hrs**

A. Introduction **2 Hrs**
B. Penicillin and cephalosporin's **2 Hrs**
C. Macrolides and amino glycosides and polypeptides **2 Hrs**
D. Quinolones and fluoroquinolines **2 Hrs**
E. Chemotherapy of fungal infections **2 Hrs**
F. Chemotherapy of viral infections **3 Hrs**
G. Chemotherapy of malaria **2 Hrs**
H. Chemotherapy of tuberculosis and leprosy **3 Hrs**
I. Pharmacology of anthelmintics **2 Hrs**
J. Anti-neoplastic agents **4 Hrs**

3. Drugs acting on Immune system **3 Hrs**

A. Immunostimulants
B. Immunosupressant

4. Clinical trial: **8 Hrs**

A. Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls. **3 Hrs**
B. Management of Clinical trials: Role and responsibilities of Stakeholders of clinical trials such as FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient. **2 Hrs**
C. Guidelines for clinical research: ICH-GCP. **3 Hrs**

Subject code: 6P3
Subject: Pharmacology-IV
PRACTICAL: 3 Hrs. /week

1. To determine pA_2 value of antagonist using different tissues isolated from rats.
2. To study antipsychotic activity by using conditioned avoidance response.
3. To study antiparkinson activity using catalepsy test.
4. Demonstration of LD_{50} determination of some drugs or chemicals in rats or mice.
5. To study learning memory enhancing activity using radial arm maze.
6. To study learning memory enhancing activity using water maze.
7. To study learning memory enhancing activity using elevated plus maze.
8. To study addiction and abuse liability of some drugs.
9. To study analgesic activity using acetic acid induced writhing.
10. To record BP of rats by non invasive method
11. To record ECG and EEG of rats by non invasive method.

Subject code: 6T4
Subject: Pharmacognosy and Phytochemistry-IV (Recent Advances in Phytochemistry)
THEORY: 45 Hours (3 Hrs. /week)

1. Glycosides **13 Hrs**

a. Introduction, definition, occurrence, properties, classification, uses, general biogenetic pathways. General extraction and isolation methods.
b. Pharmacognostic study of following drugs

Anthraquinones:	Senna, Aloe, Rhubarb
Cardioactive:	Digitalis, Squill
Saponins:	Liquorice, dioscorea, shatavari
Bitter:	Quassia, Kalmegh
Cynogenetic:	Bitter almond
Isothiocyanate:	Black mustard
Flavonoid:	Orange peels
Coumarin:	Psoralea
Others:	Artemesia, Brahmi

2. Tannins **8 Hrs**

a. Introduction, definition, classification, properties, uses, chemical tests and general method of extraction.
b. Pharmacognostic study of following drugs
Pale catechu, Black catechu, Ashoka, Arjuna, Bahera, Amala, Myrobalon

3. Isolation, purification and therapeutic uses of following phytocompounds: Gingkolides, Diosgenin, Ginsenosides, Andrographolide **7 Hrs**

4. Extraction, isolation, purification and estimation of following phytocompounds: Alloin, Bacoside, Hesperidin, Picrosides, Digoxin **8 Hrs**

5. Spectral studies of following phytocompounds: Digoxin, Glycyrrhizin, Andrographolide, Gallic acid **9 Hrs**

Subject code: 6P4
Subject: Pharmacognosy and Phytochemistry-IV (Recent Advances in Phytochemistry)
PRACTICAL: 3 Hrs. /week

1. Isolation and identification of Andrographolide from *Andrographis paniculata* by TLC method.
2. Isolation and identification of Aloin from leaves of *Aloe* species by TLC method.
3. Determination of total content of tannins from Black catechu by UV spectroscopic method using Folin-Ciocalteu method (Demonstration).
4. Extraction of total sennosides from Senna leaves.
5. Perform UV and FTIR spectroscopic studies on Andrographolide.
6. Study of morphological and microscopical characters of -
a) Senna b) Digitalis c) Liquorice d) Shatavari e) Quassia f) Kalmegh

7. Identification of following crude drugs by their morphological characters and chemical tests
   a. Pale catechu, b. Black catechu, c. Bahera, d. Myrobalon

Subject code: 6T5
Subject: Clinical Pharmacotherapeutics-I

THEORY: **45 Hours (3 Hrs. /week)**

Introduction to rational drug use: Definition, role of pharmacist. Essential drug concept, rational drug formulations. **4 Hrs**

Etiopathogenesis and pharmacotherapy of diseases/disorders associated with following systems.

1. **Cardiovascular and Hemopoietic system:** Hypertension, Angina Pectoris, Atherosclerosis, Congestive Heart Failure, Arrhythmias, Myocardial infarction, Hyperlipidaemias, Thromboembolic disorders and Anaemia. **12 Hrs**
2. **Respiratory system:** Bronchial asthma, Chronic Obstructive Pulmonary Disease, Allergic rhinitis, Common cold & Cough, Cystic fibrosis. **6 Hrs**
3. **Gastro-intestinal system:** Peptic ulcer, Inflammatory Bowel Disease, Liver diseases. **6 Hrs**
4. **Central Nervous system:** Parkinsons disease, Alzheimer's disease, Behavioral disorders. **6 Hrs**
5. **Urogenital system:** Renal failure, Benign Prostatic Hypertrophy, Infertility, Dysmenorrhea, Menopause. **6 Hrs**
6. **Musculoskeletal system:** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosis. **5 Hrs**

Subject code: 6P5
Subject: Clinical Pharmacotherapeutics-I

PRACTICAL: **3 Hrs. /week**

1. Pharmacology of neuromuscular junction.
2. Demonstration of Anesthesia (general and local).
3. Study of drugs on some models related to central nervous system.(sedative & hypnotics, locomotor, stereotypy, muscle relaxant, analgesic & anti-inflammatory).
4. Prescription related patient oriented problems on
   - Some common problems of gastro-intestinal tract (Dyspepsia, nausea, vomiting, colic, dehydration and constipation).
   - Some common problems of respiratory system (Cough, bronchial asthma).
   - Anaemia
   - Management of some painful conditions.
   - Use of some drugs in emergency (Myocardial infarction, hypertensive emergency, acute cardiac failure, anaphylaxis, cardiovascular collapse, pulmonary embolism).
   - Some common drug poisoning (Organophosphate insecticide, atropine, sedative-hypnotic drug, morphine etc.).
5. Medication errors in prescribing, drawing up and administration of medication for diseases prescribed in theory
6. Dose calculation of commonly used drugs including drugs for I.V. infusions.
7. Presentations of analysis related to Pharmacoeconomics. Data related to prescriptions from patients with similar disease to be collected & analyse in terms of cost & effectiveness.

Subject code: 6T6
Subject: Pharmaceutical Validation
THEORY: **45 Hours (3 Hrs. /week)**

1. **Validation of Pharmaceutical Processes:** **8 Hrs**
   Process validation options, the validation committee, validation master plan, validation protocol & report. Preapproval inspection, pilot plant scales up & technical transfer, stages of validation, change control, out-of-specifications, pharmaceutical chemicals.

2. **Prospective Process Validation:** **8 Hrs**
   Introduction, Organization, Master documentation, Product development, development of manufacturing capability, full-scale product/process development, defining experimental programs, experimental design & analysis.

3. **Validation of Analytical Methods:** **5 Hrs**
   Introduction, Validation of standard methods, revalidation, parameters for method validation, selectivity & specificity, precision & reproducibility, accuracy & recovery, linearity & calibration curve, range, limit of detection & quantitation, robustness.

4. **Retrospective Validation:** **12 Hrs**
   Introduction, process validation strategies, product selection criteria for retrospective validation, organizing for retrospective validation, written operating procedures, other considerations, selection & evaluation of processing data, compressed tablet (Drug A), Coated tablet (Drug B), Soft gels (Soft gelatin capsules, Drug C), Solution dosage form (Drug D), Semi solid dosage form (Drug E), computer aided analysis of data, Validation experiments to set product alert limits, reliability of the validated process, selection & evaluation of packaging data.

5. **Validation of Solid dosage form:** **12 Hrs**
   Introduction, validation of raw materials, analytical methods validation, Equipment/ facility validation, definition and control of process variables, In-process tests, finished product tests, guidelines for process validation of solid dosage form, Tablets, tablet composition, process evaluation & selection, equipment evaluation, Hard gelatin capsules, capsule composition, process evaluation and selection, encapsulation, equipment evaluation, outsourcing implications on validation.

SEMESTER-VII

Subject code: 7T1
Subject: Pharmaceutics (DFT-I) (Conventional)
THEORY: **45 Hours (3 Hrs. /week)**

1. Preformulation Considerations **5 Hrs**
Concept, study of physical properties: description, microscopic examination, particle size, partition coefficient, dissolution, solubility, membrane permeability, drug stability, crystal structure and polymorphism.
Study of chemical properties of drug like hydrolysis, oxidation, reduction, racemization, polymerization etc. and their influence on stability.

2. Tablets: **12 Hrs**
Rationale, market perspectives, types of tablets, tablet excipients, methods of tablet manufacture (wet, dry & direct compression), granulation, tablet compression: physics, mechanism, compression cycle, tablet processing problems and defects, tablet evaluation.
Types of coating (sugar, press & film coating), coating formulation, film forming materials, coating process & equipments, coating defects , evaluation of coated tablet.

3. Capsule: Hard gelatin capsule **4 Hrs**
Advantages & disadvantages, material for production and manufacturing of capsule shell, Capsule size, method of capsule filling, evaluation of capsule.
Softgels: Shell and content, manufacturing process and quality control.

4. Ointment: **4 Hrs**
Ointment bases, preparation & preservation of ointment bases, drug absorption from various ointment bases, evaluation of ointments.

5. Suppositories: **3 Hrs**
Displacement value, drug absorption from various suppositories, suppository bases, storage and evaluation of suppositories.

6. Cosmetics: **5 Hrs**
Fundamentals, structure and function of skin and hair, classification, formulation and preparation and packaging of various skin products, cold cream, vanishing cream, moisturizing cream, face powders & dentifrices, toothpastes & tooth powders.

7. Sterile Dosage Form: **12 Hrs**
Type of injections, parenteral routes of administrations, water for injection, pyrogenicity, non aqueous vehicle, isotonicity and method of its adjustment. large & small volume parenteral, ophthalmic, ear and nasal solutions and suspensions. Formulation and development of sterile dosage forms, active ingredients, solvent and vehicles, surfactant and solubilizers, antimicrobials, antioxidants, buffers, chelating agents, tonicity adjusters. Containers and closures for sterile dosage forms. Compounding, processing, filtration, sealing, sterilization, packaging and labeling of sterile dosage forms. Quality control tests like sterility, pyrogen, clarity, safety and leakage testing. Ophthalmic solutions.

Subject code: 7P1
Subject: Pharmaceutics (DFT-I) (Conventional)
PRACTICAL: **3 Hrs. /week**

1. Preparation and evaluation of following dosage forms.
   i. Tablets
   ii. Capsules
   iii. Ointments
   iv. Cold cream, vanishing cream, toothpaste, face powder, toothpaste
   v. Small volume parenterals: solution, emulsion, suspension, powder ready to use
   vi. Large volume parenterals
   vii. Ophthalmic solutions
2. Evaluation of coated tablet (Marketed formulations)

Subject code: 7T2
Subject: Pharmaceutical Medicinal Chemistry-III
THEORY: **45 Hours (3 Hrs. /week)**

Following topics shall be treated covering nomenclature, synthetic procedure of official drugs, uses SAR including physicochemical and steric aspects and mode of action.

1. Sympathetic and parasympathetic agents **10 Hrs**
including biosynthesis and metabolism of adrenergic neurotransmitters, adrenoreceptor blockers.

Cholinergic agents, cholinergic inhibitors, anticholinergic agents including antispasmodics, ganglionic stimulants and blockers, neuromuscular blockers. **10 Hrs**

2.Cardiovascular drugs **15 Hrs**
antihypertensive, cardiotonics, antiarrythmic, anticoagulant, Antithrombotics, thrombolytics, antianginal, coronary vasodilators, hypolipidemic drugs, diuretics.

3.Steroids **10 Hrs**
Androgens and anabolic agents, estrogens, progestational agents, adrenocorticoids and oral contraceptives

Subject code: 7P2
Subject: Pharmaceutical Medicinal Chemistry-III
PRACTICAL: **3 Hrs. /week**

1. Evaluation of Pharmacopoeial standards of following drugs

Ibuprofen
Sulfanilamide
Isoniazid
Aspirin
Ascorbic acid
Sulfamethoxazole

2. Synthesis and physico-chemical characterization of following compounds
Benzotriazole from o-phenylene diamine
Phenytoin from benzoin
Barbituric acid from diethyl malonate and urea
Chlorobutanol from chloroform
Benzocain from p-amino benzoic acid and ethanol
2-methylbenzimidazole from o-nitroaniline

Subject code: 7T3
Subject: Pharmaceutical Analysis-III (Separation Techniques)
THEORY: 45 Hours (3 Hrs. /week)

1. Solvent extraction **5 Hrs**
Basic Principle, Extraction process, liquid-liquid extraction, Methods of extraction, factors affecting extraction , Selection of solvent as an extraction solvent, extraction techniques, Applications.

2. Chromatography
Introduction, Important terms, Classification, Advantages and disadvantages, Application, Difference between following methods .

i) Electrophoresis **5 Hrs**
Types of electrophoresis, requirements of electrophoretic chambers, problems in electrophoresis.

ii) Column Chromatography **5 Hrs**
Adsorption column chromatography, Development Techniques (Frontal, displacement and elution analysis), Preparation of column, Factors affecting column efficiency, Partition chromatography.

iii) Ion exchange Chromatography **5 Hrs**
Principle, Ion exchange resins/material, Properties of ion exchangers, Mechanism of ion exchange process, Factors affecting ion exchange.

iv) Paper chromatography **5 Hrs**
Principle, Choice of filter papers, Solvents, Chromatographic chambers, Development techniques (Descending, Ascending, Radial multiple chromatography, two dimensional chromatography), post development derivative techniques, Factors affecting retention factor.

v) Thin layer chromatography (TLC) **5 Hrs**
Principle, Different methods / techniques, Development of chromatogragph, Rf value (Retention factor) and factors affecting Rf value.

vi) Gas chromatography **7 Hrs**
Theory, Instrumentation (Carrier gas, Columns, stationary phases for gas-liquid and gas-solid chromatography, Detectors- flame ionization, electron capture and thermal conductivity detector), Quantitative analysis/ Derivatisation technique.

vi) High Performance Thin layer chromatography (HPTLC) **4 Hrs**
Principle, Instrumentation, Preparation of plate, Development techniques.

viii) High Performance Liquid chromatography (HPLC) **4 Hrs**
Principle, Instrumentation, Solvent treatment systems, Pumps, column packing material, Detectors.

Subject code: 7P3
Subject: Pharmaceutical analysis-III (Separation Techniques)
PRACTICAL: 3 Hrs. /week

1. Separation of mixture of amino acids / sugars / dicarboxylic acids by paper chromatography. (Minimum four)
2. Experiment based on column chromatography.(Minimum two)
3. Experiment based on TLC.(Minimum three)
4. Experiment based on ion-exchange chromatography.

5. Demonstration HPLC
6. Demonstration HPTLC
7. Demonstration GC

Subject code: 7T4
Subject: Clinical Pharmacotherapeutics-II
THEORY: **45 Hours (3 Hrs. /week)**

General prescribing guidelines for – Pediatric patients, Geriatric patients, Pregnant and breast feeding. **5 Hrs**

Etiopathogenesis and pharmacotherapy of diseases/disorders associated with following systems.

1. **Endocrine system:** Diabetes mellitus, Disorders of Thyroid gland, Adrenocortical dysfunction, Oral Contraceptives. **5 Hrs**
2. **Ophthalmology:** Glaucoma, Cataract, Retinopathy, Conjunctivitis. **4 Hrs**
3. **Infectious diseases:** Tuberculosis, Leprosy, Meningitis, Respiratory tract infections, gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Malaria, AIDS and opportunistic infections, Fungal infections, Viral infections, Gonorrhea and Syphilis. **18 Hrs**
4. **Oncology:** Basic principles of cancer therapy, Chemotherapy of Breast cancer, Leukemia, Cancer of G.I. Tract, Lungs, Prostate, Skin, Gynecological. Management of adverse effects of anticancer drugs. **9 Hrs**
5. **Dermatology:** Psoriasis, Scabies, Eczema. **4 Hrs**

Subject code: 7P4
Subject: Clinical Pharmacotherapeutics-II
PRACTICAL: **3 Hrs. /week**

1. Bioassays (3 point & 4 points) on isolated tissues of rat.
2. Relevance of chemical and physical properties of drugs in therapeutics and some demonstrations about principles of detection and estimations of drugs in biological fluids.
3. Understanding of the principles of clinical trials.
4. Study of drugs on some models related to central nervous system (anticonvulsant, anxiolytic, antianxiety, catatonia & amnesia).
5. Prescription related patient oriented problems on
    a. Diabetes mellitus
    b. Some bacterial infections (Respiratory infections, urinary tract infections, infective diarrhea etc.)
    c. Malaria and amoebiasis
    d. Some common skin problems (Fungal infections, scabies, acne etc.)
    e. Some common ophthalmic problems (Acute congestive glaucoma, iridocyclitis, trachoma, catarrhal conjunctivitis).
6. Medication errors in prescribing, drawing up and administration of medication for diseases prescribed in theory
7. Comment on common pharmaceutical preparations and formulations.
8. Exercise on adverse drug reactions.

Subject code: 7T5
Subject: Pharmacognosy and Phytochemistry-V (Phytopharmaceutical /Herbal Technology)
THEORY: **45 Hours (3 Hrs. /week)**

Role of medicinal and aromatic plants in national economy. Importance of Natural product in new drug development and problems in Discovering New Drug from higher plants. Phytopharmaceuticals: Retrospects and prospects. Global market for Herbal Products and Opportunities in India. **5 Hrs**

1. Alkaloids **10 Hrs**

Introduction,definition, occurrence, properties, classification, chemistry. General Biosynthetic pathways for Indole, Tropane Quinoline and Isoquinoline alkaloids Systematic pharmcognostic study of following crude drugs containing Alkaloids.

a. Indole-Ergot, Rauwolfia, Nux-vomica, Vinca.
b. Tropane - Datura, Coca, Belladona.
c. Purines -Tea, Theobroma.

d. Quinoline - Cinchona.
e. Isoquinoline - Opium, Ipecac.
f. Pyridine/ Ppiperidine - Lobelia.
g. Imidazole - Pilocarpus.
h. Quinazoline – Vasaka
i. Amino alkaloids - Colchicum, Ephedra.
j. Steroidal - Ahwagandha, kurchi, solanum khasian

2.Extraction, Isolation and Estimation of following Phytoconstituents **3 Hrs**
Quinine, Ephedrin and Atropine

3.Flavonoids **9 Hrs**
Introduction, properties, classification, chemistry, extraction and general biosynthetic Pathway.

1. Flavones: Roman chamomile, *Passiflora incarnate,* Grape fruit.
2. Isoflavones: Derris Roots, Soyabean,
3. Flavonol: Buch Wheat, Green Tea
4. Flavonones: Liquorice, Citrus Peels
5. Chalcones: Safflower
6. Bioflavones- Gingko
7. Anthocynidine- Blueberry, Blackcurrent,Vine

4.Standardization of Herbal Drugs **6 Hrs**
Importance of standardization and problems involved in the stanardisation. Standardization of single Drug and compound Formulations, W.H.O. guidelines for quality standardised Herbal formulations, Validation of Herbal products. Estimation of parameters limit Used for standardization and herbal extracts

5.Screening methods for herbal drugs & formulations **4 Hrs**
Antioxidants, antidiabetic, hepatoprotective & antimicrobial drugs.

6.Patenting of Herbal Drugs **3 Hrs**
Definition, Benefits of patent protection, patent application, Intellectual Property Rights with Special reference to phytoconstituents.

7.Herbal Drug Interactions **5 Hrs**
General introduction to interaction and classification. Study of fallowing drugs and their possible side effects and interactions.
Hypercium, kava-kava, Ginkobiloba, Ginseng, garlic, Ginger & Ephedra.

Subject code: 7P5
Subject: Pharmacognosy and Phytochemistry-V (Phytopharmaceutical /Herbal Technology)
PRACTICAL: **3 Hrs. /week**

1. Extraction, Isolation and Identification of Cinchona alkaloids by TLC.
2. Extraction, Isolation and Identification of curcumin by TLC.
3. Extraction, Isolation and Identification of caffeine by TLC.
4. Study of morphological, microscopical characters & chemical / microchemical tests for following crude drugs:
   a. Leaf: Datura, Vinca, Vasaka
   b. Roots: Rauwolfia
   c. Barks: Cinchona, Kurchi,
   d. Stem: Ephedra
   e. Seed: Nux-Vomica
   f. Wood: Quassia
5. Determination of Ash value & Extractive values of crude drugs
6. Determination of the alcohol content of Asava and aristha by suitable method (only Demonstration)
7. Estimation of the crude fibre contents in given sample
8. Estimation of the total tannins by Folin-Dennis reagent method
9. Evaluation of antimicrobial activity of herbal drugs
10. Evaluation of antioxidant activity of herbal drugs

Subject code: 7T6
Subject: Biopharmaceutics and Pharmacokinetics
THEORY: **45 Hours (3 Hrs. /week)**

1. **Absorption of Drug:** Physiology of Cell membrane, Mechanisms of drug absorption, Factors affecting drug absorption- i) Physicochemical ii) Physiological iii) Pharmaceutical. Non-oral routes of drug absorption (buccal, sublingual, transdermal, nasal and parenteral). **7 Hrs**
2. **Drug distribution:** Introduction, factors affecting drug distribution. Concept of apparent volume of distribution. Protein-drug binding. Significance of drug-protein binding and drug displacement interactions. Kinetics of protein binding. **5 Hrs**
3. **Drug metabolism and elimination:** Study of factors affecting metabolism. Pathways of metabolism. Types of drug excretion, Renal excretion, concept of clearance, factors affecting renal clearance, Non renal routes of elimination. Extraction ratio and first-pass effect, hepatic clearance, biliary excretion. **6 Hrs**
4. **Dissolution studies:** Introduction to Biopharmaceutical classification system, Theories of dissolution, In-vitro studies dissolution testing, and all latest models: Zero order, Matrix, First order, Higuchi. Hixon Crowel model.In-vitro in-vivo correlation. **6 Hrs**
5. **Bioavailability and Bioequivalence:** Definition and concept of absolute & relative bioavailability. Purpose of bioavailability testing. Methods of assessing bioavailability. Bioequivalence study and introduction to various study designs. Biowaivers. **7 Hrs**
6. Introduction to pharmacokinetics, Introduction to compartmental and physiological models. **1 Hr**
7. **Compartment models:** Assumptions of one and two compartment open model. Assessment of pharmacokinetic parameters after i. v. bolus and oral administration of drug following one and two compartment model. **8 Hrs**
8. **Non-Linear Pharmacokinetics:** Reasons for non-linearity (saturation mechanism). Michaeles Menten equation. Definition of Vmax and Km. Determination of Vmax and Km. **5 Hrs**

SEMESTER-VIII

Subject code: 8T1
Subject: Pharmaceutics (DFT-II) (NDDS)
THEORY: **45 Hours (3 Hrs. /week)**

1. Fundamental Concepts in Controlled Release **8 Hrs**
Introduction. Rationale of sustained/controlled drug delivery. Routes of drug delivery. Polymer properties influencing drug permeation. Factors influencing the design and performance of sustained/controlled drug delivery system. Physicochemical properties of a drug influencing drug product design and performance. Biological factors influencing design and performance of sustained/controlled release system.

2. Oral Controlled Drug Delivery Systems **9 Hrs**
Introduction, Design and fabrication of novel drug delivery system for oral controlled release:- osmotic pressure-controlled gastrointestinal delivery systems, hydrodynamic pressure-controlled gastrointestinal delivery systems, membrane permeation-controlled gastrointestinal delivery systems, gel diffusion-controlled gastrointestinal delivery systems, pH-controlled gastrointestinal delivery systems, ion-exchange-controlled gastrointestinal delivery systems. Modulation of gastrointestinal transit time:- gastrointestinal anatomy and dynamics, prolongation of GI retention (hydrodynamically balanced intragastric delivery system, intragastric floating gastrointestinal drug delivery system, inflatable gastrointestinal drug delivery system, intragastric osmotically controlled drug delivery system, intrarumen controlled-release drug delivery device, bio/mucoadhesive gastrointestinal drug delivery systems, co administration with GI motility-reducing drugs).

3. Ocular Controlled Drug Delivery Systems **7 Hrs**
Eye anatomical and physiological overview. Absorption of drug in eye. Controlled ocular delivery systems: - requisites of controlled ocular delivery systems, polymeric solutions, phase transition systems, mucoadhesive/bioadhesive dosage forms, collagen shields, pseudolatices, ocular penetration enhancers, ocular iontophoresis. Ocular drug delivery devices:- Matrix-type drug delivery systems, capsular-type drug delivery systems, implantable drug delivery pumps. Particulate systems for ocular drug delivery, Vesicular system for ocular drug delivery.

4. Parenteral Controlled Drug Delivery Systems **13 Hrs**

Introduction, Major routes of parenteral administration, Biopharmaceutics of sustained/controlled release parenteral drug products. Biocompatibility of polymeric materials, Sustained/controlled release dosage forms: - aqueous solution (high viscosity products, complex formation), aqueous suspension (use of viscosity builder, microspheres, microcapsules, magnetic microspheres), oil solution, oil suspensions, emulsions, biocompatible carriers (erythrocytes, biological and synthetic macromolecules), liposomes, implants, infusion devices, prodrugs. Drug targeting :- Active and passive drug targeting, carriers for targeted drug delivery system (Monoclonal antibodies, immunoliposomes, lipoproteins, polymeric micelles and nanoparticles).

5. Transdermal Drug Delivery Systems **8 Hrs**

Introduction. Fundamentals of skin permeation. Rationale for transdermal drug delivery. Approaches to development of transdermal therapeutic systems: - membrane-moderated systems, adhesive diffusion-controlled systems, matrix dispersion-type systems, microreservior system. Kinetic evaluation of transdermal therapeutic systems:- *in vitro* release kinetics, *in vitro* skin permeation kinetics, *in vitro in vivo* correlation. Skin irritation and sensitization testing of transdermal drug products.

Subject code: 8P1
Subject: Pharmaceutics (DFT-II) (NDDS)
PRACTICAL: **3 Hrs. /week**

1. To prepare floating dosage form and characterize it (Minimum two experiments).
2. To prepare microspheres by desolvation technique and characterize them.
3. To study the effect of temperature on rheological properties of thermosensitive polymers.
4. To study the effect of pH on rheological properties of Carbopol gels.
5. To prepare granules by melt granulation technique and evaluate them.
6. To prepare transdermal film and characterize it.
7. To prepare matrix tablet containing swellable polymer and perform water uptake study.
8. To prepare beads by ionotropic gelation method and characterize them.
9. To study the effect of pH on swelling properties of polymer.

Subject code: 8T2
Subject: Pharmaceutical Biotechnology and Molecular Biology
THEORY: **45 Hours (3 Hrs. /week)**

1. Basic Principles of Molecular Biology and Recombinant DNA Technology **12 Hrs**

General structure of cell, recombination in cell.
Tools and Techniques of rDNA technology - Enzymes, cloning vectors, gene cloning, gene library, Southern blotting, Western blotting, Colony hybridization, Polymerase chain reaction, Preparation of Recombinant DNA.

Pharmaceutical Application of rDNA technology- Production of recombinant proteins, insulin, growth hormones, interferon, monoclonal antibodies.

2. Plant Tissue Culture **10 Hrs**

Development of plant tissue cultures, Cellular totipotency, Organ cultures, callus and suspension cultures, Organogenesis, somatic embryo genesis, Protoplast fusion. Germplasm storage including cryopreservation.

3. Animal Tissue Culture **10 Hrs**

Animal cell & tissue culture, advantages and disadvantages, laboratory technique, primary culture, cell-lines and cloning. Disaggregation of tissue and primary culture, cultured cells and evolution of cell lines, cloning of cell lines, Large Scale Cell cultures in Biotechnology, Somatic cell fusion. Genetic recombination in animal cells, Mammalian cell cultures.

4. Introduction to fermentation process **8 Hrs**

Fermenter- Construction, type and working. Fermentation monitoring. Fermentation medium and its sterilization.
Downstream processing – *In situ* recovery of fermentation products. Isolation of fermentation products with special reference to penicillins, streptomycin, tetracyclines and vitamin B12.

5. Immobilization technology **5 Hrs**

Need, Principle, Methods- Adsorption, Entrapment, Covalent bonding, Cross-linking. Application of immobilized cell and enzymes.

Subject code: 8P2
Subject: Pharmaceutical Biotechnology and Molecular Biology
PRACTICAL: **3 Hrs. /week**

1. Protein separation by gel electrophoresis
    a. Preparation of Electrophoresis apparatus.
    b. Stacking of Gel & Well Preparation.
    c. Estimation of total Protein content from sample & preparation of standard curve.
    d. Sample preparation & loading of sample into sample wells & running of Gel.
    e. Staining.
2. Estimation of Protein with standard curve by Ninhydrine method.
3. Estimation of Protein with standard curve by Biuret method.
4. Isolation of DNA from bacteria (Demonstration).
5. Isolation of DNA from plants.
6. Immobilization of enzyme/ microbial cells by entrapment in sodium alginate.
7. Immobilization of enzyme/ microbial cells by entrapment in agarose gel.
8. Fermentative production of penicillin/Neomycin (Demonstration)
9. Fermentative production of citric acid.
10. Biological assays of various fermented products.
11. Development of secondary metabolites by plant tissue culture.

Subject code: 8T3
Subject: Pharmaceutical Analysis-IV (Spectroscopy)
THEORY: **45 Hours (3 Hrs. /week)**

1. Molecular Absorption Spectroscopy

a) UV-Visible Spectroscopy: **12 Hrs**

- Brief review of Electromagnetic Spectrum & its properties.
- Absorption Law & Limitations.
- Theory of Electronic Spectroscopy.
- The Chromophore concept, Choice of Solvent and Solvent Effects.
- Modern Instrumentation (Single Beam, Double Beam) Design & Working Principle, with significant emphasis on Source, Filters, Monochromators including Gratings, Sample Holder (Cuvette) and Detectors.
- Application of UV-Visible Spectroscopy (Qualitative & Quantitative analysis) including Difference & Derivative Spectroscopy.

b) IR Spectroscopy: **8 Hrs**

- IR regions, Requirements for IR absorption.
- Basic Principle.
- Vibrational Frequency & Factors influencing vibrational frequency.
- Fundamental Modes of Vibrations in diatomic molecule
- Instrumentaion with significant emphasis on Sampling Techniques and Heat Detectors.
- Applications in identification of functional groups.

c). Atomic Absorption & Emission Spectroscopy: **5 Hrs**

- Basic Principle.
- Difference between AAS & FES.
- Instumentation, Advantages & disadvantages and Pharmaceutical applications.

2. Mass Spectroscopy: **8 Hrs**

- Introduction.
- Basic Principle.
- Instrumentation emphasis should be on Single Focusing, Double Focusing (Quadrupole MS), Hyphenated Techniques like GCMS, HPLCMS, EIMS, CIMS, FIMS, FABMS.
- Various ions in MS- Molecular Ion, Metastable Ion, Base Peak.
- General Modes of Fragmentation.

3. Nuclear Magnetic Resonance Spectroscopy: **12 Hrs**

- Introduction.

- Theory (Spinning nucleus, effect of external magnetic field, precessional motion, precessional frequency, energy transitions)
- Chemical Shift and its measurement (delta & tau), Factors influencing Chemical Shift.
- Solvents used in NMR.
- Signal splitting, Spin-Spin coupling and Decoupling.
- Instrumentation.

Subject code: 8P3
Subject: Pharmaceutical Analysis-IV (Spectroscopy)
PRACTICAL: 3 Hrs. /week

1. Calibration of UV-Visible Spectrophotometer,
2. Determination of Wavelength of maximum absorbance using UV spectrophotometer & validity of Lambert Beer's law.
3. To study the effect of solvent & pH on UV spectrophotometer of a given compound.
4. Assay of Paracetamol Tablets using UV Spectrophotometer.
5. Assay of Metformin Tablets using UV Spectrophotometer.
6. Assay of Metaprolol Tablets using UV Spectrophotometer.
7. Assay of Propanolol Tablets using UV Spectrophotometer.
8. Assay of Furesemide Tablets using UV Spectrophotometer.
9. Assay of Bromhexine Tablets using UV Spectrophotometer.
10. Assay of Hydrochlorothiazide Tablets using UV Spectrophotometer.
11. Demonstration of IR, AAS etc
12. To study IR spectra of given compound(s) (Minimum three compounds)

Subject code: 8T4
Subject: Pharmacognosy and Phytochemistry-VI (Industrial Pharmacognosy)
THEORY: 45 Hours (3 Hrs. /week)

1.Introduction
Herbal Drug regulations in India, Intellectual Property Rights with special reference to phytoconstituents. Regulation pertaining to trade drugs. Status of India in herbal export market, Trade market in medicinal plant. **5 Hrs**

2.Herbal Formulations 10 Hrs
A comparative study of Ayurvedic and modern dosage forms, Different stages of Herbal formulations , study of methods of preprations of various ayurvedic dosages forms. like Aristas, Asava, Ghutika, Tailia, Churna, Avaleha, Ghritaand Bhasms, Unani formulations like Majooms, Safoofs and their evaluation. Determination of heavy metals in herbal preparation and alcohol contents in Aristas and Asvas.

3.Herbal cosmetics 5 Hrs
Source, Historical background and present status Raw material – Oils, Waxes, Gums, Hydrophillic colloids, colours, perfumes, protective agents, Bleaching agents,Preservatives, Antioxidants and other Auxillary agents.Formulatoin aspects of incorporating Herbal extracts in various preparations like Talcum powders,Face pack,cold cream, cleansing creams, shampoo & lipstick.

4.Quality control in the production chain of herbal product 4 Hrs
Introduction, product chain, Benefits of integral quality control and basic requirements of quality control of herbal production.

5.Neutraceutials 5 Hrs
Introduction, classification, Neutraceuticals and diseases cardiovascular, obesity, Diabetes, cancer and inflammatory diseases

6.Traditional plant drugs used in herbal formulations 7 Hrs
Common names, sources, active constituents and uses of:
Punarnava (*Boerhavia diffusa*), Shankhpushpi (*Convolvulus microphylla*), Lehsun (*Allium sativum*), Guggul (*Commiphora mukul*), Kalmegh (*Andrographis peniculata*), Tulsi (*Ocimum sanctum*), Valerian (*Valerian officinalis*), Artemisia (*Artemisia annua*), Chirata (*Swertia chirata*), Asoka (*Saraca indica*), Saffron (*Crocus sativa*), Shilajit, Brahmi *(Bacopa monnieri* and *Centella asiatica*), Salai (*Boswellia serrata*), Giloe (*Tinospora cordifolia*).

7.GMP for production of phytomedicine 4 Hrs

Introduction,personnel,Building and facilities, sanitation, Equipments, maintenance, computer system validation,calibration,warehousing , quality manual and site master file.

8.Marine Drugs **5 Hrs**

Sources and Pharmacological activities of newer medicinal agents of Marine source with special reference to Anti-inflammatory, cardiovasucular, anticancer agents and marine toxins.

Subject code: 8P4
Subject: Pharmacognosy and Phytochemistry-VI (Industrial Pharmacognosy)
PRACTICAL: **3 Hrs. /week**

1. Perform and develop qualitative "fingerprint profile" of following herbal drugs by official thin layer chromatographic methods-
    a. *Andrographis paniculata*
    b. *Bacopa monnieri*
    c. *Boswellia serrata*
2. Isolation of caffeine from Tea powder
3. Isolation of tannic acid from Myrobalan
4. Determination of heavy metals in herbal drugs by Atomic Absorption Spectroscopy (Demonstration)
5. Formulation and evaluation of following category of Aurvedic preparations (Minimum one of each category)
    i. Asava and Arista
    ii. Churna
    iii. Lepas
    iv. Ghrita and Taila
    v. Natural sunccreen oil
    vi. Natural blooming bath oil

Subject code: 8T5
Subject: Pharmacovigilence (Drug safety)
THEORY: **45 Hours (3 Hrs. /week)**

1. Introduction to Pharmacovigilance, Development of Pharmacovigilance system in India, Various legislations enacted, Safety regulations, WHO, CIOMS and Pharmacovigilance, ICH guidelines **6 Hrs**
2. **Methods of Pharmacovigilance:** Passive surveillance, Stimulated surveillance, Active surveillance, Comparative observational studies, Targeted surveillance. Case report and its contents and various data bases **4 Hrs**
3. **Adverse Drug Reactions (ADR):** Definition, Classification of ADRs, Type A and B reactions **6 Hrs**
4. **Causality Assessment:** Various types of causality assessment. Criteria of causality evaluation. Do's and Dont's of causality evaluation **4 Hrs**
5. **MedDRA:** Advantages, Structure of MedDRA, System Organ Class **4 Hrs**
6. **Single detection:** Definition, benefit and risk evaluation, data mining and case studies **7 Hrs**
7. **Special cases:** Study of special cases fall under Pharmacovigilance purview **4 Hrs**
8. **Special population:** Paediatric, Geriatric, and Pregnant population **6 Hrs**
9. **Drug safety of Biopharmaceuticals and Biosimilars:** Safety concerns of Biopharmaceuticals and Biosimilars, Immunogenicity, Limitations pertaining to drug safety, Risk management plan **4 Hrs**

Subject code: 8T6
Subject: Industrial Pharmacy
THEORY: **45 Hours (3 Hrs. /week)**

1. **Pilot Plant Scale up Techniques:** Significance of pilot plant study, requirements, raw materials, preparation of master procedures, Product considerations: solid dosage forms, injections, semisolids and ophthalmic products **6 Hrs**
2. **Pelletization Techniques:** A general overview of pellets, preparation of pellets by extrusion/spheronization, centrifugal method, fluid bed processes. Properties of pellets: size and size distribution, shape, density/porosity, mechanical properties. Formulation aspect of pellets. **6 Hrs**
3. **Microencapsulation:** Core and coat properties, Techniques of microencapsulation: phase separation, coacervation, multi orifice, spray congealing, polymerization, air suspension and coating pan, evaluation of microcapsules. **6 Hrs**
4. **Aerosols:** Principle, components of aerosol package-propellents (types), container, valves and actuators, aerosol formulations and different types of systems, manufacture, stability testing and quality of aerosols. **6 Hrs**
5. **Optimization Techniques in Pharmaceutical Formulation and processing:** Concept of optimization, optimization parameters, optimization methods. **5 Hrs**
6. **Packaging of Pharmaceuticals;** Desirable characteristics, Detail study of different types of container and closure (glass, plastic and rubbers) including their merits and demerits. Temper-resistant packaging, control of packaging materials. Selection and evaluation of pharmaceutical packaging materials. **7 Hrs**
7. **cGMP:** Introduction, Regulatory objectives of cGMP, Organization and Personnel, Buildings and Facilities, Production and Process control, packaging and Labeling control, Record and Reports. **6 Hrs**
8. **Safety management:** Industrial hazards due to fire, accident, mechanical and electrical equipment, chemicals and pharmaceutical safety measures. **3 Hrs**

RECOMMENDED BOOKS

Pharmaceutics

(Subject code : 1.1,1.6,2.1,3.1,3.6,4.1,4.6,5.1,5.6,6.1,7.1,7.6,8.1,8.6)

1. A Kydoneius. Treatis on controlled drug delivery: Fundamentals, Optimization, Applications. Marcel dekker, New York.
2. A. J. Winfield, RME Richardson. Pharmaceutical Practice. Churchill Livingstone. USA.
3. A. R., Gennero, Remington The Science and Practice of Pharmacy. Vol. I-II, Lippincott William and Wilkins
4. Alexander T. Florence, David Attwood, Physicochemical principals of pharmacy, Pharmaceutical press
5. Alfred Martin, Physical Pharmacy and Pharmaceutical Sciences, Lippincott Williams and Wilkins
6. Alfred Martin, Pilar Bustomonte. Problem solving : Physical Pharmacy, Lea and Febiger Publication
7. AM Hillary, AW Lloyd, J Swarbrick. Drug delivery and targeting for pharmacists and pharmaceutical scientists. Taylor and Francis, New York.
8. B. M., Mittal, - A Textbook of Forensic Pharmacy, Vallabh Prakashan
9. British Pharmaceutical Codex
10. British Pharmacopoeia, MHRA, London
11. CM Correa, AA Yusuf. Intellectual property and international trade: The TRIPS agreements. Kluwer Law International, London.
12. D Mathews. Globalizing intellectual property rights: The TRIPS Agreement. Taylor and Franchis Group. London.
13. D. R. Gupta, R. K. Rajput. Purchasing and Store keeping. McGraw Hill.
14. David Attwood, Alexander T. Florence, Physical Pharmacy, Pharmaceutical Press

15. DJ Pisano, D Mantus. FDA Regulatory affairs: a guide for prescription drugs,medical devices, and biologics. CRC Press, Washington DC.
16. E. A., Rawlins, Ed., Bentley's Textbook of Pharmaceutics, Ballierwe Tindall, (ELBS publication)
17. E. S. Shotton, Physical Pharmaceutics, Oxford University Press
18. G.S. Banker and C.T. Rhode, Modern Pharmaceutics, Marcel Dekker Inc., NY.
19. Graham Cole (Ed). Pharmaceutical Production Facilities: Design and Applications. Taylor and Francis.
20. H. C. Ansel, L. V. Allen & N. G. Popovich, Pharmaceutical Dosage Form and Drug Delivery Systems, Lippincott, Willaims & Wilkins, Philadelphia.
21. H. M. Burlage and C. O. Lee. Physical and Technical Pharmacy. McGraw Hill Book Co. New York.
22. H. S. Bean, A. H. Beckett. J. E. Carless, Advances in Pharmaceutical sciences, Academic Press
23. H. Weihrich & H. Koontz, Management: A global perspectives, Tata McGraw Hill Publishing Co. Ltd. Delhi.(International Edition)
24. H.A. Lieberman, L. Lachman & J.B. Schwartz, Pharmaceutical Dosage Forms: Tablets, Marcel Dekker Inc., NY.
25. H.A. Lieberman, L. Lachman & J.B. Schwartz, Pharmaceutical Dosage Forms: Disperse system, Marcel Dekker Inc., NY.
26. H.A. Lieberman, L. Lachman, Pharmaceutical Dosage Forms: Parenteral Medication, Edited By: K. E. Avis, Marcel Dekker Inc., NY.
27. Indian Pharmacopoeia, Published by The Indian Pahrmacopoeia Commission, Gaziabad.
28. J. E. Hoover. Dispensing of Medication. Mack Publishing Co. USA.
29. J. Kuanpoth. Patents Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future. Edward Elgar Publishing Inc. Massachusetts.
30. J. Swarbrick. Encyclopedia of Pharmaceutical Technology. Vol 1-6. Informahealthcare. USA
31. JD Nally. Good manufacturing Practices for Pharmaceuticals. Informa healthcare, New York.
32. JR Robinson, VHL Lee. Controlled drug delivery: Fundamentals and application, Marcel Dekker, New York.
33. L. Lachman; H.A. Liberman; J.L.Kanig.The Theory and Practice of Industrial Pharmacy,Verghese Publishing House, Mumbai.
34. L. V. Allen Jr., N. G. Popovich and H. C. Ansel "Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems ", Lippincotts Williams and Wilkin.
35. Leon Shargel, Susanna Wu-pong Andrew Yu. Applied Biopharmaceutics and Pharmacokinetics. McGraw Hill.
36. LL Augsburger and SW Hoag. (Eds). Pharmaceutical Dosage Forms: Tablets. Vol. 1: Unit Operations and Mechanical Properties. Informa healthcare, New York.
37. M C Allwood and Blackwell.Textbook of Hospital Pharmacy.
38. M. C. Smith, Principles of Pharmaceutical Marketing, CBS publisher, New Delhi.
39. M. E. Aulton, D.M. Collett(Eds). Pharmaceutical Practice. Churchill Livingstone. USA.
40. M. E., Aulton "Pharmaceutics The Science of Dosage Form Design" Churchill Livingstone, London
41. M. J., Stocklosa, H. C. Ansel, Pharmaceutical Calculations, by K.M. Varghese Company
42. M. M. Rieger, Harry's Cosmetology, Chemical Publishing Co. Inc. New York.
43. M.A. Voet. The Generic Challenge: Understanding Patents, FDA and Pharmaceuticals Life-Cycle Management. Brown Wolker Press. Florida.
44. Milo Gibaldi. Biopharmaceutics Clinical Pharmacokinetics. Lea & Febiger book publication USA.
45. MP Mathieu. New drug development: a regulatory overview. Parexel International Corporation, Waltham, MA.
46. NK Jain. Controlled and novel drug delivery, CBS publishers and distributors, New Delhi.
47. NS Gopalakrishnan. Intellectual property and criminal law. National law school of India University. Banglore.
48. O. Kayser, H. Warzecha. Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications. Wiley Blackwell. Weinheim.
49. PJ Groves. Intellectual property rights and their valuation. Gresham Books, an imprint of woodhead publishing limited. England.
50. R A Guarino. New Drug Approval Process. Marcel Dekker. New York.
51. R.A. Nash and I. R. Berry. Pharmaceutical Process Validation. Marcel Dekker, Inc.
52. Remington's: The Science and Practice of Pharmacy, Lippincott, Willaims & Wilkins, Philadelphia.

53. Robert E. Notari. Biopharmaceutics and Clinical Pharmacokinetics: An Introduction. Marcel Dekker, New York.
54. Robert Perry, Don Green, James Maloney, Perry's Chemical Engineers' Handbook, McGraw Hill Inc., Singapore.
55. Roger Walker and Clive Edwards. Clinical Pharmacy and Therapeutics. Churchill Livingstone.
56. S. Chaudhari. The WTO and India's Pharmaceutical Industry: Patent Protection, TRIPs and Developing Countries. Oxford University Press.
57. S. J. Carter, Cooper and Gunn's Tutorial pharmacy, CBS Publishers & distribution, Dehli
58. S. J. Turco, R. E. King, Sterile Dosage Forms: Their preparation and clinical application, Lippincott, Willaims & Wilkins, Philadelphia.
59. S.J. Carter (Ed). Cooper and Gunn's Dispensing Pharmacy. CBS Publications.
60. SP Vyas, RK Khar. Controlled drug delivery: concepts and advances. Vallabh Prakashan, Delhi.
61. Thomas Jacobson and Albert Wertheimer. Modern Pharmaceutical Industry. Jones and Barlett publishers. LONDON, UK.
62. United States Pharmacopoeia & National Formulary, The United States Pharmacopoeial Convention, Washington DC.
63. W.E. Hassen. Hospital pharmacy, Lec & Febiger Publications.
64. Walter Badger and Julius Banchero, Introduction to Chemical Engineering, Tata-McGraw Hill Publishing Company Ltd, New Delhi.
65. Warren McCabe, Julian Smith and Peter Harriott, Unit operations of chemical engineering, McGraw Hill Inc., Singapore.
66. WR Cornish. Intellectual property. Sweet and Maxwell, London.
67. X Li, BR Jasti. Design of Controlled Release Drug Delivery Systems. McGraw-Hill, New York
68. YW Chein. Novel Drug Delivery Systems. Marcel Dekker New York.

Pharmaceutical Chemistry
(Subject code : 1.2,1.4,2.2,2.4,3.2,4.2,4.3,5.2,6.2,6.6,7.2,7.3,8.3)

1. A. Bahal and B.S. Bahl, A Text Book of Organic Chemistry, S. Chand & Company Ltd., New Delhi
2. A.H. Beckett, J.B. Stenlake, Practical Pharmaceutical Chemistry, Part I and Part II, CBS Publishers and Distributors, New Delhi.
3. A.I. Vogel, Elementary Practical Organic Chemistry, Part III, Quantitative Organic Analysis, Second Edition, CBS Publishers and Distributors, Delhi.
4. A.L. Lehninger, Principles of Biochemistry, CBS Publishers & Distributors Pvt. Ltd., India.
5. Alfonso R. Gennaro, Lippincott Williams and Wilkins, Remington, The Science and Practice of Pharmacy, A Wolters Kluwer Company, Philadelphia.
6. Ashutosh Kar, Advanced Practical Medicinal Chemistry, New Age International Publication.
7. Ayers: "Quantitative Chemical Analysis," (Harper International Ed.), Harper & Row.
8. B.K. Sharma. Instrumental Methods of Chemical Analysis, Goel Publishing House, Meerut.
9. Bentley and Driver, Textbook of Pharmaceutical Chemistry, Oxford University Press, Walton Street, Oxford
10. British Pharmacopoeia, MHRA, London
11. C.K. Mathews, K.F. Van Holde, K.G. Ahern, Biochemistry, Pearson Education.
12. Clarence A. Discher, Modern Inorganic Pharmaceutical Chemistry, Wiley, New York.
13. D. Voet, J.G. Voet, C.W. Pratt, Fundamentals of Biochemistry, John Wiley & Sons, Inc.
14. D.A., Skoog, F.J. Holler, S.R. Crouch, Principles of Instrumental Analysis. Baba Barkha Nath Printers, Haryana.
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Allied Subjects
(Subject code : 2.6,3.5,4.5,8.2)

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Note: Latest edition of the book is recommended.

Annexure-I

Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur

B. Pharm. Syllabus

Credit-grade based performance and assessment system (CGPA)

Absorption Scheme for B. Pharm. (Old Course) To B. Pharm. (New Course) semester pattern

1. The first year B. Pharm. (old course) students either ATKT or failure at his/her will can be absorbed in B. Pharm. Semester-I (new course) as fresh student.

   However, the passed or ATKT students of first year B. Pharm. (old course) can be absorbed in B. Pharm. semester-III (new course). He/she has to pass the subjects 1T6-Hospital Pharmacy, 2T4-Pharmaceutical Analysis-I (Titrations) and 2P4- Pharmaceutical Analysis-I (Titrations) of semester I and II of B. Pharm. (new course) and the subjects in which he/she has failed.

2. (i)The passed / ATKT students of second B. Pharm. (old course) have to appear and pass the following 6 theory and 4 practical subjects in addition to the subjects in which he/she has failed (for ATKT students), his / her result of semester V and VI of B. Pharm. (new course) shall not be declared unless he / she clears the subjects of semester I, II, III and IV.

   (ii) In case of failure, students of second B. Pharm. (old course) have to be absorbed in semester III of B. Pharm. (new course), they have to pass the following 6 theory papers and 4 practical subjects, in addition to the subjects in which he/she has failed.

Sr. No.	Subject code	Theory Subjects	Sr. No.	Subject code	Practical subjects
		Semester I B. Pharm (new course)			
1.	1T6	Hospital Pharmacy			
		Semester III B. Pharm (new course)			
2.	3T3	Pathophysiology and Clinical Biochemistry (Pathophysiology of common diseases)	1.	3P3	Pathophysiology and Clinical Biochemistry (Pathophysiology of common diseases)
3.	3T5	Pharmaceutical Microbiology and Immunology-I	2.	3P5	Pharmaceutical Microbiology and Immunology-I
		Semester IV B. Pharm. (new course)			
4.	4T3	Pharmaceutical Analysis-II (Electroanalytical and Physical methods)	3.	4T3	Pharmaceutical Analysis-II (Electroanalytical and Physical methods)
5.	4T5	Pharmaceutical Microbiology and Immunology-II	4.	4T5	Pharmaceutical Microbiology and Immunology-II
6.	4T6	Pharmaceutical Management			

3 (i). The passed / ATKT students of third B. Pharm. (old course) have to appear and pass the following 6 theory and 3 practical subjects in addition to the subjects in which he/she has failed (for ATKT students), unless he/she clears these subjects of semester III, IV, V and VI of B. Pharm. (new course), his / her result of semester VII and VIII shall not be declared.

(ii) Similarly, the failure students of third year B. Pharm. (old course) have to appear and pass the following 6 theory and 3 practical subjects in addition to the subjects in which he/she has failed.

Sr. No.	Subject code	Theory Subjects	Sr. No.	Subject code	Practical subjects
		Semester III B. Pharm (new course)			
1.	3T3	Pathophysiology and Clinical Biochemistry (Pathophysiology of common diseases)	1.	3P3	Pathophysiology and Clinical Biochemistry (Pathophysiology of common diseases)
		Semester IV B. Pharm. (new course)			
2.	4T6	Pharmaceutical Management			
		Semester V B. Pharm. (new course)			
3.	5T5	Clinical Pharmacy	2.	5P5	Clinical Pharmacy
4.	5T6	Regulatory Affairs and Intellectual Property Right			
		Semester VI B. Pharm. (new course)			
5.	6T5	Clinical Pharmacotherapeutics-I	3.	6P5	Clinical Pharmacotherapeutics-I
6.	6T6	Pharmaceutical Validation			

4. The failure students of final B. Pharm. (old course) have to clear their all backlog subjects of old course in 1+3 attempts. After these attempts they have to appear and clear the matchable subject(s) to these subject(s) in which they have failed as per "Scheme of Matchable subjects" given in Annexure II.

   The new B. Pharm. course is semester based with Credit and Grade system. The above absorbtion scheme is unfeasible considering the number of theory papers and especially, the practical subjects they have to pass and practically difficult for grant of Credits and Grade. Hence, it is recommended as follows:

   "Students of second year B. Pharm. (old course) and onwards shall be given 100 percent carry over for the purpose of keeping terms in the higher classes and shall be granted 1+3 attempts to pass their each examinations. Upon completion of these attempts, the failures shall be absorbed as per matchable subjects (Annexure-I) of the B. Pharm. (new course)"

   Note: The above recommendation is based on the similar earlier notification issued by N.U. notification no. Acad/60, dated 6th September 2004 (letter no. Acad/s/382/1274, dated 6th September 2004) and notification no. Acad/N/20 dated 31st January 2011.

Annexure-II

Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur

B. Pharm. Syllabus

Credit-grade based performance and assessment system (CGPA)

Scheme of Absorption & Matchable Subjects

OLD SYLLABUS		NEW SYLLABUS	
Subject Code	**Name of Subject**	**Subject Code**	**Name of Subject**
B. Pharm-I			
1T1	Pharmaceutics-I (General & Dispensing)	2.1	Pharmaceutics-II (General & Dispensing)
1T2	Pharmaceutical Chemistry-I (Organic)	2.2	Pharmaceutical Chemistry-II (Organic)
1T3	Pharmaceutical Chemistry-II (In-organic)	1.2	Pharmaceutical Chemistry-I (Inorganic)
1T4	Pharmaceutical Biochemistry	1.4	Pharmaceutical Biochemistry
1T5	Pharmacology-I (Physiology, Anatomy & Health Education)	2.3	Human Anatomy & Physiology
1T6	Pharmacognosy & Phytochemistry-I	1.5	Pharmacognosy & Phytochemistry I
1T7	Statistics & Computer Application in Pharmacy	2.6	Statistics & Computer Application in Pharmacy
B. Pharm-II			
2T1	Pharmaceutics-II (Physical)	5.1	Pharmaceutics-V (Physical Pharmacy)
2T2	Pharmaceutics-III (Engineering)	4.1	Pharmaceutics-IV (Unit Operations)
2T3	Pharmaceutical Chemistry-III (Organic)	4.2	Pharmaceutical chemistry-IV (Heterocyclic and Macromolecules)
2T4	Pharmaceutical Analysis-I	2.4	Pharmaceutical Analysis-I
2T5	Pharmacology-II	3.4	Pharmacology-I
2T6	Pharmaceutical Jurisprudence and Regulatory Affairs	3.6	Pharmaceutical Jurisprudence and Ethics
2T7	Biophysics & Molecular Biology	-	-
B. Pharm-III			
3T1	Dosage Form Technology-I	7.1	Pharmaceutics (DFT-I) (Conventional)
3T2	Pharmaceutical Microbiology and Immunology	3.5	Pharmaceutical Microbiology & Immunology
3T3	Pharmaceutical Medicinal Chemistry-I	5.2	Pharmaceutical Medicinal Chemistry-I
3T4	Pharmaceutical Analysis-II	4.3	Pharmaceutical Analysis-II (Electroanalytical and Physical Methods)
3T5	Pharmacology-III	5.3	Pharmacology-III
3T6	Pharmacognosy & Phytochemistry-II	5.4	Pharmacognosy & Phytochemistry-III (Chemistry of Natural Products)
3T7	Pharmacy Practices and Management	1.6	Hospital Pharmacy
B. Pharm-IV			
4T1	Dosage Form Technology-II	8.1	Pharmaceutics (DFT-II) (NDDS)
4T2	Biopharmaceutics and Pharmacokinetics	7.6	Biopharmaceutics and Pharmacokinetics
4T3	Biotechnology & Fermentation Processes	8.2	Pharmaceutical Biotechnology & Molecular Biology
4T4	Pharmaceutical Medicinal Chemistry-II	7.2	Pharmaceutical Medicinal Chemistry-III
4T5	Pharmaceutical Analysis-III	7.3	Pharmaceutical Analysis-III (Separation Technique)
4T6	Pharmacology-IV	6.3	Pharmacology-IV
4T7	Pharmacognosy & Phytochemistry-III	8.5	Pharmacognosy & Phytochemistry-V (Phytopharmaceutical / Herbal technology)
4T8	Quality Assurance	6.6	Pharmaceutical Validation

Pharmacy Council of India

New Delhi

Rules & Syllabus for the Bachelor of Pharmacy (B. Pharm) Course

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[Framed under Regulation 6, 7 & 8 of the Bachelor of Pharmacy (B. Pharm) course regulations 2014]

CHAPTER- I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the B. Pharm. Degree Program (CBCS)of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

2. Minimum qualification for admission

2.1 First year B. Pharm:

Candidate shall have passed 10+2 examination conducted by the respective state/central government authorities recognized as equivalent to 10+2 examination by the Association of Indian Universities (AIU) with English as one of the subjects and Physics, Chemistry, Mathematics (P.C.M) and or Biology (P.C.B / P.C.M.B.) as optional subjects individually. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

2.2. B. Pharm lateral entry (to third semester):

A pass in D. Pharm. course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

3. Duration of the program

The course of study for B.Pharm shall extend over a period of eight semesters (four academic years) and six semesters (three academic years) for lateral entry students. The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semestershall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

7.2. Minimum credit requirements

The minimum credit points required for award of a B. Pharm. degree is 208. These credits are divided into Theory courses, Tutorials, Practical, Practice School and Projectover the duration of eight semesters. The credits are distributed semester-wise as shown in Table IX. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

The lateral entry students shall get 52 credit points transferred from their D. Pharm program. Such students shall take up additional remedial courses of 'Communication Skills' (Theory and Practical) and 'Computer Applications in Pharmacy' (Theory and Practical) equivalent to 3 and 4 credit points respectively, a total of 7 credit points to attain 59 credit points, the maximum of I and II semesters.

8. Academic work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

9. Course of study

The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII.

Table-I: Course of study for semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I– Theory	3	1	4
BP102T	Pharmaceutical Analysis I – Theory	3	1	4
BP103T	Pharmaceutics I – Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
BP105T	Communication skills – Theory *	2	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	2	-	2
BP107P	Human Anatomy and Physiology – Practical	4	-	2
BP108P	Pharmaceutical Analysis I – Practical	4	-	2
BP109P	Pharmaceutics I – Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
BP111P	Communication skills – Practical*	2	-	1
BP112RBP	Remedial Biology – Practical*	2	-	1
	Total	**32/34$/36#**	**4**	**27/29$/30#**

#Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course**.**

$Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course**.**

* Non University Examination (NUE)

Table-II: Course of study for semester II

Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3	-	3
BP206T	Environmental sciences – Theory *	3	-	3
BP207P	Human Anatomy and Physiology II –Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical*	2	-	1
	Total	**32**	**4**	**29**

*****Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3	1	4
BP302T	Physical Pharmaceutics I – Theory	3	1	4
BP303T	Pharmaceutical Microbiology – Theory	3	1	4
BP304T	Pharmaceutical Engineering – Theory	3	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4	-	2
BP306P	Physical Pharmaceutics I – Practical	4	-	2
BP307P	Pharmaceutical Microbiology – Practical	4	-	2
BP 308P	Pharmaceutical Engineering –Practical	4	-	2
	Total	**28**	**4**	**24**

Table-IV: Course of study for semester IV

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3	1	4
BP402T	Medicinal Chemistry I – Theory	3	1	4
BP403T	Physical Pharmaceutics II – Theory	3	1	4
BP404T	Pharmacology I – Theory	3	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3	1	4
BP406P	Medicinal Chemistry I – Practical	4	-	2
BP407P	Physical Pharmaceutics II – Practical	4		2
BP408P	Pharmacology I – Practical	4	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4	-	2
	Total	**31**	**5**	**28**

Table-V: Course of study for semester V

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial PharmacyI– Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Industrial PharmacyI – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
	Total	**27**	**5**	**26**

Table-VI: Course of study for semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3	1	4
BP606T	Quality Assurance –Theory	3	1	4
BP607P	Medicinal chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
	Total	**30**	**6**	**30**

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3	1	4
BP702T	Industrial PharmacyII – Theory	3	1	4
BP703T	Pharmacy Practice – Theory	3	1	4
BP704T	Novel Drug Delivery System – Theory	3	1	4
BP705P	Instrumental Methods of Analysis – Practical	4	-	2
BP706PS	Practice School*	12	-	6
	Total	**28**	**5**	**24**

***** Non University Examination (NUE)

Table-VIII: Course of study for semester VIII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management	3 + 3 = 6	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardization of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraceuticals			
BP813PW	Project Work	12	-	6
	Total	**24**	**4**	**22**

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	**27/29$/30#**
II	29
III	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	**209/211$/212#**

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.

#Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course.

10. Program Committee

1. The B. Pharm. program shall have a Program Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Program Committee shall be as follows:

   A senior teacher shall be the Chairperson; One Teacher from each department handling B.Pharm courses; and four student representatives of the program (one from each academic year), nominated by the Head of the institution.

3. Duties of the Program Committee:

   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessionalexam (Internal Assessment) and before the end semester exam.

11. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table – X.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to VIII shall beconducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables-X: Schemes for internal assessments and end semester examinations semester wise

Semester I

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP101T	Human Anatomy and Physiology I– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP102T	Pharmaceutical Analysis I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP103T	Pharmaceutics I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP104T	Pharmaceutical Inorganic Chemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP105T	Communication skills – Theory *	5	10	1 Hr	15	35	1.5 Hrs	50
BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory*	5	10	1 Hr	15	35	1.5 Hrs	50
BP107P	Human Anatomy and Physiology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP108P	Pharmaceutical Analysis I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP109P	Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP110P	Pharmaceutical Inorganic Chemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP111P	Communication skills – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
BP112RBP	Remedial Biology – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	**70/75$^{\$}$/80$^{\#}$**	**115/125$^{\$}$/130$^{\#}$**	**23/24$^{\$}$/26$^{\#}$ Hrs**	**185/200$^{\$}$/210$^{\#}$**	**490/525$^{\$}$/ 540$^{\#}$**	**31.5/33$^{\$}$/ 35$^{\#}$ Hrs**	**675/725$^{\$}$/ 750$^{\#}$**

$^{\#}$Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

$^{\$}$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

***** Non University Examination (NUE)

Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP201T	Human Anatomy and Physiology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP202T	Pharmaceutical Organic Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP203T	Biochemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP204T	Pathophysiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP205T	Computer Applications in Pharmacy – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP206T	Environmental sciences – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP207P	Human Anatomy and Physiology II –Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP208P	Pharmaceutical Organic Chemistry I– Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP209P	Biochemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP210P	Computer Applications in Pharmacy – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	**80**	**125**	**20 Hrs**	**205**	**520**	**30 Hrs**	**725**

***** The subject experts at college level shall conduct examinations

Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP301T	Pharmaceutical Organic Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP302T	PhysicalPharmaceuticsI –Theory	10	15	1 Hr	25	75	3 Hrs	100
BP303T	Pharmaceutical Microbiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP304T	Pharmaceutical Engineering – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP305P	Pharmaceutical Organic Chemistry II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP306P	Physical Pharmaceutics I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP307P	Pharmaceutical Microbiology – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP308P	Pharmaceutical Engineering – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**60**	**100**	**20**	**160**	**440**	**28Hrs**	**600**

Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP401T	Pharmaceutical Organic Chemistry III– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP402T	Medicinal Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP403T	Physical Pharmaceutics II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP404T	Pharmacology I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP405T	Pharmacognosy I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP406P	Medicinal Chemistry I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP407P	Physical Pharmaceutics II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP408P	Pharmacology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP409P	Pharmacognosy I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**70**	**115**	**21 Hrs**	**185**	**515**	**31 Hrs**	**700**

Semester V

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Industrial PharmacyI– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Industrial PharmacyI– Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**65**	**105**	**17 Hr**	**170**	**480**	**27 Hrs**	**650**

Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**75**	**120**	**18 Hrs**	**195**	**555**	**30 Hrs**	**750**

Semester VII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP701T	Instrumental Methods of Analysis – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP702T	Industrial Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP703T	Pharmacy Practice – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP704T	Novel Drug Delivery System – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP705 P	Instrumental Methods of Analysis – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP706 PS	Practice School*	25	-	-	25	125	5 Hrs	150
Total		**70**	**70**	**8Hrs**	**140**	**460**	**21 Hrs**	**600**

***** The subject experts at college level shall conduct examinations

Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharmaceutical Marketing – Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardization of Herbals – Theory							
BP807ET	Computer Aided Drug Design – Theory							
BP808ET	Cell and Molecular Biology – Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology – Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812PW	Project Work	-	-	-	-	150	4 Hrs	150
	Total	**40**	**60**	**4 Hrs**	**100**	**450**	**16 Hrs**	**550**

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table-XI:Scheme for awarding internal assessment: Continuous mode

Theory		
Criteria	**Maximum Marks**	
Attendance (Refer Table – XII)	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
Total	**10**	**5**
Practical		
Attendance (Refer Table – XII)	2	
Based on Practical Records, Regular viva voce, etc.	3	
Total	**5**	

Table- XII: Guidelines for the allotment of marks for attendance

Percentage of Attendance	**Theory**	**Practical**
95 – 100	4	2
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

11.2.1. Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical Sessional examinations is given below. The average marks of two Sessional exams shall be computed for internal assessment as per the requirements given in tables – X.

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for theory Sessional examinations

For subjects having University examination

I. Multiple Choice Questions (MCQs)	=	10 x 1 = 10
OR		OR
Objective Type Questions (5 x 2)	=	05 x 2 = 10
(Answer all the questions)		
I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 2 out of 3)	=	2 x 5 = 10

Total	=	30 marks

For subjects having Non University Examination

I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 4 out of 6)	=	4 x 5 = 20

Total	=	30 marks

Question paper pattern for practical sessional examinations

I. Synopsis	=	10
II. Experiments	=	25
III. Viva voce	=	05

Total	=	40 marks
		----------

12. Promotion and award of grades

A student shall be declared PASSand eligible for getting gradein a course of B.Pharm.program if he/she secures at least 50% marks in that particular course including internal assessment.For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination.

13. Carry forward of marks

In case a studentfails to secure the minimum 50% in any Theory or Practical course as specified in 12,then he/she shall reappear for the end semester examinationof that course. However his/her marks of the Internal Assessmentshallbe carried overand he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A studentshall have the opportunity to improvehis/her performance only oncein the Sessional exam component of the internal assessment. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Re-examination of end semester examinations

Reexamination ofend semester examinationshall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

Table-XIII: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I, III, V and VII	November / December	May / June
II, IV, VI and VIII	May / June	November / December

Question paper pattern for end semester theory examinations

For 75 marks paper

I. Multiple Choice Questions(MCQs) = 20 x 1 = 20
OR OR
Objective Type Questions (10 x 2) = 10 x 2 = 20
(Answer all the questions)
II. Long Answers (Answer 2 out of 3) = 2 x 10 = 20
III. Short Answers (Answer 7 out of 9) = 7 x 5 = 35

Total = 75 marks

For 50 marks paper

I. Long Answers (Answer 2 out of 3) = 2 x 10 = 20
II. Short Answers (Answer 6 out of 8) = 6 x 5 = 30

Total = 50 marks

For 35 marks paper

I. Long Answers (Answer 1 out of 2) = 1 x 10 =10
II. Short Answers (Answer 5 out of 7) = 5 x 5 = 25

Total = 35 marks

Question paper pattern for end semester practical examinations

I. Synopsis = 5
II. Experiments = 25
III. Viva voce = 5

Total = 35 marks

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16. Academic Progression:

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. Academic progression rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of V semester until all the courses of I and II semesters are successfully completed.

A student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of I, II, III and IV semesters are successfully completed.

A student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of I, II, III, IV, V and VI semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to VIII semesters within the stipulated time period as per the norms specified in 26.

A lateral entry student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of III and IV semesters are successfully completed.

A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of III, IV, V and VI semesters are successfully completed.

A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms specified in 26.

Any student who hasgiven more than 4 chances for successful completion of I / III semester courses and more than 3 chances for successful completion of II / IV semester courses shall be permitted to attend V / VII semester classes ONLY during the subsequent academic year as the case may be. In simpler terms there shall NOT be any ODD BATCH for any semester.

Note: Grade ABshould be considered as failed and treated as one head for deciding academic progression. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.The letter grades and their corresponding grade points are given in Table – XII.

Table – XII: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of ABand a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtainedin all the courses by the student during the semester. For example, if a student takes five courses(Theory/Practical) in a semester with credits C1, C2, C3, C4 and C5 and the student's grade pointsin these courses are G1, G2, G3, G4 and G5, respectively, and then students' SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

The SGPA is calculated to two decimal points.It should be noted that, the SGPA for any semester shall take into consideration the F and ABSgrade awarded in that semester. For example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed as:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * \text{ZERO} + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all VIII semesters and their courses. The CGPA shall reflect the failed statusin case of F grade(s),till the course(s) is/are passed. When the course(s)is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8}{C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + C_8}$$

where $C_1, C_2, C_3,\ldots$ is the total number of credits for semester I,II,III,…. and $S_1,S_2, S_3,\ldots$is the SGPA of semester I,II,III,…. .

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	= CGPA of. 7.50 and above
First Class	= CGPA of 6.00 to 7.49
Second Class	= CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a projectunder the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done		15 Marks
Methodology adopted		20 Marks
Results and Discussions		20 Marks
Conclusions and Outcomes		20 Marks
	Total	**75 Marks**

Evaluation of Presentation:

Presentation of work		25 Marks
Communication skills		20 Marks
Question and answer skills		30 Marks
	Total	**75 Marks**

Explanation: The 75 marks assigned to the dissertation book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

22. Industrial training (Desirable)

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

23. Practice School

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college leveland grade point shall be awarded.

24. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the B.Pharm program shall not be eligible for award of ranks.Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

25. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

26. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

27. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

No condonation is allowed for the candidate who has more than 2 years of break up period and he/she has to rejoin the program by paying the required fees.

CHAPTER - II: SYLLABUS

Semester I

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the various experiments related to special senses and nervous system.
5. Appreciate coordinated working pattern of different organs of each system

Course Content:

Unit I **10 hours**

- **Introduction to human body**
  Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.
- **Cellular level of organization**
  Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine
- **Tissue level of organization**
  Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

Unit II **10 hours**

- **Integumentary system**
  Structure and functions of skin
- **Skeletal system**
  Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system
  Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

- **Joints**
  Structural and functional classification, types of joints movements and its articulation

Unit III **10 hours**

- **Body fluids and blood**
- Body fluids, composition and functions of blood, hemopoeisis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.
- **Lymphatic system**

  Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

Unit IV **08 hours**

Peripheral nervous system:
Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.
Origin and functions of spinal and cranial nerves.

- **Special senses**
  Structure and functions of eye, ear, nose and tongue and their disorders.

Unit V **07 hours**

- **Cardiovascular system**
  Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject**.**

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones

6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

BP102T. PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

Scope: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

Objectives: Upon completion of the course student shall be able to

- understand the principles of volumetric and electro chemical analysis
- carryout various volumetric and electrochemical titrations
- develop analytical skills

Course Content:

UNIT-I **10 Hours**

(a) Pharmaceutical analysis- Definition and scope

i) Different techniques of analysis

ii) Methods of expressing concentration

iii) Primary and secondary standards.

iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

(b)Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

(c)Pharmacopoeia, Sources of impurities in medicinal agents,limit tests.

UNIT-II **10 Hours**

- **Acid base titration**: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves
- **Non aqueous titration**: Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

UNIT-III **10 Hours**

- **Precipitation titrations**: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.
- **Complexometric titration**: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.
- **Gravimetry**: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.

- Basic Principles,methods and application of diazotisation titration.

UNIT-IV **08 Hours**

Redox titrations

(a) Concepts of oxidation and reduction

(b) Types of redox titrations (Principles and applications)

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT-V **07 Hours**

- **Electrochemical methods of analysis**
  - **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications.
  - **Potentiometry** - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
  - **Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I **Limit Test of the following**

(1) Chloride
(2) Sulphate
(3) Iron
(4) Arsenic

II **Preparation and standardization of**

(1) Sodium hydroxide
(2) Sulphuric acid
(3) Sodium thiosulfate
(4) Potassium permanganate
(5) Ceric ammonium sulphate

III **Assay of the following compounds along with Standardization of Titrant**

(1) Ammonium chloride by acid base titration
(2) Ferrous sulphate by Cerimetry
(3) Copper sulphate by Iodometry
(4) Calcium gluconate by complexometry
(5) Hydrogen peroxide by Permanganometry
(6) Sodium benzoate by non-aqueous titration
(7) Sodium Chloride by precipitation titration

IV **Determination of Normality by electro-analytical methods**

(1) Conductometric titration of strong acid against strong base
(2) Conductometric titration of strong acid and weak acid against strong base
(3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.

BP103T. PHARMACEUTICS- I (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course Content:

UNIT – I **10 Hours**

- **Historical background and development of profession of pharmacy**: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
- **Dosage forms:** Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT – II **10 Hours**

- **Pharmaceutical calculations**: Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.

- **Powders:** Definition, classification, advantages and disadvantages,Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT – III **08 Hours**

- **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- **Biphasic liquids:**
- **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type ofEmulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV **08 Hours**

- **Suppositories**: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V **07 Hours**

- **Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms

BP109P. PHARMACEUTICSI (Practical)

3 Hours / week

1 . Syrups

a) Syrup IP'66

b) Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs a) Piperazine citrate elixir

b) Paracetamol pediatric elixir

3.Linctus a) Terpin Hydrate Linctus IP'66

b) Iodine Throat Paint (Mandles Paint)

4. Solutions

a) Strong solution of ammonium acetate

b) Cresol with soap solution

c) Lugol's solution

5. Suspensions

a) Calamine lotion

b) Magnesium Hydroxide mixture

c) Aluminimum Hydroxide gel

6. Emulsions a) Turpentine Liniment

b) Liquid paraffin emulsion

7. Powders and Granules

a) ORS powder (WHO)

b) Effervescent granules

c)Dusting powder

d)Divded powders

8. Suppositories

a) Glycero gelatin suppository

b) Coca butter suppository

c) Zinc Oxide suppository

8. Semisolids

a) Sulphur ointment

b) Non staining-iodine ointment with methyl salicylate

c) Carbopal gel

9. Gargles and Mouthwashes

a) Iodine gargle

b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy,Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

Scope: This subject deals with the monographs of inorganic drugs and pharmaceuticals.

Objectives: Upon completion of course student shall be able to

- know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- understand the medicinal and pharmaceutical importance of inorganic compounds

Course Content:

UNIT I **10 Hours**

- **Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

  General methods of preparation, assay for the compounds superscripted with **asterisk (*),** properties and medicinal uses of inorganic compounds belonging to the following classes

UNIT II **10 Hours**

- **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.
- **Major extra and intracellular electrolytes**: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.
- **Dental products**: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III **10 Hours**

- **Gastrointestinal agents**

  Acidifiers: Ammonium chloride* and Dil. HCl

  Antacid: Ideal properties of antacids, combinations of antacids, Sodium

Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV **08 Hours**

- **Miscellaneous compounds**

  Expectorants: Potassium iodide, Ammonium chloride*.

  Emetics: Copper sulphate*, Sodium potassium tartarate

  Haematinics: Ferrous sulphate*, Ferrous gluconate

  Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite333

  Astringents: Zinc Sulphate, Potash Alum

UNIT V **07 Hours**

- **Radiopharmaceuticals**: Radio activity, Measurement of radioactivity, Properties of α, β, γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I^{131}, Storage conditions, precautions & pharmaceutical application of radioactive substances.

BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

I **Limit tests for following ions**

Limit test for Chlorides and Sulphates
Modified limit test for Chlorides and Sulphates
Limit test for Iron
Limit test for Heavy metals
Limit test for Lead
Limit test for Arsenic

II **Identification test**

Magnesium hydroxide
Ferrous sulphate
Sodium bicarbonate
Calcium gluconate
Copper sulphate

III **Test for purity**

Swelling power of Bentonite
Neutralizing capacity of aluminum hydroxide gel
Determination of potassium iodate and iodine in potassium Iodide

IV **Preparation of inorganic pharmaceuticals**

Boric acid
Potash alum
Ferrous sulphate

Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia

BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

Course content:

UNIT – I **07 Hours**

- **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context

- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers

- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

UNIT – II **07 Hours**

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication

- **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

UNIT – III **07 Hours**

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT – IV **05 Hours**

- **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview
- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V **04 Hours**

- **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

BP111P.COMMUNICATION SKILLS (Practical)

2 Hours / week

Thefollowing learning modules are to be conducted using wordsworth® English language lab software

Basic communication covering the following topics

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

Pronunciations covering the following topics

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

Advanced Learning

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999

BP 106RBT.REMEDIAL BIOLOGY (Theory)

30 Hours

Scope: To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

Objectives: Upon completion of the course, the student shall be able to

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- know understand the basic components of anatomy & physiology animal with special reference to human

UNIT I **07 Hours**

Living world:

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering plants

- Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidones.

UNIT II **07 Hours**

Body fluids and circulation

- Composition of blood, blood groups, coagulation of blood
- Composition and functions of lymph
- Human circulatory system
- Structure of human heart and blood vessels
- Cardiac cycle, cardiac output and ECG

Digestion and Absorption

- Human alimentary canal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

Breathing and respiration

- Human respiratory system
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratory volumes

UNIT III **07 Hours**

Excretory products and their elimination

- Modes of excretion
- Human excretory system- structure and function
- Urine formation
- Rennin angiotensin system

Neural control and coordination

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- Endocrine glands and their secretions
- Functions of hormones secreted by endocrine glands

Human reproduction

- Parts of female reproductive system
- Parts of male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

UNIT IV **05 Hours**

Plants and mineral nutrition:

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis

- Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

UNIT V **04 Hours**

Plant respiration: Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators

Cell - The unit of life

- Structure and functions of cell and cell organelles.Cell division

Tissues

- Definition, types of tissues, location and functions.

Text Books

a. Text book of Biology by S. B. Gokhale
b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

a. A Text book of Biology by B.V. Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d.Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

BP112RBP.REMEDIAL BIOLOGY (Practical)

30 Hours

1. Introduction to experiments in biology
   a) Study of Microscope
   b) Section cutting techniques
   c) Mounting and staining
   d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

Objectives: Upon completion of the course the student shall be able to:-

1. Know the theory and their application in Pharmacy
2. Solve the different types of problems by applying theory
3. Appreciate the important application of mathematics in Pharmacy

Course Content:

UNIT – I **06 Hours**

- **Partial fraction**

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction , Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics

- **Logarithms**

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

- **Function***:*

Real Valued function, Classification of real valued functions,

- **Limits and continuity** :

Introduction , Limit of a function, Definition of limit of a function ($\in$ - δ definition) , $\lim_{x\to a}\frac{x^n - a^n}{x-a} = na^{n-1}$, $\lim_{\theta\to 0}\frac{\sin\theta}{\theta} = 1,$

UNIT –II **06 Hours**

- **Matrices and Determinant:**

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants , Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix , Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem,Applicationof Matrices in solving Pharmacokinetic equations

UNIT – III **06 Hours**

- **Calculus**

Differentiation : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function , Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**, Derivative of x^n *w.r.t*x,where *n* is any rational number, Derivative of e^x,, Derivative of $\log_e x$, Derivative of a^x,Derivative of trigonometric functions from first principles **(without Proof)**, Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application

UNIT – IV **06 Hours**

- **Analytical Geometry**

Introduction: Signs of the Coordinates, Distance formula,

Straight Line : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line

Integration:

Introduction, Definition, Standard formulae, Rules of integration , Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

UNIT-V **06 Hours**

- **Differential Equations** : Some basic definitions, Order and degree, Equations in separable form , Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**
- **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal

Semester II

BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to:

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Content:

Unit I **10 hours**

- **Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid.structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts,reflex activity)

Unit II **06 hours**

- **Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine

and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

- **Energetics**

  Formation and role of ATP, Creatinine Phosphate and BMR.

Unit III

- **Respiratory system** **10 hours**

  Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

  Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

- **Urinary system**
  Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit IV **10 hours**

- **Endocrine system**
  Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal
  gland, pancreas, pineal gland, thymus and their disorders.

Unit V **09 hours**

- **Reproductive system**

  Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

- **Introduction to genetics**

  Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject**.**

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve
6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA

4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

Scope: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. identify/confirm the identification of organic compound

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I **07 Hours**

- **Classification, nomenclature and isomerism**

  Classification of Organic Compounds

  Common and IUPAC systems of nomenclature of organic compounds

  (up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

UNIT-II10 Hours

- **Alkanes*, Alkenes* and Conjugated dienes***

  SP^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

  Stabilities of alkenes, SP^2 hybridization in alkenes

  E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

  Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

UNIT-III10 Hours

- **Alkyl halides***

  SN_1 and SN_2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

  SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reactions

  Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

- **Alcohols*-** Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

UNIT-IV10 Hours

- **Carbonyl compounds* (Aldehydes and ketones)**

  Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

UNIT-V **08 Hours**

- **Carboxylic acids***

  Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids ,amide and ester

  Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid

- **Aliphatic amines* -** Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

1. Systematic qualitative analysis of unknown organic compounds like
    1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
    2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
    3. Solubility test
    4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
    5. Melting point/Boiling point of organic compounds
    6. Identification of the unknown compound from the literature using melting point/ boiling point.
    7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
    8. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

BP203 T. BIOCHEMISTRY (Theory)

45 Hours

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of course student shell able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Course Content:

UNIT I **08 Hours**

- **Biomolecules**

  Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

- **Bioenergetics**

  Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.

  Energy rich compounds; classification; biological significances of ATP and cyclic AMP

UNIT II **10 Hours**

- **Carbohydrate metabolism**

  Glycolysis – Pathway, energetics and significance

  Citric acid cycle- Pathway, energetics and significance

  HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

  Glycogen metabolism Pathways and glycogen storage diseases (GSD)

  Gluconeogenesis- Pathway and its significance

  Hormonal regulation of blood glucose level and Diabetes mellitus

- **Biological oxidation**

  Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT III **10 Hours**

- **Lipid metabolism**

  β-Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

- **Amino acid metabolism**

  General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

  Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)

  Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

  Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV **10 Hours**

- **Nucleic acid metabolism and genetic information transfer**

  Biosynthesis of purine and pyrimidine nucleotides

  Catabolism of purine nucleotides and Hyperuricemia and Gout disease

  Organization of mammalian genome

  Structure of DNA and RNA and their functions

  DNA replication (semi conservative model)

  Transcription or RNA synthesis

  Genetic code, Translation or Protein synthesis and inhibitors

UNIT V **07 Hours**

- **Enzymes**

  Introduction, properties, nomenclature and IUB classification of enzymes

  Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

  Enzyme inhibitors with examples

  Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

  Therapeutic and diagnostic applications of enzymes and isoenzymes

  Coenzymes –Structure and biochemical functions

BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

BP 204T.PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes.This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives: Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Course content:

Unit I **10Hours**

- **Basic principles of Cell injury and Adaptation:**
  Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury**,**Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage)**,**Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia)**,**Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis &Alkalosis,Electrolyte imbalance

- **Basic mechanism involved in the process of inflammation and repair:**
  Introduction, Clinical signs of inflammation, Different types of Inflammation,Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's,Mediators of inflammation,Basic principles of wound healing in the skin,Pathophysiology of Atherosclerosis

Unit II **10Hours**

- **Cardiovascular System:**
  Hypertension, congestive heart failure, ischemic heart disease (angina,myocardial infarction, atherosclerosis and arteriosclerosis)
- **Respiratory system:**Asthma, Chronic obstructive airways diseases.
- **Renal system:**Acute and chronic renal failure .

Unit II **10Hours**

- **Haematological Diseases:**
  Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia
- **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones
- **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.
- **Gastrointestinal system:** Peptic Ulcer
-

Unit IV **8 Hours**

- Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.
- **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout
- **Principles of cancer:** classification, etiology and pathogenesis of cancer
- **Diseases of bones and joints:**Rheumatoid Arthritis, Osteoporosis,Gout

- **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit V **7 Hours**

- **Infectious diseases:**Meningitis,Typhoid, Leprosy, Tuberculosis

Urinary tract infections

- **Sexually transmitted diseases:**AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore;1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston;Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Course content:

UNIT – I **06 hours**

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement ,Two's complement method, binary multiplication, binary division

Concept of I nformation Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT –II **06 hours**

Web technologies:Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III **06 hours**

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

UNIT – IV **06 hours**

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT-V **06 hours**

Computers as data analysis in Preclinical development:
Chromatographic dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMS)

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3 Retrieve the information of a drug and its adverse effects using online tools
4 Creating mailing labels Using Label Wizard , generating label in MS WORD
5 Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to**:**

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

Course content:

Unit-I **10hours**

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Unit-II **10hours**

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Unit- III **10hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

SEMESTER III

BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. prepare organic compounds

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I **10 Hours**

- **Benzene and its derivatives**
  - **A.** Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
  - **B.** Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
  - **C.** Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
  - **D.** Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II **10 Hours**

- **Phenols*** - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- **Aromatic Amines* -** Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts
- **Aromatic Acids* –**Acidity, effect of substituents on acidity and important reactions of benzoic acid.

UNIT III

10 Hours

- **Fats and Oils**

a. Fatty acids – reactions.

b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV **08 Hours**

- **Polynuclear hydrocarbons:**

a. Synthesis, reactions

b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT V **07 Hours**

- **Cyclo alkanes***

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

I Experiments involving laboratory techniques

- Recrystallization
- Steam distillation

II Determination of following oil values (including standardization of reagents)

- Acid value
- Saponification value
- Iodine value

III **Preparation of compounds**

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.

8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

Scope: The course deals with the various physica and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing nad determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I **10 Hours**

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT-II **10Hours**

States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols – inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

Physicochemical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT-III **08 Hours**

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions,

surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

UNIT-IV **08Hours**

Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

UNIT-V **07 Hours**

pH, buffers and Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

BP306P. PHYSICAL PHARMACEUTICS – I (Practical)

4 Hrs/week

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl_4 and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

Scope:

- Study of all categories of microorganisims especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc..

Objectives: Upon completion of the subject student shall be able to;

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. To understand the importance and implementation of sterlization in pharmaceutical processing and industry
3. Learn sterility testing of pharmaceutical products.
4. Carried out microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Course content:

Unit I **10 Hours**

Introduction, history of microbiology, its branches, scope and its importance.
Introduction to Prokaryotes and Eukaryotes
Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).
Study of different types of phase constrast microscopy, dark field microscopy and electron microscopy.

Unit II **10 Hours**

Identification of bacteria using staining techniques (simple, Gram's &Acid fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous,radiation and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

Equipments employed in large scale sterilization.

Sterility indicators.

Unit III **10 Hours**

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV **08 Hours**

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.
Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.
Assessment of a new antibiotic.

Unit V **07Hours**

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industry and research.

BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

Objectives: Upon completion of the course student shall be able:

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

Course content:

UNIT-I **10 Hours**

- **Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.
- **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.
- **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

UNIT-II **10 Hours**

- **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator.

- **Distillation:** Basic Principles and methodology of simple distillation,flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT- III **08 Hours**

- **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.

- **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

UNIT-IV **08 Hours**

- **Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT- V **07 Hours**

- **Materials of pharmaceutical plant construction, Corrosion and its prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – Mcabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

BP308P - PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

I. Determination of radiation constant of brass, iron, unpainted and painted glass.
II. Steam distillation – To calculate the efficiency of steam distillation.
III. To determine the overall heat transfer coefficient by heat exchanger.
IV. Construction of drying curves (for calcium carbonate and starch).
V. Determination of moisture content and loss on drying.
VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic andlogarithmic probability plots.
IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment.
XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
XII. To study the effect of time on the Rate of Crystallization.
XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

SEMESTER IV

BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives: At the end of the course, the student shall be able to

1. understand the methods of preparation and properties of organic compounds
2. explain the stereo chemical aspects of organic compounds and stereo chemical reactions
3. know the medicinal uses and other applications of organic compounds

Course Content:

Note: To emphasize on definition, types, mechanisms, examples, uses/applications

UNIT-I **10 Hours**

Stereo isomerism

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and achiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

UNIT-II **10 Hours**

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

UNIT-III **10 Hours**

Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

UNIT-IV **8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V **07 Hours**

Reactions of synthetic importance

Metal hydride reduction ($NaBH_4$ and $LiAlH_4$), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

Recommended Books (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

BP402T. MEDICINAL CHEMISTRY – I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. understand the chemistry of drugs with respect to their pharmacological activity
2. understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. know the Structural Activity Relationship (SAR) of different class of drugs
4. write the chemical synthesis of some drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I **10 Hours**

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II **10 Hours**

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine,

Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III **10 Hours**

Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT- IV **08 Hours**

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

Phenothiazeines: SAR of Phenothiazeines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Trifluprомazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazeines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C. Anticonvulsants: SAR of Anticonvulsants**,** mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methabarbital. **Hydantoins:**

Phenytoin*, Mephenytoin, Ethotoin **Oxazolidine diones:**

Trimethadione, Paramethadione **Succinimides:**

Phensuximide, Methsuximide, Ethosuximide* **Urea and**

monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid , Gabapentin, Felbamate

UNIT – V **07 Hours**

Drugs acting on Central Nervous System

General anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbitutrates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I Preparation of drugs/ intermediates

1 1,3-pyrazole

2 1,3-oxazole

3 Benzimidazole

4 Benztriazole

5 2,3- diphenyl quinoxaline

6 Benzocaine

7 Phenytoin

8 Phenothiazine

9 Barbiturate

II Assay of drugs

1 Chlorpromazine

2 Phenobarbitone

3 Atropine

4 Ibuprofen

5 Aspirin

6 Furosemide

III Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)

45Hours

Scope: The course deals with the various physica and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing nad determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I **07 Hours**

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization& protective action.

UNIT-II **10 Hours**

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

UNIT-III **10 Hours**

Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.

UNIT-IV **10Hours**

Micromeretics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

UNIT-V **10 Hours**

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

1. Determination of particle size, particle size distribution using sieving method
2. Determination of particle size, particle size distribution using Microscopic method
3. Determination of bulk density, true density and porosity
4. Determine the angle of repose and influence of lubricant on angle of repose
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination sedimentation volume with effect of different suspending agent
7. Determination sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

BP 404 T. PHARMACOLOGY-I (Theory)

45 Hrs

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Objectives: Upon completion of this course the student should be able to

1. Understand the pharmacological actions of different categories of drugs
2. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences

Course Content:

UNIT-I **08 hours**

1. General Pharmacology

a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

UNIT-II **12 Hours**

General Pharmacology

a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
b. Adverse drug reactions.
c. Drug interactions (pharmacokinetic and pharmacodynamic)
d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III **10 Hours**

2. Pharmacology of drugs acting on peripheral nervous system

a. Organization and function of ANS.

b.Neurohumoral transmission,co-transmission and classification of neurotransmitters.

c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.

d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).

e. Local anesthetic agents.

f. Drugs used in myasthenia gravis and glaucoma

UNIT-IV **08 Hours**

3. Pharmacology of drugs acting on central nervous system

a. Neurohumoral transmission in the C.N.S.special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.

b. General anesthetics and pre-anesthetics**.**

c. Sedatives, hypnotics and centrally acting muscle relaxants.

d. Anti-epileptics

e. Alcohols and disulfiram

UNIT-V **07 Hours**

3. Pharmacology of drugs acting on central nervous system

a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.

b. Drugs used in Parkinsons disease and Alzheimer's disease.

c. CNS stimulants and nootropics.

d. Opioid analgesics and antagonists

e. Drug addiction, drug abuse, tolerance and dependence.

BP 408 P.PHARMACOLOGY-I (Practical)

4Hrs/Week

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,.Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology

6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher

8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,

9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.

10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

45 Hours

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

Objectives: Upon completion of the course, the student shall be able

1. to know the techniques in the cultivation and production of crude drugs
2. to know the crude drugs, their uses and chemical nature
3. know the evaluation techniques for the herbal drugs
4. to carry out the microscopic and morphological evaluation of crude drugs

Course Content:

UNIT-I **10 Hours**

Introduction to Pharmacognosy:

(a) Definition, history, scope and development of Pharmacognosy

(b) Sources of Drugs – Plants, Animals, Marine & Tissue culture

(c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leafconstants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II **10 Hours**

Cultivation, Collection, Processing and storage of drugs of natural origin:

Cultivation and Collection of drugs of natural origin

Factors influencing cultivation of medicinal plants.

Plant hormones and their applications.

Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT-III **07 Hours**

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance.

Applications of plant tissue culture in pharmacognosy.

Edible vaccines

UNIT IV **10 Hours**

Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V **08 Hours**

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:

Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

Lipids(Waxes, fats, fixed oils) : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources

BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

1. Analysis of crude drugs by chemical tests: **(**i)Tragaccanth (ii) Acacia (iii)Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and paliside ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs by M.A. Iyengar

SEMESTER V

BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I **10 Hours**

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody

H_1–antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

H_2-antagonists: Cimetidine*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan,

Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II **10 Hours**

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.

Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

UNIT- III **10 Hours**

Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

UNIT- IV **08 Hours**

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.
Drugs for erectile dysfunction: Sildenafil, Tadalafil.
Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol
Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone
Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT – V **07 Hours**

Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP 502 T. Industrial PharmacyI (Theory)

45 Hours

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objectives: Upon completion of the course the student shall be able to

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
2. Know various considerations in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content:

3 hours/ week

UNIT-I **07 Hours**

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II **10 Hours**

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

UNIT-III **08 Hours**

Capsules:

a. ***Hard gelatin capsules:*** Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. ***Soft gelatin capsules:*** Nature of shell and capsule content, size of capsules,importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT-IV **10 Hours**

Parenteral Products:

a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity

b. Production procedure, production facilities and controls,
aseptic processing

c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT-V **10 Hours**

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

BP 506 P. Industrial PharmacyI (Practical)

4 Hours/week

1. Preformulation studies on paracetamol/asparin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Qulaity control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

BP503.T. PHARMACOLOGY-II (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition,emphasis on the basic concepts of bioassay.

Objectives: Upon completion of this course the student should be able to

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
3. Demonstrate the various receptor actions using isolated tissue preparation
4. Appreciate correlation of pharmacology with related medical sciences

Course Content:

UNIT-I **10hours**

1. Pharmacology of drugs acting on cardio vascular system

a. Introduction to hemodynamic and electrophysiology of heart.
b. Drugs used in congestive heart failure
c. Anti-hypertensive drugs.
d. Anti-anginal drugs.
e. Anti-arrhythmic drugs.
f. Anti-hyperlipidemic drugs.

UNIT-II **10hours**

1. Pharmacology of drugs acting on cardio vascular system

a. Drug used in the therapy of shock.
b. Hematinics, coagulants and anticoagulants.
c. Fibrinolytics and anti-platelet drugs
d. Plasma volume expanders

2. Pharmacology of drugs acting on urinary system

a. Diuretics
b. Anti-diuretics.

UNIT-III **10hours**

3. Autocoids and related drugs

a. Introduction to autacoids and classification
b. Histamine, 5-HT and their antagonists.
c. Prostaglandins, Thromboxanes and Leukotrienes.
d. Angiotensin, Bradykinin and Substance P.
e. Non-steroidal anti-inflammatory agents
f. Anti-gout drugs
g. Antirheumatic drugs

UNIT-IV **08hours**

5. Pharmacology of drugs acting on endocrine system

a. Basic concepts in endocrine pharmacology.
b. Anterior Pituitary hormones- analogues and their inhibitors.
c. Thyroid hormones- analogues and their inhibitors.
d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
d. Insulin, Oral Hypoglycemic agents and glucagon.
e. ACTH and corticosteroids.

UNIT-V **07hours**

5. Pharmacology of drugs acting on endocrine system

a. Androgens and Anabolic steroids.
b. Estrogens, progesterone and oral contraceptives.
c. Drugs acting on the uterus.

6. Bioassay

a. Principles and applications of bioassay.
b.Types of bioassay
c. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine,digitalis, histamine and 5-HT

BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

Scope: The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

Objectives: Upon completion of the course, the student shall be able

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation.
3. to understand the herbal drug interactions
4. to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I **7 Hours**

Metabolic pathways in higher plants and their determination

a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II **14 Hours**

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following

secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,
Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta
Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis
Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,
Tannins: Catechu, Pterocarpus
Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony
Glycosides: Senna, Aloes, Bitter Almond
Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III **06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

a) Terpenoids: Menthol, Citral, Artemisin
b) Glycosides: Glycyrhetinic acid & Rutin
c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine
d) Resins: Podophyllotoxin, Curcumin

UNIT-IV **10 Hours**

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT V **8 Hours**

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
   a. Caffeine - from tea dust.
   b. Diosgenin from Dioscorea
   c. Atropine from Belladonna
   d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstitutents by TLC
6. Analysis of crude drugs by chemical tests: **(**i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

Scope: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

Objectives: Upon completion of the course, the student shall be able to understand:

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Course Content:

UNIT-I **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties**.**

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III **10 Hours**

- **Pharmacy Act –1948**: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and

Penalties

- **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV **08 Hours**

- **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V **07 Hours**

- **Pharmaceutical Legislations –** A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- **Code of Pharmaceutical ethics** D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- **Medical Termination of Pregnancy Act**
- **Right to Information Act**
- **Introduction to Intellectual Property Rights (IPR)**

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh

2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9.Bare Acts of the said laws published by Government. Reference books (Theory)

SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives: Upon completion of the course student shall be able to

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

UNIT – I **10 Hours**

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II **10 Hours**

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

UNIT – III **10 Hours**

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV **08 Hours**

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V **07 Hours**

Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

1 Sulphanilamide

2 7-Hydroxy, 4-methyl coumarin

3 Chlorobutanol

4 Triphenyl imidazole

5 Tolbutamide

6 Hexamine

II Assay of drugs

1 Isonicotinic acid hydrazide

2 Chloroquine

3 Metronidazole

4 Dapsone

5 Chlorpheniramine maleate

6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition,emphasis on the principles of toxicology and chronopharmacology.

Objectives: Upon completion of this course the student should be able to:

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisoningsand
3. appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I **10hours**

1. Pharmacology of drugs acting on Respiratory system

a. Anti -asthmatic drugs
b. Drugs used in the management of COPD
c. Expectorants and antitussives
d. Nasal decongestants
e. Respiratory stimulants

2. Pharmacology of drugs acting on the Gastrointestinal Tract

a. Antiulcer agents.
b. Drugs for constipation and diarrhoea.
c. Appetite stimulants and suppressants.
d. Digestants and carminatives.
e. Emetics and anti-emetics.

UNIT-II **10hours**

3. Chemotherapy

a. General principles of chemotherapy.

b. Sulfonamides and cotrimoxazole.

c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III **10hours**

3. Chemotherapy

a. Antitubercular agents

b. Antileprotic agents

c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV **08hours**

3. Chemotherapy

l. Urinary tract infections and sexually transmitted diseases.

m. Chemotherapy of malignancy.

4. Immunopharmacology

a. Immunostimulants

b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V **07hours**

5. Principles of toxicology

a. Definition and basic knowledge of acute, subacute and chronic toxicity.

b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity

c. General principles of treatment of poisoning

d. Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning.

6. Chronopharmacology

a. Definition of rhythm and cycles.

b. Biological clock and their significance leading to chronotherapy.

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Objectives: Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I **11 Hours**

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation
Source of Herbs
Selection, identification and authentication of herbal materials
Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming.
Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.

UNIT-II **7 Hours**

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.
Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-III **10 Hours**

Herbal Cosmetics

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:
Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations :
Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT- IV **10 Hours**

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs
Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:
a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-V **07 Hours**

General Introduction to Herbal Industry
Herbal drugs industry: Present scope and future prospects.
A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine
Components of GMP (Schedule – T) and its objectives
Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

Scope: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arised therein.

Objectives: Upon completion of the course student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

Course Content:

UNIT-I **10 Hours**

Introduction to Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II **10 Hours**

Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT- III **10 Hours**

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E ,t1/2,Vd,AUC,Ka, Clt and CL_R- definitions methods of eliminations, understanding of their significance and application

UNIT- IV **08 Hours**

Multicompartment models: Two compartment open model. IV bolus
Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settins.

UNIT- V **07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.
c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

- Biotechnology has a long promise to revolutionize the biological sciences and technology.
- Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- It is basically a research-based subject.

Objectives: Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

Unit I **10 Hours**

a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.

c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.

d) Brief introduction to Protein Engineering.

e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.

f) Basic principles of genetic engineering.

Unit II **10 Hours**

a) Study of cloning vectors, restriction endonucleases and DNA ligase.

b) Recombinant DNA technology. Application of genetic engineering in medicine.

c) Application of r DNA technology and genetic engineering in the production of:

i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.

d) Brief introduction to PCR

Unit III **10 Hours**

Types of immunity- humoral immunity, cellular immunity

a) Structure of Immunoglobulins

b) Structure and Function of MHC

c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.

d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.

e) Storage conditions and stability of official vaccines

f) Hybridoma technology- Production, Purification and Applications

g) Blood products and Plasma Substituties.

Unit IV **08Hours**

a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.

b) Genetic organization of Eukaryotes and Prokaryotes

c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.

d) Introduction to Microbial biotransformation and applications.

e) Mutation: Types of mutation/mutants.

Unit V **07 Hours**

a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.

b) Large scale production fermenter design and its various controls.

c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,

d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substituties.

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal

Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives: Upon completion of the course student shall be able to:

- understand the cGMP aspects in a pharmaceutical industry
- appreciate the importance of documentation
- understand the scope of quality certifications applicable to pharmaceutical industries
- understand the responsibilities of QA & QC departments

Course content:

UNIT – I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedures

UNIT - II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III **10 Hours**

Quality Control: Quality control test for containers, rubber closures and secondary packing

materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV **08 Hours**

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

SEMESTER VII

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT –I **10 Hours**

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT –II **10 Hours**

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III **10 Hours**

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT –IV **08 Hours**

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)-Introduction, theory, instrumentation, advantages and applications.

UNIT –V **07 Hours**

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2. Estimation of dextrose by colorimetry
3. Estimation of sulfanilamide by colorimetry
4. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5. Assay of paracetamol by UV- Spectrophotometry
6. Estimation of quinine sulfate by fluorimetry
7. Study of quenching of fluorescence
8. Determination of sodium by flame photometry
9. Determination of potassium by flame photometry
10. Determination of chlorides and sulphates by nephelo turbidometry
11. Separation of amino acids by paper chromatography
12. Separation of sugars by thin layer chromatography
13. Separation of plant pigments by column chromatography
14. Demonstration experiment on HPLC
15. Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

BP 702 T. INDUSTRIAL PHARMACYII (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Objectives: Upon completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I **10 Hours**

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II **10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III **10 Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV **08 Hours**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V **07 Hours**

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

BP 703T. PHARMACY PRACTICE (Theory)

45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Objectives: Upon completion of the course, the student shall be able to

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

Unit I: **10 Hours**

a) Hospital and it's organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

b) Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting

drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Unit II: 10 Hours

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

b) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

c) Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview

Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III: 10 Hours

a) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services

Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

c) Patient counseling

Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

d) Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

e) Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

Unit IV 8 Hours

a) Budget preparation and implementation

Budget preparation and implementation

b) Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

c) Over the counter (OTC) sales

Introduction and sale of over the counter, and Rational use of common over the counter medications.

Unit V 7 Hours

a) Drug store management and inventory control

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

b) Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical Pharmacy Practice- essential concepts and skills,* 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy,* 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course content:

Unit-I **10 Hours**

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates.Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II **10 Hours**

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implantsand osmotic pump

Unit-III **10 Hours**

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV **08 Hours**

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V **07 Hours**

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

SEMESTER VIII

BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel**.**

Objectives: Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems**.**

Course content:

Unit-I **10 Hours**

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples

Unit-II **10 Hours**

Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples

Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

Parametric test: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference

Unit-III **10 Hours**

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV **8 Hours**

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels

Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit-V **7Hours**

Design and Analysis of experiments:

Factorial Design: Definition, 2^2, 2^3design. Advantage of factorial design

Response Surface methodology: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

BP 802T SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

Scope:
The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives:
After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issuesrelated to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related tohealth and pharmaceutical issues

Course content:

Unit I: 10 Hours

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

Hygiene and health: personal hygiene and health care; avoidable habits

Unit II: 10 Hours

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III: 10 Hours

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National

programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV: **08 Hours**

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

Unit V: **07 Hours**

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

Recommended Books (Latest edition)*:*

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Unit I **10 Hours**

Marketing:

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role of market research.

Unit II **10 Hours**

Product decision:

Classification, product line and product mix decisions, product life cycle,product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III **10 Hours**

Promotion:

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Unit IV **10 Hours**

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V **10 Hours**

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order)and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia,UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives: Upon completion of the subject student shall be able to;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

Course content:

Unit I **10Hours**

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II **10Hours**

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III **10Hours**

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical

Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV **08Hours**

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

Unit V **07Hours**

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Course Content

Unit I **10 Hours**

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II **10 hours**

Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

Unit III **10 Hours**

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

- Passive surveillance – Spontaneous reports and case series
- Stimulated reporting
- Active surveillance – Sentinel sites, drug event monitoring and registries
- Comparative observational studies – Cross sectional study, case control study and cohort study
- Targeted clinical investigations

Communication in pharmacovigilance

- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV **8 Hours**

Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

Unit V **7 hours**

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones& Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal

11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives: Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

Unit I **10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

Unit II **10 hours**

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines

WHO Guidelines on GACP for Medicinal Plants.

Unit III **10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV **08 hours**

Stability testing of herbal medicines.Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

Unit V **07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives: Upon completion of the course, the student shall be able to understand

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Course Content:

UNIT-I **10 Hours**

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

UNIT-II **10 Hours**

Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III **10 Hours**

Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

UNIT-IV **08 Hours**

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V **07 Hours**

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics.Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

45 Hours

Scope:

- Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- This is done both on a microscopic and molecular level.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organismssuch as humans, plants, and sponges.

Objectives: Upon completion of the subject student shall be able to;

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Course content:

Unit I **10Hours**

a) Cell and Molecular Biology: Definitions theory and basics and Applications.
b) Cell and Molecular Biology: History and Summation.
c) Properties of cells and cell membrane.
d) Prokaryotic versus Eukaryotic
e) Cellular Reproduction
f) Chemical Foundations – an Introduction and Reactions (Types)

Unit II **10 Hours**

a) DNA and the Flow of Molecular Information
b) DNA Functioning
c) DNA and RNA
d) Types of RNA
e) Transcription and Translation

Unit III **10 Hours**

a) Proteins: Defined **and** Amino Acids
b) Protein Structure

c) Regularities in Protein Pathways
d) Cellular Processes
e) Positive Control and significance of Protein Synthesis

Unit IV **08 Hours**

a) Science of Genetics
b) Transgenics and Genomic Analysis
c) Cell Cycle analysis
d) Mitosis and Meiosis
e) Cellular Activities and Checkpoints

Unit V **07 Hours**

a) Cell Signals: Introduction
b) Receptors for Cell Signals
c) Signaling Pathways: Overview
d) Misregulation of Signaling Pathways
e) Protein-Kinases: Functioning

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

BP809ET. COSMETIC SCIENCE(Theory)

45Hours

UNIT I **10Hours**

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums**.**

UNIT II **10 Hours**

Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages.Application of these products in formulation of cosmecuticals.

Antiperspants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioner,anti-dandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phylene diamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III **10 Hours**

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste**.**

UNIT IV **08 Hours**.

Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties

Soaps,and syndet bars. Evolution and skin benfits.

UNIT V **07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

References

1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3) Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

Upon completion of the course the student shall be able to,

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and researchmethodology
- Design and execute a research hypothesis independently

Unit –I	**08 Hours**
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	
Unit –II	**10 Hours**
Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. b. **Study of screening animal models for** Diuretics, nootropics, anti-Parkinson's,antiasthmatics, **Preclinical screening models:** for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	

Unit –III **Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics	
Unit –IV **Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data	**05 Hours**

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

Course Content:

UNIT-I **10 Hours**

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II **10 Hours**

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray

Crystallography, rotating crystal technique, single crystal diffraction,powder diffraction, structural elucidation and applications.

UNIT-III **10 Hours**

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV **08 Hours**

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques:General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT-V **07 Hours**

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS

No. of hours :3 **Tutorial:1** **Credit point:4**

Scope :

This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Objective:

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to :

1. Understand the need of supplements by the different group of people to maintain healthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Appreciate the components in dietary supplements and the application.
4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

UNIT I **07 hours**

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.
b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II **15 hours**

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin
b) Sulfides: Diallyl sulfides, Allyl trisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols
h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT III **07 hours**

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

b) Dietary fibres and complex carbohydrates as functional food ingredients..

UNIT IV **10 hours**

a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.

c) Functional foods for chronic disease prevention

UNIT V **06 hours**

a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.

b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors *2000 Functional foods* Woodhead Publ.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

Semester VIII – Elective course on Pharmaceutical Product Development

No of Hours: 3 Tutorial:1 Credit points:4

Unit-I **10 Hours**

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

Unit-II **10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

i. Solvents and solubilizers
ii. Cyclodextrins and their applications
iii. Non - ionic surfactants and their applications
iv. Polyethylene glycols and sorbitols
v. Suspending and emulsifying agents
vi. Semi solid excipients

Unit-III **10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

i. Tablet and capsule excipients
ii. Directly compressible vehicles
iii. Coat materials
iv. Excipients in parenteral and aerosols products
v. Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

Unit-IV **08 Hours**

Optimization techniques in pharmaceutical product development.A study of various optimization techniques for pharmaceutical product development with specific examples.Optimization by factorial designs and their applications.A study of QbD and its application in pharmaceutical product development.

Unit-V **07 Hours**

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition,Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman andLeon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton,3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman andJoseph B. Schwartz
11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis andH.A. Libermann.
13. Advanced Review Articles related to the topics.

Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur

Proposed Syllabi and Scheme of

Master of Pharmacy

(Semester, Credit & Grade system)

2012-13

Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur

M. Pharm. Syllabus

Credit-grade based performance and assessment system (CGPA)

Features of the Credit System

With effect from Academic Session 2012- 2013

FEATURES OF THE CREDIT SYSTEM

- Master's degree would be of 80 credits each.
- One credit course of theory will be of one clock hour per week running for 15 weeks.
- Two credit course of theory will be of two clock hours per week running for 15 weeks.
- Four-credit course of theory will be of four clock hours per week running for 15 weeks.
- One credit course of practical will consist of 2 hours of laboratory exercise for 15 weeks.
- Two credit courses of practical will consist of 4 hours of laboratory exercise for 15 weeks.
- Four credit course of practical will consist of 8 hours of laboratory exercise for 15 weeks.

FIRST TWO SEMESTERS SHALL HAVE 5 THEORY COURSES, 2 PRACTICAL COURSES AND 1 SEMINAR FOR EACH SEMESTER

- 3 Theory courses x 4 credits = 12 credits
- 2 Theory courses x 2 credits = 04 credits
- 2 Laboratory courses x 4 credits = 08 credits
- 1 Seminar x 2 credits = 02 credits

Total = 26 credits

EVERY STUDENT SHALL COMPLETE 80 CREDITS IN A MINIMUM OF FOUR SEMESTERS.
FIRST TWO SEMESTERS WILL HAVE 26 CREDITS EACH, THIRD SEMESTER WILL BE OF 08 CREDITS AND FOURTH SEMESTER WILL BE OF 20 CREDITS.

- Two semesters 2x 26 credits = 52 credits
- Third semester 1x 08 = 08 credits
- Forth semester 1x 20 = 20 credits

Four semesters total credits = 80 credits

SCHEME OF SYLLABUS AND CREDIT SYSTEM

The syllabus for the first semester includes three (03) theory courses common to all M. Pharm. Specializations, one theory course of respective specialization and an elective subject, so consist of total five theory papers and two laboratory courses and one seminar. Two credits have been allocated for seminar. Marks out of 50 will be allotted. Evaluation of seminar shall be done by three internal Examiners appointed by the Head/Principal of the Department/Institute based on scientific contents, communication, representation and skill in oral presentation.

The syllabus for the second semester includes two (02) theory courses common to all M. Pharm. Specializations, two theory course of respective specialization and an elective subject, so consist of total five theory papers and two laboratory courses and one seminar. Two credits have been allocated for seminar. Marks out of 50 will be allotted. Evaluation of seminar shall be done by three internal Examiners appointed by the Head/Principal of the Department/Institute based on scientific contents, communication, representation and skill in oral presentation.

The syllabus for the third semester includes one theory course of respective specialization and an elective subject, so consist of total two theory papers and one seminar. Two credits

have been allocated for seminar. Marks out of 50 will be allotted. Evaluation of seminar shall be done by three internal Examiners appointed by the Head/Principal of the Department/Institute based on scientific contents, communication, representation and skill in oral presentation. The topic for the research envisaged for the dissertation shall be assigned to him/her within one month from the date of commencement of third semester.

One elective subject can be chosen by minimum 8 and maximum 12 students of a particular college/institution during a semester. Each student has to clear three different elective subjects during his/her course of studies from the list given in Annexure-I

Total four credits have been allocated for the seminar on dissertation on completed research work for dissertation prior to thesis submission in fourth semester.

Scheme for Marks Distribution of Seminar on Dissertation (Semester IV)

CONTENT	MARKS	CREDIT
1. Introduction, justification, scope of dissertation work, organization of materials, methods and references.	**25**	**01**
2. Experimental work, observations, results and conclusion	**50**	**02**
3. Presentation skill, questioning and defending	**25**	**01**
Total	**100**	**04**

• Twelve credits have been allocated for the dissertation work.

Scheme for Marks Distribution for Dissertation Work

CONTENT	MARKS	CREDIT
1. Introduction, information retrieval system	**50**	**02**
2. Experimental work	**100**	**04**
3. Scientific content	**50**	**02**
4. Results / Conclusion	**50**	**02**
5. Organization of Scientific materials, dissertation thesis and references	**50**	**02**
Total	**300**	**12**

• Four credits each have been allocated for the Viva-voce on dissertation.

Scheme for Marks Distribution for Viva-voce

CONTENT	MARKS	CREDIT
1. Reading research paper and depth of knowledge on work topic	**50**	**02**
2. Discussion	**25**	**01**
3. Report	**25**	**01**
Total	**100**	**04**

• One credit = 25 marks; two credits = 50 marks and four credits = 100 marks.
• Four credits (theory) = 100 marks

Internal Examination External Examination
(20 marks) (80 marks)

• Four credits (Practical) = 100 marks

Internal Examination External Examination
(20 marks) (80 marks)

The Internal Assessment marks for theory should be based on Class Test and Attendance as follows:-

a) Class Test - 15

Marks will be based upon average marks of two Class Tests.

b) Attendance - Mark/s

75% to 80% - 1
81% to 85% - 2
86% to 90% - 3
91% to 95% - 4
96% to 100% - 5

Academic calendar showing dates of commencement and end of teaching, internal assessment tests & term end examination shall be duly notified before commencement of each semester every year by the affiliated colleges.

• Credit system offers more options to students and has more flexibility.

• Students can get requisite credits from the concerned colleges where she/he is mutually permitted on terms mutually agreed to complete the same and be eligible to appear for term end examination.

• The term end examination, however, shall be conducted by the RTM Nagpur University, Nagpur in the allotted centers.

• The research project shall be compulsory.

• These activities, including preparation of the result-sheets for the students, would be co-ordinated by the Departmental Examination Committee comprising Course in-charges and HOD or Head of the institution.

• Grades-Marks for each course would be converted to grades as shown in Table 1.

Table 1: Conversion of marks to grades in credit system

Marks Obtained	Grade	Grade Points
100-85	A^+	10
84-75	A	9
74-65	B^+	8
64-60	B	7
59-55	C	6
54-50	D	5
49 and less (internal)	FR	0-Failed (Clear course)

• A student who passes the internal tests but fails in Term End Examination of a course shall be given FR grade.

• Student with FR grade in a course would be granted credit for that course but not the grade for that course.

• Grade points earned in each paper shall be calculated as – Grade points obtained (vide Table 1 above) x Credits for the paper.

The computation of Semester Grade Point Average (SGPA) and Cumulative Grade Point Average (CGPA) of an examinee shall be as given below:-

The marks will be given in all examinations which will include college assessment marks and the total marks for each Theory /Practical shall be converted into Grades as per Table I. SGPA shall be calculated based on Grade Points corresponding to Grade as given in Table I and the Credits allotted to respective Theory / Practical shown in the scheme for respective semester.

SGPA shall be computed for every semester and CGPA shall be computed only in IV semester. The CGPA of IV semester shall be calculated based on SGPA of all four semesters as per following computation :-

SGPA	=	C1 x G1 + C2 x G2 + ... + Cn Gn
		C1 + C2 + ... + Cn

Where C1 = Credit of individual Theory / Practical
G1 = Corresponding Grade Point obtained in the Respective Theory / Practical

CGPA	=	(SGPA) I X (Cr) I + (SGPA) II X (Cr) II + (SGPA) III X (Cr) I II+ (SGPA) IV X (Cr) IV
		(Cr) I + (Cr) II + (Cr) III + (Cr) IV

Where, (SGPA) I = SGPA of I Semester
(Cr) I = Total Credits for I Semester
(SGPA) II = SGPA of II Semester
(Cr) II = Total Credits for II Semester
(SGPA) III = SGPA of III Semester
(Cr) III = Total Credits for III Semester
(SGPA) IV = SGPA of IV Semester
(Cr) IV = Total Credits for IV Semester

CGPA	Final Grade
9.0 – 10	A+
8.0 – 8.9	A
7.0 – 7.9	B+
6.0 – 6.9	B
5.5 – 5.9	C
5.0 – 5.4	D
4.9 and less	FR (Failed)

Final Mark List will only show the grade and grade points and not the marks.

CGPA equal to 6.00 and above shall be considered as equivalent to First Class which shall be mentioned on Grade Card of IV Semester as a foot note.

ACADEMIC CALENDAR AND TERMS

The terms and academic activities of the college affiliated to RTM, Nagpur University under CGPA shall be as prescribed by the University for respective academic session.
Beginning of First Term (Semester I and III) : As per University academic calendar
Vacation : As per University academic calendar
Beginning of Second Term (Semester II and IV) : As per University academic calendar

Draft Syllabus Prescribed for Master of Pharmacy

The several courses leading to the Master Degree of Pharmacy covers following subjects namely

1. Pharmaceutics
2. Pharmaceutical Chemistry
3. Pharmacology
4. Pharmacognosy
5. Biotechnology
6. Quality Assurance
7. Industrial Pharmacy
8. Pharmacoinformatics
9. Clinical Pharmacy
10. Natural Products
11. Pharmaceutical Management

SCHEME OF TEACHING AND EXAMINATION

APPENDIX–A

Pharmaceutics

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPH-S4	Advanced Pharmaceutics	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MPH-6	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPH-S9	Product Development and Formulation	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPH-S10	Novel Drug Delivery Systems	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPH-12	Seminar (II)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MPH-S13	Biopharmaceutics and Pharmacokinetics	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPH-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPH-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MPH-17	Dissertation		24									300(12)
	S4/402	MPH-18	Seminar on Dissertation											100(4)
	S4/403	MPH-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPH-S : Subject specialization in pharmaceutics

APPENDIX – B

Pharmaceutical Chemistry

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPC-S4	Advanced Pharmaceutical Chemistry-I	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MPC-6	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPC-S9	Advanced Pharmaceutical Chemistry-II	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPC-S10	Advanced Pharmaceutical Chemistry-III	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPC-12	Seminar (II)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MPC-S13	Advanced Pharmaceutical Chemistry-IV	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPC-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPC-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MPC-17	Dissertation		24									300(12)
	S4/402	MPC-18	Seminar on Dissertation											100(4)
	S4/403	MPC-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPC-S : Subject specialization in pharmaceutical chemistry

APPENDIX–C

Pharmacology

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPL-S4	Advanced Physiology & Pathophysiology	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MPL-6	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPL-S9	Advanced Systemic Pharmacology	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPL-S10	Advanced Pharmacology & Pharmacotherapeutics	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPL-12	Seminar (II)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MPL-S13	Molecular Pharmacology and Toxicology	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPL-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPL-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MPL-17	Dissertation		24									300(12)
	S4/402	MPL-18	Seminar on Dissertation											100(4)
	S4/403	MPL-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPL-S : Subject specialization in pharmacology

APPENDIX–D

Pharmacognosy

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPG-S4	Advanced Pharmacognosy and Phytochemistry	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MPG-6	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPG-S9	Standardization of Natural Products	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPG-S10	Herbal Drug Formulation and Development	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPG-12	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MPG-S13	Selected Topics in Pharmacognosy	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPG-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPG-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MPG-17	Dissertation		24									300(12)
	S4/402	MPG-18	Seminar on Dissertation											100(4)
	S4/403	MPG-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPG-S : Subject specialization in pharmacognosy and phytochemistry

APPENDIX–E

Biotechnology

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MBT-S4	Fundamentals of Biotechnology	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MBT-6	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MBT-S9	Molecular Biology	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MBT-S10	Fermentation Technology	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2	4	10		02	40			25		50(2)
	S2/206	MBT-12	Seminar (II)											50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MBT-S13	Advanced Tissue and Cell Culture Techniques	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MBT-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MBT-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MBT-17	Dissertation		24									300(12)
	S4/402	MBT-18	Seminar on Dissertation											100(4)
	S4/403	MBT-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MBT-S : Subject specialization in biotechnology

APPENDIX–F

Quality Assurance

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MQA-S4	Pharmaceutical Validation	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MQA-6	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MQA-S9	Quality Assurance of Cosmeceuticals	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MQA-S10	Novel Drug Delivery Systems	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MQA-12	Seminar (II)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MQA-S13	Quality Management	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MQA-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MQA-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MQA-17	Dissertation		24									300(12)
	S4/402	MQA-18	Seminar on Dissertation											100(4)
	S4/403	MQA-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MQA-S : Subject specialization in quality assurance

APPENDIX–G

Industrial Pharmacy

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MIP-S4	Advanced Industrial Pharmacy-I	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MIP-6	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MIP-S9	Advanced Industrial Pharmacy-II	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MIP-S10	Advances in Drug Delivery Systems	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MIP-12	Seminar (II)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MIP-S13	Industrial Process Validation and Production Management	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MIP-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MIP-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MIP-17	Dissertation		24									300(12)
	S4/402	MIP-18	Seminar on Dissertation											100(4)
	S4/403	MIP-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches
MIP-S : Subject specialization in industrial pharmacy

APPENDIX–H

Pharmacoinformatics

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPI-S4	Information Technology	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MPI-6	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPI-S9	Bioinformatics	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPI-S10	Molecular Biology	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPI-12	Seminar (II)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MPI-S13	Selected Topics in Pharmacoinformatics	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPI-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPI-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MPI-17	Dissertation		24									300(12)
	S4/402	MPI-18	Seminar on Dissertation											100(4)
	S4/403	MPI-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPI-S : Subject specialization in pharmacoinformatics

APPENDIX–I

Clinical Pharmacy

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MCP-S4	Advanced Clinical Pharmacy & Pharmacotherapeutics-I	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MCP-6	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MCP-S9	Advanced Clinical Pharmacy & Pharmacotherapeutics-II	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MCP-S10	Clinical Research	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MCP-12	Seminar (II)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MCP-S13	Community & Clinical Pharmacy	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MCP-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MCP-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MCP-17	Dissertation		24									300(12)
	S4/402	MCP-18	Seminar on Dissertation											100(4)
	S4/403	MCP-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MCP-S : Subject specialization in clinical pharmacy

APPENDIX–J

Natural Product

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MNP-S4	Industrial Pharmacognosy	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2		10		02	40			25		50(2)
	S1/106	MNP-6	Seminar (I)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MNP-S9	Natural Products & Bio-organic Chemistry	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MNP-S10	Standardization of Natural Products	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MNP-12	Seminar (II)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MNP-S13	Selected Topics in Natural Products	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MNP-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MNP-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MNP-17	Dissertation		24									300(12)
	S4/402	MNP-18	Seminar on Dissertation											100(4)
	S4/403	MNP-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MNP-S : Subject specialization in natural product

APPENDIX–K

Pharmaceutical Management

Semester	Paper Code		Title of Paper	Scheme of Teaching in Hrs/week		Scheme of Internal Examination		Scheme of External Examination						Total Marks (Credits)
				Lecture	Practical	Theory	Practical	Theory		Practical		Minimum Marks (Credit) for Passing		
								Hrs.	Marks	Hrs.	Marks	Theory	Practical	
Semester-I	S1/101	MC-S1	Advanced Analytical Techniques	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/102	MC-S2	Research Methodology & Biostatistics	2		10		02	40			25		50(2)
	S1/103	MC-S3	Drug Regulatory Affairs	4		20		03	80			50		100(4)
	S1/104	MPM-S4	Pharmaceutical Management-I (General and Personnel)	4	8	20	20	03	80	08	80	50	50	200(8)
	S1/105		Elective-I	2	4	10		02	40			25		50(2)
	S1/106	MPM-6	Seminar (I)											50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-II	S2/201	MC-S7	Validation & cGMP	2		10		02	40			25		50(2)
	S2/202	MC-S8	Biological Evaluation	4	Demo	20		03	80			50		100(4)
	S2/203	MPM-S9	Pharmaceutical Management II (Production)	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/204	MPM-S10	Pharmaceutical Marketing Management	4	8	20	20	03	80	08	80	50	50	200(8)
	S2/205		Elective-II	2		10		02	40			25		50(2)
	S2/206	MPM-12	Seminar (II)		4									50(2)
				16	**20**	**80**	**40**	**13**	**320**	**16**	**160**			**650(26)**
Semester-III	S3/301	MPM-S13	Pharma Product Management	4		20		03	80			50		100(4)
	S3/302		Elective-III	2		10		02	40			25		50(2)
	S3/303	MPM-15	Seminar (Presynopsis presentation)		4									50(2)
	S3/304	MPM-16	Dissertation		24									
				06	**28**	**30**		**05**	**120**					**200(8)**
Semester-IV	S4/401	MPM-17	Dissertation		24									300(12)
	S4/402	MPM-18	Seminar on Dissertation											100(4)
	S4/403	MPM-19	Viva-voce											100(4)
														500(20)
														2000(80)

MC-S : Subject common to all branches

MPM-S : Subject specialization in pharmaceutical management

Syllabus Prescribed for Degree of Master of Pharmacy in Pharmaceutics

Semester-I

Subject code: MC-S1
Subject: ADVANCED ANALYTICAL TECHNIQUES
THEORY: 60 Hours (4 hrs. /week)

1. **Chromatographic Techniques**:
   Classification of chromatographic methods based on mechanism of separation and their basic principles.
   Gas chromatography: Instrumentation, column efficiency parameters, derivatisation methods, applications in pharmaceutical analysis.
   Liquid chromatography: Instrumentation in HPLC, normal and reversed phase packing materials, column selection, mobile phase selection, efficiency parameters, applications in pharmaceutical analysis.
   Thin Layer Chromatography overview. Instrumentation and applications of HPTLC giving emphasis to use of TLC- Densitometry in the standardization of some Medicinal Plants.
   Recent advances in Chromatography like LCMS, HPTLC MS, LC MS-MS

2. **UV-Visible Spectroscopy**:
   Basic principles, Instrumentation, Electronic transitions. Concept of chromophore and auxochrome, Effect of conjugation, solvent and pH. Instrumentation. Multicomponent analysis. Woodward-Fieser rules for calculating absorption maximum for unsaturated hydrocarbons. Difference and derivative spectra. Interpretation of spectra, Qualitative and quantitative analysis of drug molecules.

3. **Infra-Red Spectroscopy**:
   Basic principle,Interaction of infrared radiation with organic molecules and its effect on bonds. Instrumentation- Dispersive IR and FT-IR spectrophotometers. Sample preparation & Sample handling. Interpretation of IR spectra. Fermi Resonance. Brief note on Attenuated Total Reflectance. Qualitative and quantitative applications of IR.

4. **Nuclear Magnetic Resonance Spectroscopy**:
   Fundamental principles of NMR. Instrumentation. Chemical shift concept, spin-spin coupling and decoupling, shielding and deshielding, solvents. Pascle triangle, signal multiplicity in PMR. Spin-spin and spin-lattice relaxation, Nuclear overhauser effect, Interpretation of PMR, 13 C NMR.

5. **Mass Spectrometry**:
   Basic principles and instrumentation. Ionization techniques, mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks.

6. **Thermal Methods:**
   Thermogravimetry, Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

RECOMMENDED BOOKS:

1. Skoog, DA, Holler, FJ, Crouch, SR. Principles of instrumental analysis. 6th ed., Baba Barkha Nath Printers, Haryana, 2007.
2. Silverstein, RM, Webstar, FX. Spectrometric identification of organic compounds. 6th ed., John Wiley and Sons (Asia) Pvt. Ltd., Singapore, 2005.
3. William Kemp. Organic Spectroscopy, 3rd ed., Palgrave, New York, 2006
4. Conners KA. Text book of Pharmaceutical analysis, 3rd ed., John Wiley and Sons, Singapore, 2004
5. Willard HH, Merritt LL, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers and Distributors, New Delhi, 1986
6. Sharma BK. Instrumental methods of chemical analysis, 25th ed., Goel Publishing House, Meerut, 2006.
7. Beckett, AH, Stenlake, JB. Practical Pharmaceutical Chemistry, Part I and Part II, 4th ed., CBS Publishers and Distributors, New Delhi, 2004.
8. Ewing, GW. Instrumental methods of chemical analysis, 5th ed., McGraw Hill Book Company, New York, 1985.
9. Houghton P, Mukherjee PK. Evaluation of Herbal Medicinal Product, Pharmaceutical Press, London, 2009.
10. Kalsi, P S. Spectroscopy of Organic Compounds, 2nd ed., Wiley Estern Ltd., Delhi

Subject code: MC-P1
Subject: ADVANCED ANALYTICAL TECHNIQUES
PRACTICAL: 8 hrs. /week

1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures and isobestic point in case of mixtures.
2. Estimation of single drug (raw material/ formulation) by colorimetry involving different reagents. (minimum of 4 experiments)
3. Estimation of single drug (raw material/ formulations) by UV spectrophotometry. (minimum of 4 experiments)
4. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations (minimum of 4 experiments)
5. Effect of pH and solvent on UV Spectrum of certain drugs. (Minimum of 2 experiments)
6. Calibration of IR Spectrophotometer using polystyrene film and checking the performance of the instrument.
7. Interpretation of structure of drugs by Infra red spectra. (Minimum 4 compounds).
8. Experiments based on the application of derivative spectroscopy. (Minimum of 2 experiments)
9. Standardization and dissolution studies of solid dosage form (Minimum of 5 experiments)
10. Experiments using HPLC: Determination of chromatographic parameters- capacity factor, selectivity, resolution, efficiency of column HETP, asymmetric factor.
11. Estimation of drugs in biological fluids by HPLC (minimum 2 experiments)
12. Experiments based on application of HPTLC for quantification of Berberin from *Berberis aristata* and Andrographolide from *Andrographis paniculata*.

Subject code: MC-S2
Subject : RESEARCH METHODOLOGY & BIOSTATISTICS
THEORY: 30 Hours (2 hrs. /week)

Research Methodology

1. **Introduction:** Meaning & Objectives of research, types of research: basic, applied action & patent oriented research, approaches to research; research methods, research process; criteria for good research, common problems, nature and significance of research problems, qualitative & quantitative research methods.
2. **Selection of Research Topic:** Selection of research problem, literature review, evaluation of research problem, research design; meaning, concept & features of research design, experimental design, plan of research work.
3. **Methods & tools of research**
   Reliability and validity of research tool, Qualitative and quantitative studies, Primary & secondary data collection method, Preparing questionnaire and opinionnaire, identification of sources of information, searching and classifying information; organization of data collection, processing & analyzing of data & information. Limitations & sources of error.
4. **Preparing a research proposal**
   Format of research proposals: finding related literature, Individual & Institutional research proposals, submitting research proposal to funding agencies.
5. **The Research Report/Report writing**
   Style manuals, format of research report, The thesis or dissertation, style of writing, typing the report, reference form, pagination, tables, figures, evaluating a research report, summary, references.

Biostatistics

1. **Descriptive Statistics:** Classification of variable, Summary of measures of location: median and mean, Properties of the sample mean, Summary measures of dispersion: interquartile range, variance, standard deviation, Properties of sample variance and standard deviation, Graphic representation of data.
2. **Estimation and Hypothesis testing:** Null Hypothesis, confidence level, Point & interval estimation, concept of hypothesis testing & types of error, Student 't' test, Chi-Square test.
3. **Analysis of Variance:** Analysis of variance (one way & two way), Repeated measures designs, factorial designs, univariate ANOVA post hoc tests, analysis of covariance (ANCOVA), repeated measures analysis, multiple regression, and power analysis**.**

RECOMMENDED BOOKS:

1. B.D. John, A.L. Brown and R.R. Cocking, 1999. "How People Learn: brain, mind, experience and school". Washington, DC: National Academy Press.
2. J.R. Fraenkel, N.E. Wallen, 2008. "How to Design and Evaluate Research in Education*", 7th Ed*. Boston: McGraw-Hill.
3. K.E. David, 2009. Curriculum Development for Medical Education: *A Six-Step Approach*, 2nd Ed. The John Hopkins University Press. ISBN 0-8018-9367-4.
4. N. Peter, 2009. "Leadership: Theory and Practice*." 3rd Ed*. Thousand Oaks: Sage Publications.
5. G. Bordage, B. Dawson, 2003. Experimental study design and grant writing in eight steps and 28 questions. *Medical Education, 37*(4): 376-385.

6. C.R. Kothari, 2004. "Research Methodology". 2nd Ed. New Age International (p) Limited, Publishers.
7. D. Montgomary, 2000. "Design of Experiments". 5th Ed. Wiley Interscience.
8. K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd Ed. Himalaya publishing, Mumbai.
9. Schank Fr, 2008. "Theories of Engineering Experiments". 2nd Ed. Tata McGraw Hill.
10. D.C. Montgomery, 2009. "Introduction to SQC" 6th Ed. John Willy & sons.
11. Cochran & Cocks, 1957. 2nd Ed. "Experimental Design" New York, John Willy & sons.
12. J.W. Best and J.V. Kahn, 2006. "Research in Education". 10th Ed. PHI publication.
13. Adler and Granovky, "Optimization of Engineering Experiments", MIR Publications.
14. S.S. Rao, 1983. "Optimization Theory & Applications". 2nd Ed. Wiley Eastern Ltd. ND.
15. P.D. Kulkarni, 1986. "Independent Study Techniques", TTTI Chandigarh.
16. C. B. Gupta, Introduction to Statistical Methods.
17. C. E. Weatherborn, A first course in Mathematical Statistics.
18. LD Fisher, GV Belle, Biostatistics: A Methodology for Health Sciences. 2nd Edition. Wiley Interscience .2004.
19. Sanford Bolton. Pharmaceutical statistics- Practical and clinical applications. 4th edition, publisher Marcel Dekker Inc. New York.

Subject code: MC-S3
Subject : DRUG REGULATORY AFFAIRS
THEORY **60 Hours (4 hrs. /week)**

1. Aims, objects and salient features of following legislations affecting pharmaceutical industry.
    a) Industrial Development and Regulation Act 1951.
    b) Consumer Protection Act
    c) Pollution and Environmental Control Act..
2. Legislation

a. To Regulate the profession of pharmacy – The Pharmacy Act 1948
b. To control the advertisements, excise duties & prices of drug The Drugs and Magic Remedies Act & Rules (Objectionable advertisements) The Medicinal & Toiletry preparations (The Excise Duties Act- 1955 & Rules 1976).
c. To control the operations relating to dangerous drugs & opium. Narcotic Drugs & Psychotropic Substance Act 1985.

3. Standard institutes & certification agencies like ISI, BSS, ASTM, SO, WHO, US-FDA, UK-MCA, TGA. Australian TGA guidelines. US-FDA, CDER guidelines
4. Intellectual Property Rights Law:
    a) Indian Patent Act 1970 and amendments there under,
    b) Copyright (Indian) Act
    c) Guide lines for filing patents in countries like US & UK.
    d) Good Clinical Practice Guideline, Good Laboratory Practice Guidelines, GMP Guidelines
5. Drug Master File. Preparation of Site Master File, Master Formula Record and DMF Procedure for filing of Patent.
6. Management of Intellectual Property in Drugs & Pharmaceuticals
7. Drug Regulatory Agencies of the following countries with focus on historical perspectives, organization structure activities & responsibilities: India, US, Europe and Japan
8. Drug and Cosmetics Act 1940 & rules 1945 with amendments, Prevention of Food Adulteration Act 1954.

9. Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs, Comparative picture of IP, USP, BP, EP & GP.
10. New Drug Application (NDA), Investigational New Drug Application (INDA), Abbreviated New Drug Application (ANDA).
11. Material Safety Data Sheet (MSDS) preparation and Industrial Safety & Health

RECOMMENDED BOOKS: -

1. Forensic Pharmacy by B.S. Kuchekar, A. M. Khadatare and S. C. Jitkar, 6th Ed., Nirali Prakashan
2. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
3. Mittal B.M., A Textbook of Forensic Pharmacy, 9th Ed., Vallabh Prakashan
4. James Swarbrick, James C Boylon, Encyclopedia of Pharmaceutical Technology, 2nd Ed. Marcel Dekker Inc.
5. Deshpande S.W., Drugs and Cosmetic Act.1940
6. Bubuarm N.R, Whatever one should know about patent, 2nd Ed., Pharma Book Syndicate
7. Gnarino Richard A, New Drug Approval Process, 3rd Edition, Marcel Dekker Inc
8. Deshpande S.W, Drug and Magic Remedies Act 1954.
9. P. Warayan, Intellectual Property Laws, Eastern Law House.
10. Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
11. Pharmacy Law and Ethics by Dale and Appelbes, The Pharmaceutical Press, Joy Winfield.
12. Guidelines of various countries like MCA, TGA, ICH.
13. GLP regulation by Alen Hirsch Vol 38 Marcel Decker series.
14. GMP for pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.
15. I.P., B.P., U.S.P. International Pharmacopoeia

Subject code: MPH-S4
Subject : ADVANCED PHARMACEUTICS
THEORY: **60 Hours (4 hrs. /week)**

1. **Preformulation Studies:** Timings and goals of Preformulation, Pre-formulation methodology, solid state properties, partition coefficient, solubility, dissolution, crystal form and stability, Thermal Analysis, X-ray diffraction:- Techniques to generate & characterize amorphous & crystalline forms, compatibility tests, dissolution of drug substances and dosage.

2. **Kinetic Principles and Stability Testing:** Order of reaction, influence of pH, temperature, Acid - base catalysis. Effect of Ionic strength on degradation, Complex reactions, amide hydrolysis, Ring alteration, Oxidation - reduction, Chemical &Physical stability of dosage forms, Influence of packaging components on dosage form stability. Overages and ICH guidelines.

3. **Excipients:** Overview of excipients used in formulations. Factors affecting the selection. Introductory aspects of drug-excipient and excipient, package interactions.

Study of newer excipients like cyclodextrin, ion exchange resins, film coating materials, superdisintegrants, directly compressible vehicles, surfactants- micelle formation, liquid crystal phase, thickeners. Standardization of excipients.

4. **Polymer Science:-** Introduction and classification ,preparation methods of synthetic polymers, Molecular weight determination , Thermal characterization and rheology of polymers. Introduction to biodegradable & biodegradable polymers.

5. **Diffusion & Dissolution:** Concept and importance of dissolution. Steady state diffusion. Determination of diffusion coefficient & its importance. Concept & importance of dissolution. Dissolution test, Historical development & USP dissolution test. Dissolution model like Hixson-Crowell, Higuchi's Model. Drug release modeling through polymer matrix & laminates. Concept of membrane controlled delivery & its importance in dosage form design.

6. Optimization Techniques in Pharmaceutics, Formulation and Processing Optimization parameters, statistical design, and other application.

7. **Quality Control :** Process of dosage forms : Process control ; Control of quality Validation, Control of manufacturing Process, Statistical quality control, control charts, sampling plans, Automated & process control, Dosage form control, Testing programme & method, Product identification systems, Adulteration, Misbranding, maintenance of records, Bioavailability, Bioequivalence, manufacturer's reliability, Manufacturer/drug information profile.

RECOMMENDED BOOKS:

1. Lachmann and Libermann, Theory and Practice of Industrial Pharmacy. Third edition, Varghese Publishing House.
2. Leon Lachmann, Pharmaceutical dosage forms: Tablets Vol. 1-3. Third Edition, Marcel Deckker.
3. Leon Lachmann. Pharmaceutical Dosage forms: Disperse systems, Vol, 1, 2, 3. Second edition. Marcel Deckker
4. Gillbert and S. Banker. Modern Pharmaceutics.. Fourth Edition. Volume 121.
5. Remington's Pharmaceutical Sciences. Vol.I-II, 21 st Edition.
6. H.S. Bean & A.H. Beckett .Advances in Pharmaceutical Sciences Vol. 1-4.
7. Alfred Martin, Physical Pharmacy. Fifth Edition, Published by B. I. Waverly Pvt. Ltd.
8. Rawlins. Bentley's Textbook of Pharmaceutics. Eight Edition
9. Sidney H. Willig. Good manufacturing practices for Pharmaceuticals: A plan for total quality control. Second Ed.
10. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
11. D.P.S. Kohli and D.H. Shah. Drug formulation manual. Third Edition, Eastern publishers, New Delhi.
12. P. P. Sharma. How to practice GMPs. Fifth Edition, Vandana Publications, Agra.
13. Fra. R. Berry and Robert A. Nash. Pharmaceutical Process Validation. Vol-129, Second Edition. Revised and Expanded.
14. Evans, Anderson, Sweeney and Williams Applied production and operations management.
15. M. Gibson, 2001. "Pharmaceutical preformulation and formulation"1st Ed. Informa Healthcare.
16. A. Hickey, 2009. "Pharmaceutical process engineering" 2nd Ed. Marcel Dekker, Inc

17. J. Swarbrick, 2007. Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1-6, Informa Healthcare.
18. R. Sheskey and Quinn, "Pharmaceutical excipients" Pharmaceutical Press.
19. M. Chaubal, "Excipients development for. Pharmaceutical, Biotechnology, and Drug Delivery System". Informa Healthcare.
20. S.C. Sweetman. Martindale-The complete drug reference. 37th Edition, Vol. A and B, Pharmaceutical Press, UK.

Subject code: MPH-P4
Subject : ADVANCED PHARMACEUTICS
Practical: 8 hrs. /week

1. Preformulation studies on tablets.
2. To study the decomposition kinetics of any three drugs.
3. To study the effect of copper ions on the ascorbic acid stability in solution
4. To determine the aqueous solubility of given drug sample at various temperature and report its thermodynamic parameters.
5. To study the dissolution kinetics of given drug.
6. To study the effect of pH (2, 4, 6 and 8.0) on the apparent partition coefficient of a drug in n-octanol- water buffer system.
7. To study the dissolution kinetics of immediate and extended release dosage form (any five).
8. To study the effect of temperature on rheological behavior of poloxamers.
9. To study the effects of pH on rheological characteristics of carbopol gels using Brookfield viscometer.
10. To determine the best compatible additive for aspirin tablets using at least five known tablet components.
11. To study the diffusion of drug from topical gel using Franz diffusion cell.

Semester-II

Subject code: MC-S7
Subject: VALIDATION and cGMP
THEORY: 30 Hours (2 hrs. /week)

Validation

1. Definition, Government regulation, scope and advantage of validation, relationship between validation and qualification, validation master plan, FDA 21 CFR Part 11, qualifications of utilities and process equipments (protocols & reports for DQ, IQ, OQ, PQ).
2. Validation of medical devices, biotechnology processes, pharmaceutical ingredients, air handling and HVAC systems, sterile and non sterile areas, aseptic processes and sterilization methods, purified water system, distilled water and water for injection.

cGMP

1. Concepts and Philosophy of cGMP in manufacturing, processing, packaging, and holding of Drugs.
2. Organization and Personnel: Responsibilities, qualification, experience, training, personal hygiene and clothing.
3. Buildings and Facilities: Location, design, plant layout, maintenance and sanitation, environmental control, utilities and services like gas, water, control of contamination and maintenance of sterile areas.
4. Raw materials: Purchase specifications, selection of vendors, control on raw materials and finished dosage forms.

RECOMMENDED BOOKS:

1. Pharmaceutical Process Validation, Edited by Robert A. Nash, Alfred H. Wachter, Vol. 129, Marcel Dekker Inc.
2. Good Manufacturing Practices for Pharmaceuticals by Sidney H. Willing and Murray M. Tuckerman, Vol. 16, Marcel Dekker Inc.
3. Encyclopedia by pharmaceutical technology edited by James Swarbrick, James C. Boylan, Marcel Dekker Inc.gtg
4. How to practice GMPs by Sharma PP, 3rd Ed., Vandana Publication.
5. Drug and Cosmetic Act and Rules (Governent of India).
6. Current Good Manufacturing Practices by Potdar MA, Pharma-Med Press, Hyderabad.
7. Pharmaceutical Quality Assurance by Potdar MA, Nirali Prakashan, Pune.

Subject code: MC-S8
Subject: BIOLOGICAL EVALUATION
THEORY: **60 Hours (4 hrs. /week)**

1. **Principles of Pharmacological and Pre-clinical Evaluation of drugs.** Commonly used laboratory animals in pharmacological research, limitations of animal tests Standard techniques used in laboratory animals, euthanasia of experimental animals, Regulations for laboratory animal care and ethical requirements.

2. Bioassays: Basic principles of bioassays, official bioassays, experimental models, design of bioassays.

3. Toxicology: Principles of toxicity evaluations. Safety evaluation of new drugs in animals including acute, sub-acute, sub chronic and chronic toxicity. ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity. Various guidelines for toxicity studies. International guidelines and regulatory agencies for toxicity studies like ICH, OECD, FDA, WHO etc.

4. Modern Methods of Pharmacological evaluations: Radioligand binding assay, patch clamp, stereotaxic technique and ELISA. Recent advances in transgenic and genetically modified animals for drug screening and other sophisticated methods

5. Alternatives to animal screening procedures: Cell line - handling, maintenance and propagation of cell lines, their uses and limitations. In-vitro testing of drugs.

6. Preclinical Evaluation: Preclinical models employed and organization of screening of new drugs of following categories:

i) Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, nootropics, antiparkinsonian agents, analgesics, antipyretics.
ii) Anti-inflammatory agents, anticonvulsants, local aneasthetics, CNS stimulants.
iii) Cardiac glycosides, antiarrhythmic, antihypertensive, antianginal, anti-atherosclerotic,
iv) Antiulcer agents, Laxatives, Bronchodilators, antitussives,
v) Diuretics.
vi) Histamine antagonists.
vii) Muscle relaxants, Anticholinesterases, anticholinergics, adrenolytics.
viii) Hypoglycemics, antifertility agents, androgens.
ix) Anti-thyroid agents, Dermatological agents, Antitumor agents.
x) Anthelmintics, Antimalarials, Antileprotics.
xi) Drugs used for glaucoma, cataract and eye inflammation.

RECOMMENDED BOOKS:

1. Laurence D R and Bacharach A L, Evaluation of Drug Activities: Pharmacometrics, Academic Press, London & New York.
2. Nodine J H and Siegler P E, Animal and Clinical Pharmacological Techniques in Drug
3. Evaluation, Year Book Medical Publishers Chicago.
4. Turner R A and Hebbron P, Screening Methods in Pharmacology, Vol I & II, Academic Press, New York, 2009.
5. Vogel H G, Drug Discovery and Evaluation, Pharmacological Assays, Springer_verlog Berlin Heidelberg, 2007.

6. S. K. Gupta, Drug screening methods, Jaypee Brothers Medical Publisher (P) Ltd, New Delhi 2005.
7. Sheth U K, Dadkar N K and Kamat U G, Selected topics in Experimental Pharmacology, Kotari Book Depot, Mumbai.
8. Jann Hau, Handbook of Laboratory Animal Science, Animal Models, Vol I and II. CRC Press 2004 3rd edition.
9. Perry W L M, Pharmacological Experiments on Isolated preparations, E & S Livingstone, London.
10. Burn J H, Practical Pharmacology, Blachwell Scientific Co., Oxford.
11. Parmar N S and Shivkumar, Pharmacological Screening Methods, Sciences 2006.
12. Thomson E.B. Drug Bioscreening, John-Wiley and Sons, New York, 1990.
13. Review articles published in various medical and pharmaceutical journals and CPCSEA, OECD, FDA, WHO, ICH guidelines from respective website.

Subject code: MPH-S9
Subject: PRODUCT DEVELOPMENT AND FORMULATION
THEORY: 60 Hours (4 hrs. /week)

1. **Fundamental Aspects of Product Development**: Studies of wettability, solubility, dissolution, and absorption, surfactant and hydrocolloids and their role in drug delivery and targeting.

2. **Pilot Plant Scale-up** Techniques: Purpose and functions, concepts of pilot plant for development and control. Planning for pilot plant, size of pilot plant. Organization and personnel, basic consideration in developing the process for production of pharmaceutical dosage forms. Pilot plant study design for tablets, tablet coating, capsules, liquid orals and semi-solids.

3. **Designing of Oral Pharmaceuticals:** Formulation, evaluation, stability Studies and recent advances in dosage form; tablet, capsule, suspension, emulsion; microencapsulation, advances in coating techniques. Advances in pelletization techniques

4. **Development of Parenterals:** Concepts, formulation, evaluation of large and small volume parenterals, environmental control and quality assurance in manufacturing.

5. **Ophthalmic Preparation:** Introduction, Physiology of eye, formulation consideration and evaluation of ophthalmic products (ointments, suspension, eye drops, contact lenses, occuserts etc.), container and closures.

6. **Suppositories:** Selection of suppository bases, characteristics of bases, formulation, preparation, evaluation and packaging of suppositories, stability studies and recent development.

7. **Dermatological Preparations:** Anatomy and physiology of skin, mechanism of absorption through skin including mathematical treatment, formulation and evaluation of ointments, creams, paste, gels including herbal cosmetic creams.

Note: The designing and development of dosage form should be covered at advanced level considering recent advances in dosage form technology

RECOMMENDED BOOKS:

1. Remingtons "Pharmaceutical Sciences" 21st edition.
2. Lachman "The Theory and Practice of Industrial Pharmacy" 3rd edition, Varghese Publisher.
3. M. E. Aulton, Pharmaceutics "The Science of Dosage form design". Second Edition.
4. Husa's Pharmaceutical dispensing; a textbook and reference manual on drug development, pharmaceutical compounding, and dispensing. 6th Edition, Editor: Eric W. Martin. Managing editor: John E. Hoover.
5. Gillbert and S. Banker. Modern Pharmaceutics.. Fourth Edition. Volume 121.
6. J. Swarbrick, 2007. Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1-6, Informa Healthcare.

Subject code: MPH-S10
Subject: NOVEL DRUG DELIVERY SYSTEMS
THEORY: 60 Hours (4 hrs. /week)

1. Fundamentals of controlled release drug delivery systems :
Fundamentals and Rationale of Sustained / controlled drug delivery, factors influencing the design & performance of sustained/ Controlled release products, Drug Targeting, Use of polymers in controlled release of active agents, Pharmacokinetic / Pharmacodynamic basis of controlled drug delivery systems, regulatory requirements.

2. Oral drug delivery: Formulation, fabrication and evaluation of various oral controlled drug delivery systems including dissolution and diffusion controlled delivery systems, gastro retentive, colon targeted and pulsatile drug delivery. TIMERx, MASSRx & COSRx, Procise technology, RingCap technology, Theriform Technology, Accudep Technology, THREEFORM Technology, DissoCube IDD Technology, Zydis Technology for poorly soluble drugs, Orasolv & Durasolv technolohy, Egalet Technology, Buccal Mucoadhesives, Periochips.

3. Parenteral controlled release system: Scope, terminology & techniques used, injectable controlled release, formulation. Implantable drug delivery, microspheres, liposomes & their quality control.

4. Mucosal drug delivery models: Buccal, rectal, nasal & vaginal drug delivery. Mechanisms of transports of drugs through mucosal routes, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation (for each route).

5. Transdermal drug delivery system: Permeation through skin including mechanism, permeation enhances, In-vitro skin permeation, technologies for developing transdermal drug delivery system, mechanism of release kinetics, evaluation of transdermal drug delivery systems.

6. Ocular Drug Delivery: Transport of drugs through ocular tissues, approaches to improve ocular drug delivery.

7. Site specific drug delivery system: Active & passive targeting, resealed erythrocyte, monoclonal antibodies, drug targeting by particulate carrier system, drug targeting to brain, lung & colon.

8. Protein & peptide drug delivery system: Physical aspects, biochemistry of protein drug (structure, properties & stability- Mechanisms of destabilization. Techniques of stabilization of Proteins and Peptides.) General methods of analysis of protein & peptide drugs, barrier to transport & Pharmacokinetics, different route of delivery, practical considerations. Importance of pre-formulation & formulation considerations, toxicity immunogenicity, stability& regulatory perspective.

9. Regulatory consideration in controlled release: Demonstration of safety, efficiency & controlled release nature. WHO conditions.

RECOMMENDED BOOKS:

1. Remington's pharmaceuticals sciences. 21 st Edition, Lippincott Wiilliams and Willkins- Vol. I & II
2. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Yie W. Chien. Vol- 50.
3. J. R. Robinson and Vincent H. L. Lee Controlled drug delivery system. Marcel Dekker Second Edition, Revised and Expanded. Vol- 29.
4. N.K. Jain .Novel and controlled drug delivery systems, C.B.S. publishers and Distributors, New Delhi.
5. N.K. Jain. Advances in Novel and Controlled Drug Delivery, C.B.S. publishers and Distributors, New Delhi.
6. Robinson, J.R. & Lee, V.H.I.,: Controlled and Novel Drug Delivery Marcel Dekker, New York. Second Edition, Revised and Expanded Vol- 29.
7. Kim. C., Controlled Release Dosage form Design, Technomic Publishing Co, Basel.
8. J. Swarbrick, 2007. Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1-6, Informa Healthcare.
9. R. Williams, D. Taft and J. McConville, "Advanced formualtion design to optimize therapeutic outcomes" Marcel Dekker, Inc.
10. L. Xiaoling, B.R. Jasti, "Design of Controlled Release Drug Delivery Systems" McGraw-Hill.
11. B. O. Mashkevich, "Drug delivery research advances" Nova Science Publishers, Inc.
12. W.M. Saltzman, 2001 "Drug delivery_Engineering Principles for Drug Thera". Oxford University Press.
13. E. Touitou, W.B. Boca "Enhancement in Drug Delivery" CRC PressBrian.
14. M.J. Rathbone, J. Hadgraft, M.S. Roberts, "Modified-Release Drug Delivery Technology" Marcel Dekker Inc.

Subject code: MC-P8
Subject: BIOLOGICAL EVALUATION
PRACTICAL:

1. Demonstrations will be based on the topics mentioned in Biological Evaluation theory

Subject code: MPH-P9
Subject: PRODUCT DEVELOPMENT AND FORMULATION
PRACTICAL: 8 hrs. /week

1. Determination of molecular weight of the given polymer.
2. Enhancement of solubility of the given drug by solid dispersion technique.
3. Performance of water attack on treated soda lime glass container.
4. Formulation and characterization of topical gels of some anti-inflammatory drugs.
5. Comparison of release rate profile of conventional and sustained release tablets.
6. Preparation of microcapsules by different techniques and their evaluation
7. Formulation and evaluation of ophthalmic dosage forms.
8. Performance of physical stability and dissolution studies of the suspension of given drug.
9. Formulation and evaluation of suppositories of given drug.
10. Determination of the effect process variable on physicochemical characteristics and in-vitro release profile of microcapsule.

Subject code: MPH-P10
Subject: NOVEL DRUG DELIVERY SYSTEMS
PRACTICAL: 8 hrs. /week

1. Formulation and evaluation of sustained release matrix tablet (of any two drugs).
2. Formulation and evaluation of floating microspheres.
3. Formulation and evaluation of floating tablet.
4. Formulation and in vitro evaluation of transdermal patches.
5. Development and evaluation of ocular inserts of a given drug.
6. Preparation and evaluation of buccal film of any two cardiovascular drugs.
7. Taste masking of some bitter drugs by ion-exchange resins.
8. Formulation and evaluation of nasal in situ gel.
9. Preparation and characterization of liposomes.
10. Preparation characterization of wax embedded microcapsules of a given drug.

Semester-III

Subject code: MPH-S13
Subject: BIOPHARMACEUTICS AND PHARMACOKINETICS
THEORY: 60 Hours (4 hrs. /week)

1. Introduction to biopharmaceutics and clinical pharmacokinetics
Definition of Biopharmaceutics, Pharmacokinetic, clinical Pharmacokinetic and its importance.

2. Absorption of drugs
GI absorption of drugs, Cell membrane structure and physiology. Mechanism of drug absorption. Factors influencing drug absorption and bioavailability. Non-oral absorption of drugs. Concepts and kinetics of physiological parameters of absorption.

3. Distribution of drugs
Factors affecting distribution of drugs. Tissue permeability of drugs. Physiological barriers to diffusion of drugs. Organ / Tissue size and perfusion rate. Binding of drugs to blood components and tissue. Factors affecting it. Miscellaneous factors (Age, Pregnancy, Obesity etc) Volume of distribution.

4. Elimination of drug
Concept of clearance. Hepatic metabolism: chemical pathways and factors affecting it. Renal excretion: principle processes and factors affecting It. Non renal excretion: Concepts and kinetics of physiological parameters of elimination

5. Bioavailability and bioequivalence
a) Objective of bioavailability studies, determination bioavailability parameters of bioavailability rate of absorption extent of absorption, relative bioavailability, determination of AUC (using planimeter, counting squares trapezoidal rule and cutting and weighing studies). Study designs of bioavailability and bioequivalence testing. Statistical concept in determination of bioavailability and bioequivalence testing.
b) Drug dissolution rate and bioavailability
Theories of dissolution in-vitro drug dissolution testing models
In-vitro – in-vivo correlation
c) In-vitro and in-situ absorption studies
Various In-vitro & in-situ models – selection of animals

6. Pharmacokinetics
Basic consideration, Pharmacokinetic models, Compartment modeling: One compartment model–IV bolus, IV infusion, Extra-vascular; Multi Compartment models; Two compartment model–IV bolus, IV infusion, Extra-vascular. Application of pharmacokinetics in new drug development and designing of dosage forms and novel drug delivery systems.

7. Non linear pharmacokinetics
Saturable enzymatic elimination process, drug elimination by capacity limited pharmacokinetics, mixed drug elimination, time dependent pharmacokinetics, bioavailability of drug that follow non linear pharmacokinetics, non linear pharmacokinetics due to protein binding (e.g. phenytoin)

RECOMMENDED BOOKS

1. M. Rowland, T.N. Tozer, 2011. "Clinical Pharmacokinetics and Pharmacodynamics: Concept and Applications", 4th Ed. Lippincott, Williams and Wilkins.
2. L. Shargel, S. Wu-Pong, B. C Andrew, 2005. "Applied Biopharmaceutics and pharmacokinetics", Fifth Ed. McGraw-Hill Medical Pub. Division.
3. M. Gibaldi and D. Perrier, Second Edition. 1982. "Pharmacokinetics". M. Dekker.
4. B.N. La Du, H. G. Mandel & E. L. Way, 1972. "Fundamental of drug metabolism and disposition". Williams & Wilkins, Baltimore.
5. T.Z. Csaky, 1975. "Intestinal absorption and malabsorption". Raven Press.
6. S. Niazi, 2007. "Handbook of Bioequivalence testing". Informa Health Care.
7. D.J. Cutler, "Pharmaceutical Product Development: In vitro-In vivo Correlation". Informa Health Care.

Syllabus Prescribed for Degree of Master of Pharmacy in Pharmaceutical Chemistry

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MPC-S4
Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-I
THEORY: 60 Hours (4 hrs. /week)

1. **Various Reaction Mechanisms:**
   a. Substitution Reaction: Nucleophilic substitution reaction in aliphatic systems, SN1, SN2 reactions, Hydride transfer reaction, Cram's rule, Participation of neighbouring group in nucleophilic substitution reaction and rearrangements. Aromaticity, electrophilic and nucleophilic substitution in aromatic systems, Reactivity, orientation in electrophilic substitution.

   b. Elimination Reaction: Beta Elimination reactions, E1, E2 and E1cb mechanisms, Hoffman and saytzeff's rule for elimination, stereochemistry of E2 reaction, Elimination from alicyclic compounds.

   c. Addition Reaction: Electrophilic and Nucleophilic additions, Stereochemistry involved, Markonikov's rule.

   d. Free Radical Reaction: Formation, Detection, Reactions, Homolysis and free radical displacements, addition and rearrangements of free radicals.

2. **Esterification reactions and ester hydrolysis.**

3. **Heterocylic chemistry:**
   Nomenclature, synthesis, physical, chemical and spectroscopic properties of pyrrole furan, thiophen, pyridine, pyridazine, pyrimidine, pyrazine, quinoline, isoquinoline, indole, oxazole, imidazole and benzimidazole.

4. **Oxidation and reduction reactions:**
   Oxidation reaction involving use of potassium permanganate, potassium dichromate, chromic acid, selenium dioxide, periodic acid, N-bromo succinimide and oppenaure oxidation. Reduction reactions using metal and acid, metal amine reduction, catalytic reduction, hydrogenation of double bond, triple bond and aromatic rings, birch reduction, Meerwein-Pondroff-Verley reduction.

5. **Modern synthetic methods:**
   a) Green Synthesis: Introduction; Green reagents; green catalysts; ionic solvents; phase transfer catalysis in green synthesis; application of phase transfer catalysts in green synthesis of heterocyclic compounds: Williamson's synthesis, Wittig reaction.

b) Microwave assisted synthesis: Introduction; microwave reactions in water (Hofmann elimination, hydrolysis and oxidation); microwave reactions in organic solvents; solid state reactions; advantages of microwave technique.

RECOMMENDED BOOKS:

1. Morrison RT and Boyd RN, Organic Chemistry, 11th edition, Prentice-Hall of India Pvt. Ltd, New Delhi,
2. Thomas L. Gilchrist, 2008, Heterocyclic Chemistry, 3rd edition, Pearson Education.
3. Raj K. Bansal, 2010, Heterocyclic Chemistry, 5th edition, New Age International Publishers.
4. J. March, 2005, Advanced Organic Chemistry – Reaction, Mechanism and Structure, 4th edition, A Wiley-Interscience Publication, John Wiley & Sons, New York.
5. Peter Sykes, 1985, A Guidebook to Mechanism in Organic Chemistry, 6th edition, Longmann Scientific and Technical, Copublished with John Wiley & Sons, Inc, New York.
6. James Clark & Duncan Macquarrie, 2002, Handbook of Green Chemistry and Technology, Blackwell Science Ltd
7. William M. Nelson, Green solvents for Chemistry: Perspectives and Practice, Oxford University Press
8. VK Ahluwalia & M Kidwai, 2004, New Trends in Green Chemistry, Kluwer Academic Publishers.
9. VK Ahluwalia & Renu Agarwal, 2006, Organic Synthesis-Special Techniques, Alpha Science International.
10. M. Lancaster, 2002, Green Chemistry: An Introductory Text, Royal Society of Chemistry.

Subject code: MPC-P4
Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-I
Practical: 8 hrs. /week

1. Separation and identification of organic compounds from binary mixtures: Solid-solid.
2. Synthesis, physico-chemical and spectral analysis of some of the following heterocyclic compounds:
   a) Quinoline b) benzimidazole/derivative c) flavone/chromone d) indole/derivative e) phenothiazine f) oxazole/oxazolone g) benzoxazole h) 3,5 dimethylisoxazole
3. Synthesis and characterization of at least two organic compounds based on green chemistry approach.
4. Synthesis and characterization of at least two heterocyclic/ organic compounds using microwave.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MPC-S9
Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-II
THEORY: 60 Hours (4 hrs. /week)

I Stereochemistry:
1. Stereochemical nomenclature & terminology.

2. General concepts on: Chirality, Molecular dissymmetry, Elements of symmetry (plane, centre and axis with relevant examples), optical activity and specific rotation, enantiomers distereomers, Sequence rule - Relative and absolute configuration (D, L and R, S nomenclature), Projection formulae (Fischer, Howarth, Newman and Sawhorse).

3. Stereochemistry of compounds with one stereogenic centre, stereochemistry of compounds with two similar and dissimilar stereogenic centres, properties of stereoisomers. Stereochemistry of alkenes. Stereochemistry of allenes, alkylidene cycloalkane, spirans, biphenyls and fused ring.

4. Racemic modification – properties, methods and resolution.

5. Conformational analysis
Conformation and reactivity in acyclic molecules, Conformation of cyclohexane, monosubstituted cyclohexane, disubstituted cyclohexane, cyclohexene and their relative stabilities. Reactivity of alicyclic, cyclic, fused and bridge ring systems. Curtin Hammett principle in determining the course of reaction in different compounds.

6. Stereospecific and stereoselective synthesis

II Reaction Mechanism (Including stereochemistry):
7. Carbonium ions, carbanions, their generation, stability and fate.

8.Wagner-Meerwein rearrangement and related reactions, pinacol-pinacolone rearrangement, Benzil-benzilic acid rearrangement, Hofmann rearrangement, Curtius rearrangement, Schmidt reaction, Beckmann rearrangement, Lossen rearrangement, Claisen rearrangement, Cumin-hydroperoxide rearrangement, Fries rearrangement, Witting reaction.

RECOMMENDED BOOKS:

1. J. March, 2005, Advanced Organic Chemistry – Reaction, Mechanism and Structure, 4th edition, A Wiley-Interscience Publication, John Wiley & Sons, New York.
2. E.L. Eliel- Stereochemistry of Carbon Compounds, Tata McGraw-Hill Publishing Company Ltd, New Delhi
3. E.L. Eliel and S.H. Wilen, Stereochemistry of Organic Compounds, A Wiley-Interscience Publication, John Wiley & Sons, New York.
4. Thomas Laue and Andreas Plagens(Eds), 2005, Named Organic Reaction, 2nd Ed, John Wiley & Sons Ltd, England.

5. P.S. Kalsi, 2006, Stereochemistry, Conformation and Mechanism, 6th edition, New Age International (P) Limited, Publishers, New Delhi.
6. D. Nasipuri, 2003, Stereochemistry of Organic Compounds – Principles and Applications, 2nd edition, New Age International (P) Limited, Publishers, New Delhi.
7. Laszlo Kurti & Barbara Czako, Strategic application of named reaction in organic synthesis, Elsevier Academic Press.
8. Peter Sykes, 1985, A Guidebook to Mechanism in Organic Chemistry, 6th edition, Longmann Scientific and Technical, Copublished with John Wiley & Sons, Inc, New York.
9. G.R. Stephenson, 1996, Advanced Asymmetric Synthesis, 1st edition, Blackie Academic and Professional, London

Subject code: MPC-S10
Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-III
THEORY: 60 Hours (4 hrs. /week)

1. GENESIS OF NEW DRUGS:
i) A brief review of the following topics: sources of new drugs; leads from natural products; molecular modifications; random screening; high thought put screening; insilico screening; structural features and pharmacological activity; prodrugs; soft drugs; isosterism. selective optimization of side activities (SOSA) approach, , new use for old drugs – An illustrative study with suitable examples
ii) A brief account of drug discovery by recombinant DNA technology.

2. PRINCIPLE OF DRUG DESIGN:
Analogue synthesis versus rational design; discovery of lead compounds, Pharmacophoric identification, Prodrugs and soft drug. Physicochemical properties in relation to drug action; metabolic transformation of drugs and its role in development of new drug molecules.
QSAR in drug design.
a) Physical properties related to potency.
b) Calculation, measurements and significance of various parameter used in QSAR – (Lipophilicity, steric, Electronic effects). c) applications of Hansch Analysis.
Computers in drug design:
Introduction; computer graphics and molecular visualization; computational chemistry overview, force field methods; geometry optimization; conformational searching; molecular dynamics simulations; quantum mechanics; structure based drug design and Pharmacophore perception, predictive ADME.

3. MEDICINAL CHEMISTRY OF
a. Antiviral Agents and agents under development of HIV infection.
b. Immunosuppressant and Immunostimulants.
c. Agents used in Neurodegenerative disease Like Alzheimer's and Parkinsonism.
d. GABAnergic Agonists.
e. Antidiabetic agents like Peroxisome Proliferator Activated Receptors inhibitors, Dipeptidyl Peptidase 4 (DPP 4) Inhibitors like Sitagliptin, Vildagliptin, Protein Tyrosine Phosphatase 1 B (PTP 1 B).
f. Antihypertensives like Direct Renin Inhibitors e.g. Aliskiren

NOTE: "A study of" includes an account of their origin and development, classification, structures, mechanism of action, SAR, uses and toxicity.

4. RECENT ADVANCES IN FOLLOWING CATEGORY:

a. Cephalosporin
b. Anticancer agents.
c. Non-steroidal anti-inflammatory agents
d. Antihypertensive agents

Synthesis of Following Drugs:

a. Cefaclor, Cefotaxim, Cefadroxil, Cephalexin
b. chlorambucil, methotrexate, Trimetrexate, Tamoxifen
c. paracetamol, ibuprofen, aceclofenac, Allopurinol
d. Propranolol, Nifedipine, Fosinopril, Candesartan

5. A STUDY OF:

a) Penicillin
b) Anthihyperlipidemic agents
b) Phosphodiesterase inhibitors
c) Quinolone antibacterial agents

RECOMMENDED BOOKS:

1. E.J. Ariens, 1975, Drug Design, Academic Press New York.
2. S.H. Salkovisky, A.A. Sinkula and S.C. Valvani, Physical Chemical Properties of Drug, Marcel Dekker Inc. New York.
3. M.E. Wolff, Burger's Medical Chemistry, Vol. III, 5th Edition, John Willey and Sons. New York.
4. R.F. Doerge, Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, 9th edition, J. Lippincott Co., Philadelphia.
5. Wilson & Gisvold's Text book of Medicinal Chemistry, 9th edition, J. B. Lippincott.
6. Hansch, Sammes, Taylor, Comprehensive Medicinal Chemistry series I-IV, Academic Press.
7. Ed. Stevenson & Wi, Latest, 1990, Recent advances in chiral separations, Plenum Press.
8. Ed. Fennirl Hicham, 2000, Combinatorial Chemistry, Oxford University
9. D. Sriram, Medicinal Chemistry, 2nd edition, Pearson.

Subject code: MPC-P9
Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-II
Practical: 8 hrs. /week

1. Synthesis from some of the following reactions and their characterization:
   1) Beckmann rearrangement 2) Fries rearrangement 3) Benzil benzilic acid rearrangement
   4) Hofmann rearrangement 5) Pinacol pinacolone rearrangement 6) Methylation
   7) Metal/acid reductions 8) Friedel-Crafts alkylation & Acylation 9) Nitration using different reagents
2. Asymmetric synthesis of some organic/medicinal compounds.
3. Resolution of racemic mixture/modification.
4. Microwave assisted synthesis of any two compounds and their characterization

Subject code: MPC-P10
Subject: ADVANCED PHARMACEUTICAL CHEMISTRY-III
Practical: 8 hrs. /week

1. Practical based on some topics covered in the theory part including synthesis of medicinal compounds basic operations like Molecular distillation, fractional crystallization, and purification by column chromatography and preparative TLC

2. Synthetic studies of following drugs with characterization by chemical test, UV and IR method
Acetyl Salicylic acid using acetyl chloride (2 Steps)
Chloramin –T (3 Steps)
Sulphanilamide (3 Steps)
5,5-Diphenyl Hydantoin
Dimethyl –p-phenylenediamine (3 steps)
Sulfanilic acid
Chalcones

3. Microwave assisted synthesis of organic/medicinal compounds and their characterization

Semester-III

Subject code: MPC-S13
Subject: **ADVANCED PHARMACEUTICAL CHEMISTRY-IV**
THEORY: **60 Hours (4 hrs. /week)**

The following topics will be discussed keeping in view the recent advances:

1. **Psychopharmacological agents:** Biochemical basis of mental disorders; abnormal protein factors; endogenous amines and related substances; faulty energy metabolism; genetic disorders and nutritional disorders; phenothiazines – chemistry; synthesis. Screening methods; pharmacological actions; SAR; mechanism of action; uses; toxicity; ring analogues of phenothiazines; fluorobutyrophenones; Development of atypical antipsychotics cloyepire synthesis of chlorpromazine, prochlorperazine, fluphenazine, haloperidol.

2. **Anxiolytics, sedatives and hypnotics:** Benzodiazepines and related compounds; barbiturates; other classes; mechanism of acition, SAR; uses and toxicity Synthesis of Chlordiazepoxide, diazepam, alprazolam, Phenobarbital, meprobamate.

3. **Antidepressants:** MAO inhibitors; tricylic antidepressants; SAR; mechanism of action; uses; toxicity other classes like: selective serotonin reuptake inhibitors, selective 5-HT and NE reuptake inhibitors; selective serotoninergic reuptake inhibitors and 5-HT_{2A} antagonists; 5-HT_{1A} agonists and partial agonists and α2-antagonists. Synthesis of tranycypromine, amitriptyline, fluoxetine, buspirone.

4. **Antiepileptics & CNS stimulants:**

a) Antiepileptics: Screening methods; classification of epilepsies; symptoms; drugs used; classification; structural features common to drugs; SAR; mechanism of action; toxicity and uses; synthesis of diphenylhydantion, carbamazepine, sodium valproate.

b) CNS stimulants: an account of the drugs with CNS stimulant activity; structures and uses.

5. **Diuretics:** anatomy and physiology of nephron; classification of diuretics based on site of action; carbonic anhydrase inhibitors; thiazide and thiazide like diuretics; loop and potassium sparing diuretics; miscellaneous diuretics emerging developments in the use of diuretics to treat hypertension and congestive heart failure.

6. **Microorganism in drug development**: Microbial conversions of drugs like steroids, prostaglandins and antibiotics. These should include some biotechnology-oriented chapters like enzymes immobilization techniques.

7. **Classification of colors, preservatives and artificial sweetening agents** in food, food product, drugs and cosmetics.detection and determination of colors, preservatives and artificial sweetening agents.

8. **Radiopharmaceuticals,** Detection of radioactivity, instrumentation and measurement, methods of radiolabeling, preparation and quality control of radiopharmaceuticals, isotop dilution methods.Radioimmunoassay of selected drugs and hormones. Application of radiopharmaceuticals.

9. Radioprotective drugs

10. Synthon approach

a. Definition of terms - disconnection, synthon, functional group interconversion (FGI).
b. Basic rules in Disconnection.
c. Use of synthon approach in synthesis of some medicinal/organic compounds

11. Principal of toxicology and treatment of intoxication.

RECOMMENDED BOOKS:

1. Burger's Medicinal Chemistry, Vol. III, 5th, Edition, John Wiley Sons, New York.
2. Wilson and Gisvold's Text Book of Medicinal Chemistry, Lippincott Williams and Wilkins.
3. T.L. Lemke, D.A. Williams, V.F. Roche and S.W. Zfto, Foye's Principles of Medicinal Chemistry, 6th edition, Lippincott Williams and Wilkins.
4. Lednicer, Organic chemistry of synthetic drugs. Vogel's Textbook of practical organic chemistry by Arthur I Vogel, 5th edition, ELBS and Lognman
5. The Organic Chemistry of Drug Synthesis (3 volumes) by Daniel Lednicer & Laster A. Mitscher (John Wiley & Sons).
6. Ashutosh Kar, 2004, Advanced Practical Medicinal Chemistry, 1st edition, New Age International Publication.
7. Abraham Statman (Ed), Progress in chemical toxicology, Vol. I-V, Academic press.

Syllabus prescribed for Degree of Master of Pharmacy in Pharmacology

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MPL-S4
Subject: ADVANCED PHYSIOLOGY AND PATHOPHYSIOLOGY
THEORY: 60 Hours (4 hrs. /week)

1. Membrane Physiology, Nerve and Muscle

Physicochemical properties of cell membrane, permeability & transport. Genesis of resting membrane potential. Action potential. Contraction of skeletal and smooth muscles.

2. Blood

Principles of hemopoiesis. Erythropoiesis. Fate of RBC's. Regulation of WBC production. Functions of WBC. Immune system. Blood groups. Hemostasis and blood coagulation. Pathophysiology of Jaundice and Anemia.

3. **Cardiovascular System**

Properties of cardiac muscle. Action potential and spread of impulse in the heart. ECG. Cardiac cycle. Neural regulation of cardiac activity.Cardiac output: measurement and regulation. Neural control of circulation. Pathophysiology of Hypertension, Arrhythmia, Angina pectoris and Cardiac failure.

4. Respiratory System

Lung volumes and capacities. Mechanics of respiration. Exchange of gases in the lungs. O2 CO2 carriage, dissociation curve. Neural regulation of respiration. Chemical regulation of respiration. Pathophysiology of Pneumonia, Asthma, Hypoxia, Cyanosis and Dyspnoea.

5. **Gastrointestinal System**

General organization of G.I. tract. Motility, Nervous Control and Blood Circulation. Gastric secretion, Biliary and pancreatic secretions. Digestion and Absorption. Pathophysiology of Peptic Ulcer, Constipation and Diarrhea.

6. Endocrine System

Various endocrine glands and their related disorders.

7. Reproduction

Male reproductive physiology. Female reproductive physiology. Hypothalamic – pituitary – gonadal axis. Puberty. Pregnancy. Parturition and lactation.

8. Renal System

Renal hemodynamics and glomerular filtration. Renal tubular function. Regulation of renal function. Micturition. Regulation of Acid-Base balance. Alkalosis and Acidosis.

9. Neurophysiology

i) General

Introduction to neurophysiology. Properties of synaptic transmission. Neurotransmitters

ii) Sensory system

Coding of sensory information. Functional organization of ascending sensory pathways. Thalamus Sensory cortex. Perception of sensory stimuli. Physiology of pain and analgesia system. Pathophysiology of Hyperalgecia, Herpes Zoster and Headache.

iii) Motor system

Characteristics and properties of reflexes. Functional organization of motor system. Brain stem reflexes, stretch reflexes and tendon reflexes. Basal ganglia. Cerebellum. Vestibular neck reflexes: maintenance of equilibrium. Pathophysiology of Parkinsonism and Huntington's Chorea.

iv) Visceral and motivational system

Autonomic nervous system. Hypothalamus. Limbic system and emotions

v) EEG, sleep and higher nervous functions

Electroencephalography. Sleep and wakefulness. Learning and memory. Speech. Pathophysiology of Epilepsy, Dementia, Psychosis Schizophrenia and Alzheimer's disease.

vi) Special Senses

Structure and functions of skin. Central mechanisms of vision and visual perception. Central auditory mechanism and auditory perception. Olfaction. Physiology of taste.

RECOMMENDED BOOKS:

1. Textbook of Medical Physiology by A.C. Guyton, Saundersco. London (2011) 12th edition.
2. Review of Medical Physiology by W.F. Ganong Mc Graw Hill Medical Publishing (2005) 22nd edition.
3. The Physiological Basis of Medical Practice by C.H.Best and N.B.Taylor. The Williams and Wilkins Co. Batlimore (1991) 12th edition .
4. Understanding Medical Physiology by R. L. Bijlani, Jaypee Brothers, New Delhi (2011) 4th edition.
5. Principles of Anatomy and Physiology by G.J.Tortora and B.Derricson. John Wiley & Sons Inc N.J.
6. Robbins Pathologic Basis of Disease by R.S.Cotran, V.Kumar and T.Collins WB Saunders Co (1999) 6th edition.
7. Textbook of Pathology by Harsh Mohan. Jaypee Brothers New Delhi (2005) 5th edition.
8. Textbook of Pathology by B.N.Datta. Jaypee Brothers New Delhi (2004) 2nd edition.

Subject code: MPL-P4
Subject: ADVANCED PHYSIOLOGY AND PATHOPHYSIOLOGY
Practical: 8 hrs. /week

1. Introduction to use of Physiographs in experimental Pharmacology, Demonstration of invasive / non invasive rat blood pressure experiment, ECG, EEG etc
2. Use of anesthetics and cannulation of veins, arteries and trachea of rat. Demonstrations of methods of collection of blood from experimental animals, various methods of euthanasia.
3. Identification of phases of estrous cycle in rats.
4. Study of different tissue section of animals.
5. Use and interpretation of biochemical data viz: (Significance of screening the parameter) Diagnostic prognostic screening tests like (rationale behind performing following tests)
   a) Blood sugar : by O-toludiene, glucose oxidase
   b) Blood protein by Biuret, Lowery's method
   c) Blood urea
   d) Serum uric acid
   e) Urine calcium
   f) Serum cholesterol
   g) Serum bilirubin
   h) Blood creatinine
   i) Blood chlorides
   j) SGPT
   k) SGOT
   l) Urine amylase
   m) LDH
6. Pregnancy test in rats
7. Measurement of Glucose by glucometer
8. Qualitative tests for identification of given protein sample
9. Preparation of plasma (using diff.anti-coagulants), serum
10. Widal test
11. Rheumatoid Arthritis factor test

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MPL-S9
Subject: ADVANCED SYSTEMIC PHARMACOLOGY
THEORY: 60 Hours (4 hrs. /week)

1. Basic Principles of Pharmacology: Mechanisms of drug action, membrane transporters and drug response, adverse drug reactions, and pharmacogenetics.

2. Pharmacology of the Autonomic Nervous System:

Physiology of autonomic nervous system, Muscarinic receptor agonists and antagonists,Anticholinesterase agents, Agents acting at neuromuscular junction and autonomic ganglia,Adrenergic agonists and antagonists, 5-Hydroxytryptamine receptor agonists and antagonists.

3. Pharmacology of Autocoids:

Histamine, bradykinin, and their antagonists, Lipid derived autocoids: Eicosanoids and platelet activating factor.

4. Drugs Acting on the Central Nervous System:

Neurotransmission in central nervous system,General anesthetics, Local anesthetics, Hypnotics and sedatives, Opioid analgesics, Pharmacology of ethanol, Drug addiction and drug abuse.

5. Analgesic, Antipyretic, and Anti-inflammatory Agents

6. Drugs Affecting Renal and Cardiovascular Function:

Diuretics, Vasopressin and other agents affecting the renal conservation of water, Renin, angiotensin, and their modulators, Calcium channel blockers.

7. Immunosuppressants and Immunostimulants

8. Hormones and Their Antagonists:

Pituitary hormones and their hypothalamic releasing factors, Thyroid and antithyroid drugs, Estrogens and progestins, Androgens, Adrenocortical steroids and their synthetic analogs, inhibitors of synthesis and actions of adrenocortical hormones, Agents affecting mineral ion homeostasis and bone turnover.

9. Drugs Acting on the Blood and Blood-Forming Organs:

Hematopoietic agents: Growth factors, minerals, and vitamins, Blood coagulation and anticoagulant, thrombolytic, and antiplatelet drugs.

10. Pharmacology of Dermatological Agents

11. Ocular Pharmacology

RECOMMENDED BOOKS:

1. Goodman and Gilman, Pharmacological Basis of Therapeutics, Mc Graw Hill (2006) 11th edition.

2. Craig C R and Stitzel B E, Modern Pharmacology with Clinical Application, Lippincott Williams & Wilkins (2004) 6th edition.

3. Katzung B G, Basic and Clinical Pharmacology, Lange Medical Publisher, USA (2009) 11th edition.

4. Melmon K L and Morelli, Clinical Pharmacology: Basic Principles of Therapeutics, Mc Millan, New York (2000) 4th edition.

5. Harrisons Principles of Internal Medicine, McGraw Hill 18th edition.

6. Davidson's Principles and Practice of Medicine, Vol I and II, Churchill Livingston 14th edition.

7. Rang H P, Dale M N, Pharmacology, Churchill Livingston, UK (2011) 7th edition.

8. Roger and Walkar, Clinical Pharmacy and Therapeutics, Churchill Livingstone, London (2007) 4th edition.

9. Patten J, Neurological Differential Diagnosis, Springer-Verlag London (2005) 2nd edition.

10. Koda-Kimble, Hand book of Applied Therapeutics Lippincott Williams & Wilkins (2007) 8th edition

11. Herfidal E T and Hirschman J L, Clinical Pharmacy and Therapeutics Williams and Wilkins (1984) 3rd edition.

12. Review articles and Research articles from Medical and Pharmacological Journals

Subject code: MPL-S10
Subject: ADVANCED PHARMACOLOGY AND PHARMACOTHERAPEUTICS
THEORY: 60 Hours (4 hrs. /week)

1. Basic Principles of Clinical Pharmacology:

Monitoring of drug therapy, patient compliance, principles of pediatric and geriatric pharmacology, drug therapy in pregnant and lactating mothers.

2. Drug Therapy of Cardiovascular Disorders:

Pathophysiology and drug therapy of congestive cardiac failure, hypertension, cardiac arrhythmias, ischemic heart disease, hyperlipidemia, and atherosclerosis.

3. Drug Therapy of Neurological Disorders:

Pathophysiology and drug therapy of epilepsy, Parkinson's disease, migraine, and myasthenia gravis.

4. Drug Therapy of Psychiatric Disorders:

Pathophysiology and drug therapy of anxiety, schizophrenia, Alzheimer's disease, mood and sleep disorders, and memory.

5. Drug Therapy of Endocrine Disorders:

Pathophysiology and drug therapy of diabetes mellitus, contraception, and infertility.

6. Drug Therapy of Inflammatory Disorders:

Biology of inflammation, pathophysiology and drug therapy of osteoarthritis, rheumatoid arthritis, and gout.

7. Drug Therapy of Respiratory Diseases:

Pathophysiology and drug therapy of asthma.

8. Drug Therapy of Gastrointestinal Diseases:

Pathophysiology and drug therapy of peptic ulcers, emesis, irritable bowel syndrome, and inflammatory bowel disease.

9. Drug Therapy of Metabolic and Sexual Disorders:

Pathophysiology and drug therapy of obesity and erectile dysfunction.

10. Pharmacology of Chemotherapeutic and Antimicrobial Agents:

General considerations of antimicrobial therapy, Sulfonamides, trimethoprin, quinolones, other related agents, Penicillins, cephalosporins, and other beta-lactam antibiotics, Aminoglycosides, Protein synthesis inhibitors and miscellaneous antibacterial agents, Antifungal agents, Antiviral agents (Non-retroviral).

11. Pathophysiology of cancer and Antineoplastic Agents

12. Drug Therapy of Infectious Diseases:

Pathophysiology and drug therapy of tuberculosis, leprosy, HIV and related opportunistic infections, malaria, amoebiasis, and helminth infections.

RECOMMENDED BOOKS:

1. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London (2007) 4th edition.

2. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, McGraw Hill Companies (2011) 8th edition.

3. Russell J. Greene and Norman D. Harris, Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Pharmaceutical Press (2008) 3rd edition.

4. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics, Williams & Wilkins (1984) 3rd edition.

5. Koda and Kimble, Hand book of Applied Therapeutics: The Clinical Uses of Drugs, Lippincott Williams & Wilkins (2007) 8th edition.

6. Relevant Reviews Articles from Medical and Pharmaceutical Literature

7. Davidson's Principles of Internal Medicine, Vol-I And II, 14th Edition, Mc GrawHill

8. Harrison's Principle And Practice Of Medicine, 18th Edition, Churchill, Livingston, London

9. Chaudhari, Quintessence of Medical Pharmacology; Central Publishers, New Delhi

10. Kundu, A.K.; Bedside Clinics in Medicine, Academic Publishers, Part-I and II

11. Oxford Textbook of Medicine, Oxford University Press (2005), 4th edition.

12. Panda, U.N., Textbook of Medicine, CBS publisher, New Delhi (2000).

13. Patten, J; Neurological Differential Diagnosis, 2nd Edition

Subject code: MPL-P9
Subject: ADVANCED SYSTEMIC PHARMACOLOGY
Practical: 8 hrs. /week

1. Bioassays:

a) Estimation of potency of test substance by three point and four point bioassay method using different isolated tissues.

b) To determine the PA2 value using different isolated tissues.

2. In-vivo experiments:

a) To study antisecretory and ulcer protective effect of Cimetidine in pylorus ligated rats.

b) To study Diuretic effect of any one marketed preparation in rats.

3. Clinical:

In this module, it is expected a student should collect data from field targeted as disease oriented, drug use oriented, adverse events oriented, biochemical oriented etc and compile it with conclusive output.

4. Statistical:

a) Statistical evaluation of data and finding level of significance.

b) Hand on experience on online, offline, open source statistical software's.

5. Demonstration:

To demonstrate different experiments using simulated computer softwares.

Subject code: MPL-P10
Subject: ADVANCED PHARMACOLOGY AND PHARMACOTHERAPEUTICS
Practical: 8 hrs. /week

1. Prerequisite for Pharmacology Practicals:

In this module it is expected student should know general principles, techniques and strategies for pharmacological screening of drugs, animal care, handling, ethical requirements and regulations therein.

2. Basic Experimental Techniques:

1. Standard techniques collection of blood samples and feeding of animals
2. Administration of drugs by different routes in mice
3. Use of anaesthetics and cannulation of veins, arteries, trachea

3. Experiments on intact animals:

1. To study locomotor activity by using Actophotometer.
2. To evaluate analgesic activity of drug using tail flick latency test.
3. To determine the effect of carrageen induced edema in rats by using digital Plethysmometer.
4. To study the anticonvulsant effect of Phenobarbitone against MES induced convulsions in rats.
5. To determine the analgesic effect by using Eddy's hot plate.
6. To study effect of pentabarbitone sodium on righting reflex (hypnosis) in mice.
7. To study Anti-anxiety effect of diazepam in mice using elevated plus maze apparatus.
8. To study the Apomorphine induced compulsive behaviour (Stereotype) in mice.
9. To study the muscle relaxant property of Diazepam in mice using rotarod.
10. To study amnesic (loss of memory) effect of drug using passive avoidance step-down task paradigm in mice.
11. To study the antidepressant effect of drug using forced swimming test apparatus.

4. Toxicity Studies:

1. Regulations and guidelines of toxicity studies
2. Method of calculation of ED50 and LD50
3. Observation of behavioral changes in animals during acute and sub acute toxicity study of test drug.

5. Practicals using computer software's :

In this module it is expected student should know working of software and setting of physiologic and animal experimentation and perform at least four experiments from following or others-

1. To record temperature using thermal transducer

2. To measure blood pressure using Blood pressure transducer

3. To measure drug response curve using isotonic transducer

4. Measurement of isometric contraction using force displacement transducer.

5. To measure a change in volume using volume transducer

6. To measure a respiration using a respiratory transducer

7. To study various transducers and couplers

8. To study ECG using ECG coupler with BioPac

9. To measure vital capacity, forced expiratory volume etc., using isotonic transducer and Spirometer.

Semester-III

Subject code: MPL-S13
Subject: MOLECULAR PHARMACOLOGY AND TOXICOLOGY
THEORY: 60 Hours (4 hrs. /week)

1. Molecular mechanism of drug action: Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and phosphatidyl inositol. Ionic channels and their modulators.

2. Endogenous bioactive molecules such as cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiestrase enzyme and protein kinase C, arachidonic acid metabolites.

3. Recent trends on different classes of receptors and drugs acting on them

Angiotensin receptors, Excitatory amino acid receptors, Kinin receptors, Adrenoceptors, Low molecular weight heparins, Imidazole receptors, Cholinergic receptors, Dopamine receptors, Serotonin receptors, Hormone receptors, GABA receptors, Purinergic receptors, Glutamate receptors.

4. Ion channel and their modulators: calcium, potassium, sodium and chloride channels

5. Basic Concepts of Chronopharmacology and their implications to Drug Therapy. .

6. Concept of gene therapy and recent development in the treatment of various hereditary diseases. Transgenic mouse and its applications. Human genome mapping and its potential in drug research.

7. Toxicology: Principles of toxicology, elementary knowledged of systemic toxicology, manifestation of toxicology, Management and treatment of poisoning, immunotoxicity, toxic effect on genetic material and cell proliferation, non therapeutic toxicants, air pollutants, solvents, vapour and pesticides toxicity, food additives and contaminant toxicity, heavy metal toxicity, toxins of animal origin, radiations and radioactive material toxicity, adverse drug reactions, toxicity of drug overdosing and its management.

RECOMMENDED BOOKS:

1. Katzung, B.G; Basic and Clinical Pharmacology, Lange Medical Publisher, USA (2009) 11th edition.
2. Paul W. E. ed. Fundamental immunology, Lippincott-raven, Philadelpia 1999, 4 th edition.
3. Bowman, W.C. and Rand, M.J.; Textbook of Pharmacology, Blackwell, Oxford 2nd edition.

4. Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, Lippincott Williams & Wilkins (2004) 6th edition.
5. Bacq Z.M., Cepek, Fundamentals of Biochemical Pharmacology Pergamon Press.
6. Goodman and Gilman; Pharmacological Basis of Therapeutics, Mc Graw Hill (2006) 11th edition.
7. Rang, H.P., Dale, M.N., Pharmacology, Churchill Livingston, UK (2011) 7th edition.
8. Casarett and Doull's Toxicology: The basic science of poisons 6th edition McGra Hill, Newyork, 2001
9. Ellenhorn's Medical toxicology 2nd Edition Williums and Wilkins, Baltimore, 1997.
10. Haddad, L. M. and Winchester, J. F. eds Saunders, Philadelphia, 1983
11. Frank A. Barile, Clinical toxicology principle and mechanism. CRC press, London
12. Recent review articles in different international journals of repute.

Syllabus Prescribed for Degree of Master of Pharmacy in Pharmacognosy

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MPG-S4
Subject: ADVANCED PHARMACOGNOSY AND PHYTOCHEMISTRY
THEORY: 60 Hours (4 hrs. /week)

1. **Neutraceuticals:** Introduction, probiotics & Prebiotics, Study of some plant constituents and their products in international market, study of lycopene, proanthocyanidin and grape products, ornthine, flax seed and flax oil, melatonin and ornithine.
2. **Study of herbal extracts:** General methods for the extraction of herbal drugs, processing and analytical profile, stability, preservation and evaluation of extracts. Effect of solvent, solvent mixtures and solution on extraction.
3. **Extraction, isolation, purification and estimation of following phytoconstituents:**
   Alkaloids : Caffeine, Atropine, Berberine, Piperine
   Glycosides : Sennosides, Digoxin
   Flavonoids : Rutin, Hesperidin
   Terpenoids : Taxol, Andrographolide
   Saponins : Diosgenin, Glycyrrhizin
5. **General aspects of cultivation and collection:** Good agricultural practices in cultivation and collection. Plant growth regulators. Weeds and pest control techniques.
6. **Drug discovery from Natural Products.**
7. **Ethnobotany in Herbal Drug Evaluation.**
8. **Adverse reactions and safety in herbal medicine**

RECOMMENDED BOOKS:

1. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons Limited, New Delhi.
2. Advances in Natural Product Chemistry, extraction and isolation of biologically active compounds. S. Natori et al., Wiley, New York.
3. Phytochemical methods by J.B. Harborne, Chapman and Hall, International Ed., London.
4. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.
5. G.E. Trease and W.C. Evans., Pharmacognosy, W.B. Saunders Co. Ltd., Harcourt Publishers Ltd. UK.

6. Chaudhari R.D., Herbal Drug Industry, Eastern Publication.
7. Quality Control Methods for medicinal plant material, WHO Geneva.
8. Wagner H, Bladt S, 1996. Plant Drug Analysis- A Thin Layer Chromatography Atlas, 2nd Ed., Springer-Verlag, Berlin.
9. Stahl Egon, Thin layer chromatography, 2nd Edition, Springer Publication.
10. Mukherjee PK, 2003. GMP for Indian system of medicine. In GMP for Botanicals. Verpoorte R, Mukherjee PK (Edn.), Business Horizons Limited, New Delhi.
11. Herbal Drug technology by SS Agrawal and M Paridhavi, Orient Longman
12. Indian Herbal Pharmacopoeia, Vol. I- II, SS Handa, RRL Jammu Tawi, and IDMA Mumbai.
13. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
14. Standardization of Botanicals by V. Rajpal, Vol. I and Vol II, Eastern Publishers, New Delhi.
15. Practical Evaluation of Phytopharmaceuticals by K.R. Brain and T.D. Turner, Wright-Scientechnica, Bristol.
16. Houghton P, Mukherjee PK. Evaluation of Herbal Medicinal Product, Pharmaceutical Press, London, 2009.
17. British pharmacopoeia, 2008. The department of Health, Vol I- IV, British Pharmacopoeia Commission, London.
18. Neutraceuticals by Lisa Rapport and Brain Lockwood.

Subject code: MPG-P4
Subject: ADVANCED PHARMACOGNOSY AND PHYTOCHEMISTRY
Practical: 8 hrs. /week

1. Extraction of active principles i.e. alkaloids, glycosides, resins, essential oils, terpenoids, fixed oils, carbohydrates, fats, tannins, steroids, pectins, etc. from natural drugs.
2. Preliminary phytochemical screening of the plant extracts.
3. Extraction, isolation, purification and identification of important phytoconstituents as follows:
    a. Sennosides from Senna leaves
    b. Curcumin from Turmeric
    c. Glycyrrhizin from Liquorice
    d. Hesperidin from Orange peels
    e. Caffeine from Tea
    f. Rutin from *Ruta graveolens*
    g. Aloin from Aloes
    h. Piperine from Pepper
    i. Quinine from cinchona bark
    j. Berberine from *Berberis aristata*
    k. Diosgenin from *Dioscorea*
4. Evaluation of crude drugs by different WHO Standards.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MPG-S9
Subject: STANDARDIZATION OF NATURAL PRODUCTS
THEORY: 60 Hours (4 hrs. /week)

1. Introduction: Need of standardization, limitations of herbal medicines, current regulation of standardization of natural products, their quality, safety and efficacy assessment.
2. Application of various chromatographic techniques i.e. Paper chromatography, TLC, HPTLC, HPLC, GLC, GC-MS for the standardization of plant extracts.
3. Application of UV, FTIR, NMR (^{1}H- and ^{13}C-NMR) and Mass spectroscopy for structural elucidation of flavonoids (Rutin, Hesperidin, Kaempferol), Terpenoids (Camphor, Menthol, Eugenol, Citral) and phytosterols (B-sitosterol, stigmasterol).
4. WHO guidelines for the quality control of herbal plant materials.

RECOMMENDED BOOKS:

1. Quality Standards of Indian Medicinal Plants Vol. I- V, Indian Council of Medical Research, New Delhi.
2. WHO guide lines for the quality control of Herbal plant materials.
3. Phytochemical methods by J.B. Harborne, Chapman and Hall, International Ed., London.
4. The essential oils by E. Guenther, Vol. I- IV, Van Nostrand Co.
5. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.
6. Biological Standardization by JN Barn, DJ Finley and LG Goodwin.
7. Standardization of Botanicals by V. Rajpal, Vol. I and Vol II, Eastern Publishers, New Delhi.
8. Practical Evaluation of Phytopharmaceuticals by K.R. Brain and T.D. Turner, Wright-Scientechnica, Bristol.
9. PDR for Herbal Medicines, Second Ed., Medicinal Economics Company, New Jersey.
10. Textbook of Industrial Pharmacognosy by AN Kalia, CBS publishers and Distributors, New Delhi.
11. Mohd. Ali (2001). Techniques in Terpenoid Identification. Birla Publications, Shahdara, Delhi.
12. Advances in Natural Product Chemistry, extraction and isolation of biologically active compounds. S. Natori et al., Wiley, New York.
13. Official Methods of Analysis, Association of Official Analytical Chemists Publication, Washington, New York.

Subject code: MPG-S10
Subject: HERBAL DRUG FORMULATION AND DEVELOPMENT
THEORY: 60 Hours (4 hrs./ week)

1. Herbal based Industry: Scope, study of infrastructure, staff requirement, project profiles, plant and equipment, processing, research and development, regulatory requirement. Pilot plant scale up techniques.
2. Principles of Ayurvedic systems of medicine. Introduction to different dosage forms, Preparation and evaluation methods of Ayurvedic medicines i.e. Asavas and Aristas, Arkas, Avalehas, Churnas, Ghritas and Tailas, Guggulu preparations, Ksara, Lauha kalpas, Lepas, Vatika and Bhasmas.
3. Standardization of polyherbal formulations: syrups, powders, ointments and other semisolid preparations, tablets and capsules.
4. Evaluation aspects of Herbal products containing Ashwagandha, Kalmegh, Shatavari, Phyllanthus, Guduchi and Shilajeet by study of HPTLC and HPLC fingerprints.
5. WHO and Indian regulatory requirements of Clinical trials for herbal formulations.
6. Determination of shelf life of raw drugs, powdered drugs, extracts, fractions and finished products. Factors affecting stability of herbal formulations, ICH and other guidelines, methods of stabilization and stability testing.

RECOMMENDED BOOKS:

1. Kalia AN, Textbook of Industrial Pharmacognosy, CBS publishers and Distributors.
2. Pharmacopoeial Standards for Ayurvedic formulations – CCRAS, Delhi.
3. Good manufacturing practices for pharmaceuticals, SH Willing, Vol. 78, Marcel Dekker, NY. New drug approval process, RA Guarino, Vol 100, Marcel Dekker, NY.
4. Standardization of Botanicals by V. Rajpal, Vol. I and Vol II, Eastern Publishers, New Delhi.
5. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons Limited, New Delhi.
6. Ayurvedic formulary of India, Government of India, Ministry of Health and Family Welfare.
7. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
8. Indian Pharmacopoeia, 2010. Government of India, Ministry of Health and Family Welfare, Vol. I III, The Indian Pharmacopoeia Commission, Ghaziabad.
9. United States Pharmacopoeia, 2009. The Official Compendia of Standards, Vol. 1-3, the United States Pharmacopoeial Convention, Rockville.
10. Indian Herbal Pharmacopoeia, 1999. Vol I- II, Council of Scientific and Industrial Research, Jammu-Tawi, New Delhi.

Subject code: MPG-P9
Subject: STANDARDIZATION OF NATURAL PRODUCTS
Practical: 8 hrs. /week

1. Determination of Anthracene derivatives in senna by spectrophotometric method, Reserpine in Rauwolfia, Carvone content of Caraway fruits, Citral content in Lemon oil.
2. Determination of ascorbic acid by UV spectroscopic method in some crude drugs.
3. Paper chromatography and TLC of active principles of natural products.
4. Study of UV and FTIR spectral data of some marker compounds.
5. Separation of Solanaceous alkaloids from Belladona leaves by TLC using hyoscine and hyoscyamine as reference compounds.
6. Quantitative estimation of Ephedrine in Ephedra extracts by HPTLC method (demonstration only).
7. Quantitative estimation of Reserpine in Rauwolfia extracts by HPLC method (demonstration only).
8. Study of HPTLC and HPLC fingerprinting of some important phytoconstituents (demonstration only).

Subject code: MPG-P10
Subject: HERBAL DRUG FORMULATION AND DEVELOPMENT
Practical: 8 Hours / week

1. Formulation and evaluation of different polyherbal formulations.
2. Stress induced stability evaluation of different polyherbal formulations.
3. Quantitation of some therapeutically important phytoconstituents from herbal drug formulations by HPTLC.
4. Identification of some phytoconstituents from herbal drug formulations by TLC.
5. Evaluation of some marketed Ayurvedic formulations like Asavas and Aristas, Avalehas, Churnas, Ghritas and Vatika.
6. Evaluation of Antimicrobial activity of some important polyherbal formulations.

Semester-III

Subject code: MPG-S13
Subject: Selected Topics in Pharmacognosy
THEORY: 60 Hours (4 hrs. /week)

1. Problems and Prospects of discovering new drugs from higher plants. Natural products: its impact on industry and medicine.
2. Phytosomes
3. Anticancer and Psychosomatic drugs of plant origin
4. Marine drugs of medicinal importance.
5. Antimicrobials from higher plants.
6. Pharmacological screening methods of natural products for their a. Hepatoprotective; b. antidiabetics; c. antioxidants; d. analgesic and anti-inflammatory; e. Antihyperlipidemic; f. antimicrobials; antiepileptics activities.
7. Bioassay Guided Isolation, Separation and Structural Characterization
8. Recent advances in alkaloids: Chemistry, isolation, purification, identification and estimation by physical and chemical methods of following alkaloids: Atropine, Ephedrine, Reserpine, Ergometrine, Vinblastine, Quinine.
9. Recent advances in glycosides: Chemistry, isolation, purification, identification and estimation by physical and chemical methods of following glycosides: Rutin, Glycyrrhizin, Picrosides, Kutkosides, Diosgenin, Hesperidin.
10. Recent advances in terpenoids: Chemistry, isolation, purification, identification and estimation by physical and chemical methods of following terpenoids: Menthol, Carvone, Citral, Eugenol and Cineol.

RECOMMENDED BOOKS:

1. New natural Products and Plant Drugs with Pharmacological, Biological and Therapeutic Activity, Proceeding of the First International Congress on Medicinal Plant Research, Ed. Wagner and Wolff, Springer – Verlag, 1977.
2. Miller- Reinhold, Phytochemistry, Vol. I – III, Van Nostrand Reinhold Co., New York
3. Recent advances in Phytochemistry, Vol. 9 by V.C. Runeckles, Plenum Press.
4. Plants used against cancer by S.L. Hartwell Lioydia, 1967, 1968 and 1970.
5. Marine Pharmacognosy by DF Martin and GM Padilla, Academic Press.
6. The technology and chemistry of alkaloids by Frank E. Hamersiag, 1950, D. Van Nostrand Co.
7. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.
8. Agrawal OP, Chemistry of Organic Natural Product, Goel Publication House, UP.
9. Pridham JB, Swain T, Biosynthetic pathway in higher plants, Academic Press, New York.
10. G.E. Trease and W.C. Evans., Pharmacognosy, W.B. Saunders Co. Ltd., Harcourt Publishers Ltd. UK.
11. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons Limited, New Delhi.
12. Phytochemical methods by J.B. Harborne, Chapman and Hall, International Ed., London.
13. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.
14. Herbal Drug technology by SS Agrawal and M Paridhavi, Orient Longman.

Syllabus Prescribed for Degree of Master of Pharmacy in Biotechnology

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MBT-S4
Subject: FUNDAMENTALS OF BIOTECHNOLOGY
THEORY: 60 Hours (4 hrs /week)

1. **Microbial biotechnology:** Bacteria, actinomycetes, fungi, algae and viruses: structure, chemistry, morphology, nomenclature, general classification, molecular & genotypic taxonomy, cultural, physiological and reproductive features, methods of isolation, cultivation, and maintenance of pure cultures. Industrially important microorganisms: examples and applications.
2. **Microbial pathology:** identifying features of pathogenic bacteria, fungi and viruses, mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections.
3. **Cellular Biology:** Cell structure & function: cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Intracellular vesicular traffic, cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology- the life and death of cells in tissues.
4. **Cell Cycle and Cytoskeleton:** Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments. Microtubules, Functional Role and Therapeutic Potential of Cytoskeleton.
5. **Apoptosis and Oncogenes:** Programmed Cell Death, Tumor cells, Proto-oncogenes, oncogenic mutations, cell cycle & controls, carcinogens & repair.
6. **Differentiation and Developmental Biology:** Fertilization, Events of Fertilization, In Vitro Fertilization, Embryonic Germ Cells, Stem Cells and its Application.

RECOMMENDED BOOKS:

1. MJ Pelczar, Jr. ECS Chain, NK Kreig, 2008. Microbiology, McGraw Hill Edition, New York.
2. Modern Biotechnology by SB Primrose, 1987. Blackwell Science Inc.
3. Eukaryotic Gene Regulation by David Lachman, 2005. Taylor & Francis; 1st edition.
4. Microbial genetics by David Friefelder by David Freifelder, John E Cronan, Stanley R Maloy. 2nd edition.

5. Joe Sambrooke, 2001. Molecular cloning: A laboratory Manual. 3rd Edition, Vol. I, Cold Spring Harbor Laboratory Press.
6. LE Casida, 1968. Industrial Microbiology. The University of Michigan, Wiley.
7. Hugo and Russel, Pharmaceutical Microbiology, Blackwell Scientific Publication, Oxford.
8. Biotechnology the biological principles by M. D. Trevan, S. Bofley.

Subject code: MBT-S4
Subject: FUNDAMENTALS OF BIOTECHNOLOGY
Practical: (8 hrs /week)

1. Basic Laboratory Procedure – Instrument Introduction and Handling, Maintenance, Aseptic condition maintenance, Sterilization, Microscopy, etc.
2. Basic Microbiology Practicals: Preparations of various important media, Culturing and harvesting of microbes. Staining and identification. Maintenance.
3. To study several kinds of bacteria, yeast, moulds, actiomycets, fungi etc. by morphological and cultural techniques. Counting of micro-organisms. Total and Hable count (air, water, soil etc.).
4. Isolation of a pure culture from different samples and its identification in the Laboratory.
5. Effects of temperature on the growth of micro-organisms. To find out the normal death rate of different micro-organisms.
6. To find out the drug resistance in bacteria by testing the sensitivity of bacteria to antimicrobial agents, using filter paper discs.
7. Evaluation of potency of antibiotics by different methods.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MBT-S9
Subject: MOLECULAR BIOLOGY
THEORY: 60 Hours (4 hrs/ week)

1. **Recombinant DNA Technology:** DNA structure and functions, restriction endonucleases, plasmid cloning, methods of creating and screening gene library, cloning DNA sequences that encode eukaryotic proteins, vectors for cloning large pieces of DNA, genetic transformation, and selection of prokaryotes.
2. **Molecular Diagnostics:** DNA diagnostic systems, hybridization probes, diagnosis of malaria, fluorescent in situ hybridization procedure, molecular diagnosis of genetic diseases – PCR/OLA procedures, ligase chain reaction (LCR),
3. **Monoclonal Antibodies:** Scope and limitation of monoclonal antibodies, formation and selection of hybrid cells, identification of specific antibody producing hybrid cell lines. Applications of monoclonal antibodies in clinical, treatment, and biomedical research. Monoclonal antibodies as therapeutic agents, preventing rejection of transplanted organs, treatment of bacterial blood infections. Chemically linked monoclonal antibodies, human monoclonal antibodies, and hybrid human-mouse monoclonal antibodies.
4. **Biopharmaceuticals:** Basic principles of development of protein pharmaceuticals with special reference to human insulin, human interferons, human growth hormone, erythropoietin, variants of t-PA, immunoadhesions, and chimeric proteins.

RECOMMENDED BOOKS:

1. PI Good, A Managers Guide to Design and Conduct of Clinical trials, Wiley-Liss, Hobokem, USA, 2002.
2. BR Glick and JJ Paternak, Molecular Biotechnology: Principles and Applications of DNA Recombinant Technology. ASM Press, Washington, USA, 1994.
3. MJ Pelczar, Jr. ECS Chain, NK Kreig, 2008. Microbiology, McGraw Hill Edition, New York.
4. LE Casida, 1968. Industrial Microbiology. The University of Michigan, Wiley.
5. Prescott and Dunn's Industrial Microbiology, 1981. Gerald reed 9Ed), Chapman & Hall; 4 Sub edition.
6. Hugo and Russel, Pharmaceutical Microbiology, Blackwell Scientific Publication, Oxford.

Subject code: MBT-S10
Subject: FERMENTATION TECHNOLOGY
THEORY: 60 Hours (4 hrs. /week)

1. **Production and Analysis of different products from microorganisms by fermentation technology**: Production of culture. Production and mechanisms of ethanol fermentation. Production of alcoholic beverages, wines, alcohols, beers, brandies, rum etc.
2. **Glycerol fermentation**: Organic acids-citric, lactic, gallic, fumaric, gibberillic etc. Antibiotics-chloramphenicol, novobiocin, griseofulvin, erythromycin and other commonly used therapeutic agents.
   An outline of production of solvents and amino acids like alanine, methionine as well as fermented Ayurvedic preparations, Biofertilizers, Biogas.
3. **Isolation and Purification of Fermentation Products**: Theory, Equipment, Design, operation and application of filtration, Solvent extraction, counter-current-distribution, Adsorption and crystallization. Turbidity and cell yield determination.
4. **Production of Vaccine and Sera**: Study of Enzymes-chemistry, structure, function, requirements, mechanism of action, regulation, synthetic and artificial enzymes, Use of enzymes in biotechnology and engineered alteration of enzyme activity, specificity and stability. Mechanisms based in activation of enzymes, active site directed reagents and transition state analogues in relation to enzyme and drug development, selected aspects of immobilization of enzymes and cells, kinetics of free enzyme and immobilized enzyme and cells. Site directed mutagenesis, protein engineering and synthetic enzymes.

RECOMMENDED BOOKS:

1. Prescott and Dunn's Industrial Microbiology, 1981. Gerald reed 9Ed), Chapman & Hall; 4 Sub edition.
2. Peppier and Perlman, Microbial Technology, Vols. I - II, Academic Press.
3. EA Rawlins Bentley's Text Book of Pharmaceutics. Bailliere, Tindall & Cox, All India Travellers Booksellers Publishers & Distributors.
4. SJ Carter, Cooper Gunn's Dispensing for Pharmaceutical Students, CBS Publishers, Delhi.
5. Scragg, Biotechnology for Engineers: Biological System in Technological Processes, Ellis Horwood Ltd.
6. Trevan and Others, Biotechnology, The Biological Principles, Tata McGraw Hill Publishing Co.
7. Wang, Coonney, Domain, Fermentation and Enzyme Technology, John Wiley & Sons.
8. Angold & Others, Food Microbiology, Cambridge.
9. Juan A Asenjo, 1990. Separation Processes in Biotechnology, Marcel Dekker Inc.

Subject code: MBT-P9
Subject: MOLECULAR BIOLOGY
Practical: (8 hrs. /week)

1. Isolation of human DNA.
2. Quality assessment DNA by spectrophotometer and gel electrophoresis
3. Restriction digestion of DNA
4. Separation of DNA fragments by gel electrophoresis
5. Staining of DNA bands with ETH-Br, DNA visualization.
6. Isolation of RNA from microbial sources and estimation.

Subject code: MBT-P10
Subject: FERMENTATION TECHNOLOGY
Practical: (8 hrs /week)

1. Preparation of some biochemical products in laboratory using fermentation technology: (a) Preparation of bacterial yeast, (b) Preparation of citric acid, (c) Preparation of alcohol, (d) Preparation of antibiotics.
2. Biological assays of various fermented products.
3. Chemical analysis of various fermented products.
4. Tests for sterility of various products.
5. Standardisation of vaccine and sera.
6. Standardisation of antisera using animals.
7. Demonstration of Ab by (1) Precipitation test, (2) Immuno diffusion test, (3) Immunelectrophoresis.
8. Phagocytosis staining after engulfment of Ab coated SRBC.

Semester-III

Subject code: MBT-S13
Subject: ADVANCED TISSUE AND CELL CULTURE TECHNIQUES
THEORY: 60 Hours (4 hrs. /week)

1. **Principles of tissue and cell culture for both animal and plant**: Tissue culture techniques, isolation of tissues, nutrient media culture techniques, histological, histochemical and biochemical techniques. Cell suspensions, Culture media plating of cell suspension. Cytology of culture cells. Single cell clones, organogenesis, embryogenesis and cyto differentiation. Tumor cells. Protoplast culture.
2. **A review with useful recent advances of plant growth:** Troposm, photomorphogenesis, photoperiodism and plant growth regulations, Biosynthesis, chemical properties, distributions, classification and function (s) of : Glycosides, alkaloids, terpenoids, steroids, production of secondary metobolites, culture systems, selection of nutritional factors and other physical parameters for optimal products on applications of plant cell tissue culture : Agriculture crops, forest trees, ornamental plants, medicinal plants.
3. **Short outline of special techniques in animal cell tissue culture**: Aminocentesis, Enucleation, in-vitro mutagenesis, carcinogenesis, cryplotoxicity, cell fusion of hydridoma technique, actions of hormone on cell and organ cultures etc.
4. **Gene Transfer in Plants:** a. (i) Using vectors of Agarobacterium, (ii) DNA Mediated gene transfer–Electroporation, Microprojectile, Macro & Microinjection, Liposomes, Ultrasonication & Chemical mediated gene transfer. b. Localization of transferred gene in genetically modified plants: i. Nucleic acid Hybridization, ii. Use of Radioisotopes & Molecular Markers (Auto Radiography and Electrophoresis).
5. **Applications of Transgenic Plants:** a. Resistance of herbicide, b. Resistance to insect, fungus & virus, c. Resistance to Physiological stress, d. Production of Phytopharmaceuticals, e. Edible vaccine.

RECOMMENDED BOOKS:

1. Trevan and Others, Biotechnology, The Biological Principles, Tata McGraw Hill Publishing Co.
2. Wilman, Cells and Tissues in Cultures, Vol. 3, Academic Press.
3. Evans WC (2002) Trease & Evans' Pharmacognosy, W.B. Saunders & Co., London.
4. Pharmaceutical biotechnology S.P. Vyas and V.K. Dixit, CBS Publishers and Distributors, 2001.
5. Advanced methods in plant breeding & biotechnology by David R. Murray. CAB International Panima book distributors.1991.
6. Plant tissue culture by Dixon IRL Press Oxford Washington DC, 1985.
7. Plant Chromosome analysis, manipulation and engineering by Arun And Archana Sharma 1st Edition Harwood Academic Publishers 1999.
8. Comprehensive Biotechnology by Murray Moo-Young Vol I- IV Pergamon Press LTD, 1985.
9. Transgenic Plants by R Ranjan Agrobotanica.1999.

Syllabus Prescribed for Degree of Master of Pharmacy in Quality Assurance

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MQA-S4
Subject: PHARMACEUTICAL VALIDATION

THEORY: **60 Hours (4 hrs. /week)**

1. **Introduction:** Introduction to Pharmaceutical validation, the validation committee, validation protocol and report, pre- approval inspection, pilot plant scale up and technical transfer, stages of validation.
2. **Equipment validation:** Installation and validation of typical equipments such as dry powder mixers, fluid bed and tray dryers, tablet compression machine, capsule filling machine, autoclaves.
3. **Analytical method validation:** General principles of analytical method validation, sampling and sample handling, validation of analytical instruments i.e. UV / VIS spectrophotometers, HPLC, dissolution test apparatus.
4. **Process validation:** Regulatory basis for process validation, prospective process validation and retrospective validation. Manufacturing and process validation of sterile and non-sterile products i.e. coated tablets, capsules, ampoules and vials, ointments and creams, liquid orals and parenterals. Validation of processes like mixing, granulation, drying, compression, filtration, filling etc.
5. **Validation of solid dosage forms:** Introduction, validation of raw materials, definition and control of process variables, in-process tests, finished products tests, guidelines for process validation of solid dosage forms, tablets, tablet composition, process evaluation and selection, equipment evaluation, capsules, capsule composition, process evaluation and selection, encapsulation equipment evaluation.
6. **Validation of Stability studies:** ICH guidelines and stability protocols for different Pharmaceutical dosage forms.

RECOMMENDED BOOKS:

1. Pharmaceutical Process Validation, Edited by Robert A. Nash, Alfred H. Wachter, Vol. 129, Marcel Decker Inc.
2. Validation of Pharmaceutical Process (Sterile Products), 2nd Ed., FJ Carleton and JP Agalloco, Marcel Decker Inc.
3. Automation and validation of information in pharmaceutical processing by Despautz JF, Marcel Decker Inc.

4. Current Good Manufacturing Practices by Potdar MA, Pharma-Med Press, Hyderabad.
5. Pharmaceutical Quality Assurance by Potdar MA, Nirali Prakashan, Pune.
6. Good Manufacturing Practices for Pharmaceuticals by Sidney H. Willing and Murray M. Tuckerman, Vol. 16, Marcel Dekker Inc.
7. Microbiology in Pharmaceutical Manufacturing by Richard Prince, Davis Harwood, International Publishing.
8. Introduction to the environmental monitoring of Pharmaceutical Areas by Michel Jahnke, Davis Harwood International Publishing.

Subject code: MQA-P4
Subject : PHARMACEUTICAL VALIDATION
Practical: **8 hrs. /week**

1. Validation of analytical method (minimum four experiments)
2. Validation of following equipments:,
    a. Autoclave
    b. Hot air oven
    c. Powder Mixer (Dry)
    d. Tablet compression machine
    e. Dryers
3. Validation of at least two analytical instruments.
4. Cleaning validation of one equipment.
5. Stability study of active pharmaceutical ingredients and finished products (minimum two).
6. Validation of granulation process.
7. In-process testing of solid dosage forms.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MQA-S9
Subject: QUALITY ASSURANCE OF COSMECEUTICALS
THEORY: 60 Hours (4 hrs./week)

1. Factors to be considered in designing of cosmetic products: Regulatory requirements of cosmetic products, consumer safety consideration with microbiological preservation of cosmetic, intellectual property issue: patents of trade secrets.
2. Quality Management of cosmetics:
    i) Manufacturing techniques and evaluation of the cosmetic finished products,
        a) The skin
        Irritation and sensitization of the skin
        Nutrition and hormonal control of the skin
        Preparation for the facial skin: Vanishing cream, cold and moisturizing cream, makeup preparations and face powder.
    ii) Preparation for oral hygiene: Dentifrices, mouthwashes.
        Preparation for hands and feet
    iii) Body cosmetics: Antiperspirant and deodorant, talcum powder, sun-screen, sun tan, and anti sun burn preparation.
    iv) Preparation for hair: Shampoos, anti-dandruff preparations, hair dyes and conditioners, hair oil, depilatories, and hair grooming aids.
    v) Preparation for nails
    vi) Cosmetics for Men: shaving preparation, pre shave and after shave lotion
    vii) Baby cosmetics
    viii) Perfumes used in cosmetics
3. Toxicity testing methods, special toxicity testing like teratogenicity, and skin sensitivity testing.
4. General principle of quality control of cosmetic product
5. Stability evaluation of cosmetics

RECOMMENDED BOOKS:

1. Perfumes, Cosmetics and Soap by W.A.Poucher (Volume I,II,III) Chapman and Hall, London.
2. Cosmetic Science and Technology, Volume I,II,III by M.S. Balsam, Wiley Interscience.
3. Cosmetic and the Skin, F.V. Wells, Reinhold Book Corporation.
4. Biological Standardization by H.H.Buru, D.J.Finney and L.B.Goodnin, Geoffery Cumberlege, Oxford University Press, London.
5. Peter E. Siegler, Animal and clinical Pharmacological Technique in drug evaluation, Volume I, II, III, Meacoal Publisher Inc, Chicago.
6. J.A. Kolmerm, E.H. Spaulding and H.W.Robinson. Approved Laboratory Techniques, Appleton Century-Crodts, New York.

7. P. P. Sharma. Cosmetics- Formulation, manufacturing and Quality Control. 2nd Edition, Vandana Publications Pvt. Ltd., Delhi.
8. Harry's Cosmeticology. 7 th Ed., JB Wilkinson and RJ Moore (Ed.), Longman Scientific and Technical.

Subject code: MQA-S10
Subject: NOVEL DRUG DELIVERY SYSTEMS
THEORY: 60 Hours (4 hrs. /week)

1. Fundamentals of controlled release drug delivery systems :
Fundamentals and Rationale of Sustained / controlled drug delivery, factors influencing the design & performance of sustained/ Controlled release products, Drug Targeting, Use of polymers in controlled release of active agents, Pharmacokinetic / Pharmacodynamic basis of controlled drug delivery systems, regulatory requirements.

2. Oral drug delivery : Formulation, fabrication and evaluation of various oral controlled drug delivery systems including dissolution and diffusion controlled delivery systems, gastro retentive, colon targeted and pulsatile drug delivery. TIMERx, MASSRx & COSRx, Procise technology, RingCap technology, Theriform Technology, Accudep Technology, THREEFORM Technology, DissoCube IDD Technology, Zydis Technology for poorly soluble drugs, Orasolv & Durasolv technolohy, Egalet Technology, Buccal Mucoadhesives, Periochips.

3. Parenteral controlled release system: Scope, terminology & techniques used, injectable controlled release, formulation. Implantable drug delivery, microspheres, liposomes & their quality control.

4. Mucosal drug delivery models: Buccal, rectal, nasal & vaginal drug delivery. Mechanisms of transports of drugs through mucosal routes, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation (for each route).

5. Transdermal drug delivery system: Permeation through skin including mechanism, permeation enhances, In-vitro skin permeation, technologies for developing transdermal drug delivery system, mechanism of release kinetics, evaluation of transdermal drug delivery systems.

6. Ocular Drug Delivery: Transport of drugs through ocular tissues, approaches to improve ocular drug delivery.

7. Site specific drug delivery system: Active & passive targeting, resealed erythrocyte, monoclonal antibodies, drug targeting by particulate carrier system, drug targeting to brain, lung & colon.

8. Protein & peptide drug delivery system: Physical aspects, biochemistry of protein drug (structure, properties & stability- Mechanisms of destabilization. Techniques of stabilization of Proteins and Peptides.) General methods of analysis of protein & peptide drugs, barrier to transport & Pharmacokinetics, different route of delivery, practical considerations. Importance of pre-formulation & formulation considerations, toxicity immunogenicity, stability & regulatory perspective.

9. Regulatory consideration in controlled release: Demonstration of safety, efficiency & controlled release nature. WHO & Indian conditions.

RECOMMENDED BOOKS:

1. Remington's pharmaceuticals sciences. 21 st Edition, Lippincott Wiilliams and Willkins- Vol. I & II
2. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Yie W. Chien. Vol- 50.
3. J. R. Robinson and Vincent H. L. Lee Controlled drug delivery system. Marcel Dekker Second Edition, Revised and Expanded .. Vol- 29.
4. N.K. Jain .Novel and controlled drug delivery systems.
5. N.K. Jain. Advances in Novel and Controlled Drug Delivery.
6. Robinson, J.R. & Lee, V.H.I.,: Controlled and Novel Drug Delivery Marcel Dekker, New York. Second Edition, Revised and Expanded Vol- 29.
7. Kim. C., Controlled Release Dosage form Design, Technomic Publishing Co, Basel.
8. J. Swarbrick, 2007. Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1-6, Informa Healthcare.
9. R. Williams, D. Taft and J. McConville, "Advanced formualtion design to optimize therapeutic outcomes" Marcel Dekker, Inc.
10. L. Xiaoling, B.R. Jasti, "Design of Controlled Release Drug Delivery Systems" McGraw-Hill.
11. B. O. Mashkevich, "Drug delivery research advances" Nova Science Publishers, Inc.
12. W.M. Saltzman, 2001 "Drug delivery_Engineering Principles for Drug Thera". Oxford University Press.
13. E. Touitou, W.B. Boca "Enhancement in Drug Delivery" CRC PressBrian.
14. M.J. Rathbone, J. Hadgraft, M.S. Roberts, "Modified-Release Drug Delivery Technology" Marcel Dekker Inc.

Subject code: MQA-P9
Subject: QUALITY ASSURANCE OF COSMECEUTICALS
Practical: 8 hrs. /week

1. Evaluation of cosmetic raw materials (Minimum of 5 experiments).
2. Formulation and evaluation of various types of cosmetic preparations (Minimum of 5 experiments).
3. Evaluation of some marketed brands of cosmetic preparations (Minimum of 5 experiments).
4. Evaluation of stability of cosmetic preparation (Minimum of 5 experiments).
5. Determination of microbial load of cosmetic preparation (Minimum of 2 experiments).

Subject code: MQA-P10
Subject: NOVEL DRUG DELIVERY SYSTEMS
Practical: 8 hrs. /week

1. Formulation and evaluation of sustained release matrix tablet (of any two drugs).
2. Formulation and evaluation of floating microspheres.
3. Formulation and evaluation of floating tablet.
4. Formulation and in vitro evaluation of transdermal patches.
5. Development and evaluation of ocular inserts of a given drug.
6. Preparation and evaluation of buccal film of any two cardiovascular drugs.
7. Taste masking of some bitter drugs by ion-exchange resins.
8. Formulation and evaluation of nasal in situ gel.
9. Preparation and characterization of liposomes.
10. Preparation characterization of wax embedded microcapsules of a given drug.

Semester-III

Subject code: MQA-S13
Subject: QUALITY MANAGEMENT
THEORY: 60 Hours (4 hrs. /week)

1. Concept of Total Quality Management, Different quality management systems, ISO 9001:2000, ISO 14000, and their Philosophy, Introduction to ICH processes.
2. Documentation requirements in pharmaceutical industry for GMP compliance:
   a. Equipment, selection, purchase specifications, maintenance clean in place and sterilize in place.
   b. Manufacture and controls on various dosage forms. Manufacturing documents i.e. Master Formula, Batch formula, production record review, drug product inspection, Standard Operating Procedures, Quality audits of manufacturing processes and facilities.
   c. In process quality control on sterile and non-sterile dosage forms. Standard Operating Procedures for various operations like cleaning, filling, drying compression, coating, disinfection, fumigation, sterilization, membrane filtration etc.
   d. Packaging and labeling controls, line clearance and other packaging material.
3. Quality Audits: Raw materials, Finished Products and analytical procedures, manufacturing processes.
4. Quality control laboratory responsibilities and good laboratory practices.
5. Finished product release, quality audits, batch release documents.
6. Good warehousing practices and materials management.
7. Distribution records, handling of returned goods, recovered materials and processing.
8. Complaints and recalls, evaluation of complaints and recall procedures, related records and documents, drug product salvaging.
9. Waste and scrap disposal procedures and records.
10. Good Manufacturing Practices according to Schedule M of D & C Act
11. Environmental protection act and Factory act .

RECOMMENDED BOOKS:

1. Good Manufacturing Practices for Pharmaceuticals by Sidney H. Willing and Murray M. Tuckerman, Vol. 16, Marcel Dekker Inc.
2. Encyclopedia by pharmaceutical technology edited by James Swarbrick, James C. Boylan, Marcel Dekker Inc.
3. How to practice GMPs by Sharma PP, 3rd Ed., Vandana Publication.
4. Drug and Cosmetic Act and Rules (Governent of India)
5. Current Good Manufacturing Practices by Potdar MA, Pharma-Med Press, Hyderabad.
6. Pharmaceutical Quality Assurance by Potdar MA, Nirali Prakashan, Pune.
7. Girmaldi, Monica and Gough, Janet, The internal quality audit, Davis Harwood International Publishing.
8. Singer, Guidelines for laboratory quality auditing, Marcel Dekker
9. Lewis, Pharmaceutical experimental design, Marcel Dekker.
10. Guarino, New Drug approval process, 2nd ed., Vol 56, Marcel Dekker, New York.
11. Gough, Janet, Hosting a compliance audit. Davis Harwood International Publishing. ISO 14000 and ISO 9000 by Rothary B.

Syllabus Prescribed for Degree of Master of Pharmacy in Industrial Pharmacy

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MIP-S4
Subject: ADVANCED INDUSTRIAL PHARMACY-I
THEORY: 60 Hours (4 hrs. /week)

1. **Principles of improved Tablet Production system design :** introduction, Benefits of improved Tablet production system, Material Handling, processing step combination or elimination, Unit operation improvements, Role of Computer process Control.
2. **Compression:** Process of Compression, The Properties of Tablets influenced by Compression, Measurement of Compressional force. Energy expenditure, Transmission of force, Nature of material.Manufacture and Formulation Techniques of Chewable tablets, Medicated Lozenges and Specialized Tablets
   Compression coating-formulation, Layered Tablets and its formulation, Inlay tablets.
3. **Pelletization technology**: Introduction, Pelletization process and formulation, Requirements for pelletization.
4. **Sterile Dosage forms:** Formulation and Processing of large volume parenterals, Small volume Parenterals and Related parenteral products, Parenteral devices.
5. **Drying and Dryers:** Introduction, Mode of heat Transfer, Internal Mechanism of Moisture flow, Psychrometry, Drying Mechanisms, Drying methods for Pharmaceutical Granulation.
6. **Evaporation and Evaporators:** Introduction, Types of Evaporators, Design of Evaporators, operation of Evaporators.
7. **Pilot plant Scale Up Techniques:** General Consideration, Purpose and functions concepts of pilot plant for Development and control, Planning for pilot plant, Size of pilot plant. Organisation and Personnel, Basic Consideration in Developing the process for Production of dosage forms, GMP consideration. Transfer of Analytical methods to Quality assurance, Product consideration, Pilot plant study design for solid dosage forms, Liquid orals and semi-solids.

REFERENCE BOOKS:

1. B.S. Banker. Modern Pharmaceutics, Marcel Dekker.
2. Gennaro, Remington Pharmaceutical Sciences, Mack Publishing Company.
3. Lachman, Theory and Practice of Industrial Pharmacy, Lea and Febiger.
4. Liberman, Lachman and Schwartz. Pharmaceutical Dosage forms Tablets, Vole, II and 111, Marcel Dekker.
5. Lieverman, Lachman and Avis, Pharmaceutical dosage Forms. Parenteral Medication, Vols I and IL Marcel Dekker.

6. King and Turco, Sterile Dosage Forms, Lea and Febiger.
7. Ghebre, sellasie, Pharmaceutical Polletization technology, Marcel Dekker.
8. Swarbrick and Boylan, Encyclopedia of Pharmaceutical Technology, Vole 4 and 5, Marcel Dekker.

Subject code: MIP-P4
Subject : ADVANCED INDUSTRIAL PHARMACY-I
Practical: 8 hrs. /week

1. To study the effect of particle size, moisture content and lubricant on flowability and
2. compressibility of powders.
3. To prepare and evaluate antibiotic dispersible tablet.
4. To prepare and evaluate chewable tablet.
5. To prepare and evaluate medicated logenzes.
6. Development and evaluation of compression coated tablet of some drugs.
7. Design and characterization of drug loaded pellets by different techniques.
8. To prepare and evaluate parenteral suspension
9. To prepare and evaluate parenteral solution
10. To prepare and evaluate parenteral emulsion
11. To prepare and evaluate sterile reconstituted powder.
12. To prepare and evaluate microsphere prepared by spray drying technique

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MIP-S9
Subject: ADVANCED INDUSTRIAL PHARMACY-II
THEORY: 60 Hours (4 hrs. /week)

1. **Optimization techniques in pharmaceutical formulation and processing**
   Concept of optimization, Optimization parameters, Classical optimization, Statistical design, and Optimization methods.
2. **Stability testing**
   Physicochemical and biological factors affecting stability of drugs, Methods to find out degradation pathways, Determination of shelf life by accelerated stability testing, Overages.
3. **Bioavailability and bioequivalence studies**
   Definition, Objective of bioavailability, Parameters of bioavailability, Determination of AUC. Estimating absorption rate of drugs; Measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Drug dissolution rate & bioavailability. *In vitro* drug dissolution testing models. In-vitro in-vivo correlation. Definitions:Bio equivalence, Chemical equivalence, Therapeutic equivalence, Pharmaceutical equivalence; Testing of bioequivalence of dosage forms.
4. **Methods of enhancing bioavailability**
   Solubilization, Prodrugs, and enhancement of dissolution characteristics, cyclodextrin, permeation enhancer, solid dispersion, surfactant, bioavailability enhancers.
5. **Biochemical and molecular biology approaches to controlled drug delivery:**

   Microparticulate drug carriers : liposome, microspheres and cells, selective endocytosis of micromolecular drug carriers, antibodies for drug delivery, released erythrocytes, neosomes.
6. **Engineering :** Adequate knowledge of mechanical, electrical and electronic *parts* of pharmaceutical machinery and equipment, preventive maintenance, assessing plant and machinery efficiency and life. Material handling, transfer, transport and conveyance of bulk material.
7. **Packaging Material Science:** Packing design and specification, packaging validation trials, materials of construction. Component product validation, regulatory requirements, quality control testing and standards, GMP requirements and its deficiencies. In processes control during component manufacture, documentation sterilization of packing component, packaging and filling equipment, pharmaceutical packaging including sterile area.

RECOMMENDED BOOKS:

1. Lachmann and Libermann , Theory and Practice of Industrial Pharmacy. Third edition, Varghese Publishing House.
2. Leon Lachmann, Pharmaceutical dosage forms: Tablets Vol. 1-3. Third Edition.

3. Leon Lachmann. Pharmaceutical Dosage forms: Disperse systems, Vol, 1, 2, 3. Second edition.
4. Gillbert and S. Banker. Modern Pharmaceutics.. Fourth Edition. Volume 121.
5. Remington's Pharmaceutical Sciences. Vol.I-II, 21 st Edition.
6. Rawlins. Bentley's Textbook of Pharmaceutics. Eight Edition
7. Sidney H. Willig. Good manufacturing practices for Pharmaceuticals: A plan for total quality control. Second Ed.
8. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
9. D.P.S. Kohli and D.H. Shah. Drug formulation manual. Third Edition, Eastern publishers, New Delhi.
10. P. P. Sharma. How to practice GMPs. Fifth Edition, Vandana Publications, Agra.
11. M. Rowland, T.N. Tozer, 2011. "Clinical Pharmacokinetics and Pharmacodynamics: Concept and Applications", 4th Ed. Lippincott, Williams and Wilkins.
12. L. Shargel, S. Wu-Pong, B. C Andrew, 2005. "Applied Biopharmaceutics and pharmacokinetics", Fifth Ed. McGraw-Hill Medical Pub. Division.
13. M. Gibaldi and D. Perrier, Second Edition. 1982. "Pharmacokinetics". M. Dekker.

Subject code: MIP-S10
Subject: ADVANCES IN DRUG DELIVERY SYSTEMS
THEORY: 60 Hours (4 hrs. /week)

1. **Polymer science:** Introduction, synthesis of polymers, polymer classification, biodegradation of polymers, properties of polymers, pharmaceutical application of polymers.
2. **Sustained release formulations:** Introduction, concept, advantages and disadvantages. Physicochemical and biological properties of drugs relevant to sustained release formulations, evaluation of SRDFs.
3. **Concept and system design for rate-controlled drug delivery:** Classification of controlled drug delivery systems, rate-programmed release, activation modulated and feedback-regulated drug delivery systems, effect of system parameters on controlled release drug delivery.
4. **Controlled release oral drug delivery systems:** Dissolution, Diffusion, Combination of dissolution and diffusion controlled systems, osmotic pressure controlled release systems, floating drug delivery systems, pH dependent systems, ion exchange controlled systems.
5. **Mucoadhesive drug delivery systems:** Concepts, advantages and disadvantages, structure of oral mucosa, transmucosal permeability, mucosal membrane models, mucoadhesive polymers, permeability enhancers, *in vitro* and *in vivo* methods for buccal absorption. Nasal and pulmonary drug delivery systems and its applications.
6. **Ocular drug delivery systems:** Drawback of conventional ophthalmic dosage forms, types, formulation and evaluation of ophthalmic inserts, *in situ* ophthalmic gels.
7. **Transdermal drug delivery systems:** Anatomy and physiology of skin, permeation through skin, factors affecting permeation, basic components of TDDS, formulation approaches used in development of TDDS and their evaluation, permeation enhancers, penetration enhancement techniques, iontophoresis, sonophoresis, transferosomes, ethosomes
8. **Parenteral controlled release drug delivery systems:** Approaches for injectable controlled release formulations and development of implantable drug delivery systems.

9. **Intrauterine drug delivery systems:** Anatomy & physiology of vagina, development of intra uterine devices (IUDs), copper IUDs, hormone-releasing IUDs, and vaginal rings.
10. **Targeted drug delivery systems:** Principles of targeting, classification, advantages and disadvantages, biological processes and event involved in drug targeting, microspheres, magnetic microspheres, nanoparticles, liposomes, niosomes, dendrimers, resealed erythrocytes, and monoclonal antibodies.
11. **Protein and peptide drug delivery:** Introduction, classification and structure of protein, drug delivery systems for proteins and peptides, manifestation of protein instability and stability.
12. **Vaccine delivery:** Novel vaccination strategies, microparticles as vaccine adjuvants and delivery systems, liposomes and ISCOMs in vaccine delivery, virosomal technology, vaccines for specific targets, nanotechnology for vaccine delivery

RECOMMENDED BOOKS

1. Fried J.R. Polymer Science & Technology, 2nd edition. Prientice-Hall India Pvt. Ltd.
2. Coleman M.M., Painter P.C. Fundamentals of Polymer Science: An Introductory Text. CRC Press.
3. Lliun Lisbeth, Davis Stanley S. Polymers in Controlled Drug Delivery. Wright Bristol.
4. Robinson J.R., Lee V.H.L. Controlled Drug Delivery. Marcel Dekker, Inc.
5. Juliano R.L., Drug Delivery Systems: Characteristics and Biomedical Applications. Oxford University Press.
6. Chien Y.W. Novel Drug Delivery Systems. Marcel Dekker, Inc.
7. Vyas S.P., Khar R.K. Controlled Drug Delivery-Concepts and Advances. Vallabh Prakashan.
8. Mathiowitz E. Encyclopedia of Controlled Delivery. John Wiley & Sons, Inc.
9. Jain N.K. Controlled and Novel Drug Delivery. CBS Publishers & Distributors.
10. Carstensent J. T. Drugs and Pharm.Sci. Series, vol. 43, Marcel Dekker Inc.
11. Johnson P., Lloyd-Jones, J.G. Drug Delivery Systems: Fundamentals and Techniques. VCH.
12. Audus K.L., Juliano R.L. Targeted Drug Delivery. Springer-Verlag.
13. Lee V.H.L. Peptide and Protein Drug Delivery. Marcelk Dekker, Inc.
14. Guy R.H., Hadgraft G. Transdermal Drug Delivery. Marcel Dekker, Inc.
15. Edith Mathiowitz, Donald E. Chickering, Claus-Michael Lehr. Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches and Development. Marcel Dekker, Inc.
16. Kasliwal N. Liposomes/Niosomes As a Drug Delivery System. Lambert Academic Publishing.
17. Dietrich G., Goebel W. Vaccine Delivery Strategies. Horizon Scientific Press.
18. Kaufmann S.H.E. Novel Vaccination Strategies. Wiley-VCH.

Subject code: MIP-P9
Subject: ADVANCED INDUSTRIAL PHARMACY II
Practical: 8 hrs. /week

1. Optimization of formulations by factorial design.
2. Preformulation studies on tablets.
3. To study the decomposition kinetics of any three drugs.
4. To study the effect of copper ions on the ascorbic acid stability in solution
5. To determine the aqueous solubility of given drug sample at various temperature and report its thermodynamic parameters.
6. To study the dissolution kinetics of given drug.
7. To study the effect of pH (2, 4, 6 and 8.0) on the apparent partition coefficient of a drug in n-octanol- water buffer system.
8. To perform powdered glass test and whole container test as per USP on given glass containers.
9. Preparation and comparative evaluation with marketed products for antacid efficiency of neutralizing property of suspensions.
10. To determine water absorption capacity of different packaging materials.

Subject code: MIP-P10
Subject: ADVANCES IN DRUG DELIVERY SYSTEMS
Practical: 8 hrs. /week

1. Formulation and evaluation of sustained release matrix tablet (of any two drugs).
2. Formulation and evaluation of floating microspheres.
3. Formulation and evaluation of floating tablet.
4. Formulation and in vitro evaluation of transdermal patches.
5. Development and evaluation of ocular inserts of a given drug.
6. Preparation and evaluation of buccal film of any two cardiovascular drugs.
7. Taste masking of some bitter drugs by ion-exchange resins.
8. Formulation and evaluation of nasal in situ gel.
9. Preparation and characterization of liposomes.
10. Preparation characterization of wax embedded microcapsules of a given drug.

Semester-III

Subject code: MIP-S13
Subject: INDUSTRIAL PROCESS VALIDATION AND PRODUCTION MANAGEMENT
THEORY: 60 Hours (4 hrs. /week)

1**) Definition.** regulatory history of process validation, regulatory basis of process validation.

2) Organisation : Structure, corresponding departments, scope of validation work, protocol and documentation.

3) Validation of Sterile dosage form : Theoretical approaches, validation of steam, dry heat and ethylene oxide. Sterlization cycle. Validation of radiation and sterlising filters.

4) Validation of solid dosage form : Definition and control of process variables, guidelines for process validation of solid dosage form, validation of raw material and analytical methods.

5) Prospective process validation : Introduction, Organisation and documentation. Formulation development and development of manufacturing capability Scale up studies, qualification trials master product documents. Experimental design and analysis.

6) Retrospective process validation : Process,validation strategies. Selection and evaluation of historical data.

7) Process of raw material : Cost verses risk analysis. Establishment of specifications, test procedure for sampling. Establishment of optimum storage conditions.

8) Analytical methods validation : Assay validation during development phase. Retrospective and prospective analytical methods validation.

9) Production and planning management : Space allocation, enviormental factors, manufacturing, materials management. Forecasting cost control. Industrial relation. Enturpreunership development.

10) Safety management: Industrial hazards due to fire, accident, mechanical and electrical equipment, chemicals and pharmaceutical safety measures.

11) Drug regulatory methods : Defination. Federal food, drug and cosmetic Act. Review of Indian Laws relating to drugs. Drugs efficacy studies, implimentation review, OTC review, drug listing, drug amendments, patents copy rights, trade marks, drug recalls, product liabilities, customer complaint..

RECOMMENDED BOOKS :

1. Nash R.A., Berry I. R. Pharmaceutical Process Validation. Marcel Dekker, Inc.
2. Willing S.H., Stoker J.R. Good Manufacturing Practices in Pharmaceuticals- A Plan for Total Quality Control. Marcel Dekker, Inc.
3. Balchandra and Nambudri. Production Management-Text and cases. Prentice Hall of India-
4. Lachman. Lieberman, and Kenig. The Theory and Practice of Industrial Pharmacy. VargHese ublishers.
5. Agalloco J.P., Carleton F.J. Validation of Pharmaceutical Processes: Sterile Products. Marcel Dekker, Inc.
6. Wilin S.H. Tuckerman M.M., Hitching S. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total quality Control. Marcel Dekker, Inc.
7. Sharma D.D. Total Quality Management-Principles, Implementation and Cases. Sultan Chand & Sons.
8. Kenneth L. A. The Managers Guide to ISO 9000. Free Press.
9. Pothdar M.A. Current Good Manufacturing Practices. BS Publications.

Syllabus Prescribed for Degree of Master of Pharmacy in Pharmacoinformatics

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MPI-S4
Subject: INFORMATION TECHNOLOGY
THEORY: 60 Hours (4 hrs. /week)

1. Chemoinformatics: Introduction, molecular structures, representation and manipulation of 2D and 3D structures, generation of 3D structures visualization techniques, molecular databases, virtual screening, chemical libraries, molecular descriptors, calculation of descriptors reflecting physical and chemical properties of molecules, molecular similarities and complementarities, selection of structurally diverse and representative sets, molecular properties, solubility partition coefficient, drug like properties, data analysis, quantitative and qualitative structure activity relationship, prediction of ADME properties, application of chemoinformatics in drug research.
2. Programing in C, C^{++}, character manipulation, programming techniques for data base management and developing database oracle.
3. Programming in database environment, development of databases, relational databases, information retrieval systems, general search methods, Means-ends analysis, depth first search, breath first search, optimal search, branch and bound etc. Oracle database environment.
4. Web based search engines and the details of their search algorithms especially pertaining to bio-computing.
5. Molecular modeling : Energy minimization, geometry optimization, conformational analysis, global conformational minima determination, approaches and problems, bioactive vs. global minimum conformations, automated methods of conformational search, advantages and limitations of available software, molecular graphics, computer methodologies behind molecular modeling including artificial intelligence methods.
6. Structure activity relationships in drug design: qualitative vs. quantitative approaches, advantages and disadvantages, random screening, nonrandom screening, drug metabolism studies, clinical observations, rational approaches to lead discovery, homologation, chain

branching, ring chain transformations, bio-isosterism, insights into molecular recognition phenomenon, structure based drug design, ligand based drug design.

7. QSAR: Electronic effects, Hammett equations, lipophilicity effects, Hansch equation, steric effects, Taft equation, experimental and theoretical approaches for determination of physicochemical parameters, parameter inter-dependence, case studies, regression analysis, extrapolation vs. interpolation, linearity vs. non linearity, importance of biological data in the correct form, 3D-QSAR –example CoMFA and CoMSIA.

RECOMMENDED BOOKS:

1. Westhead, D.R, Parish, J.H. and Twyman, R.M.,Instant notes in bio informatics, BIOS scientific publishers, 2002. (ISBN. 1859962726)
2. Attwood, T.K. and parry-smith, D.J., Introduction to bioinformatics, Addison-Wesney-Longman Ltd. 1999. (ISBN 0582327881)
3. Baxevanis, A.D. and Ouellette, B.F.F., Bioinformatics; A practical guide to the analysis of genes and proteins, John wiley, 1998 (ISBN 047119196)
4. Mount, D.W, Bioinformatics: Sequence and genome analysis, cold spring harbor laboratory press. (ISBN 0879695978)
5. Lesk, A.M., Introduction to bioinformatics, Oxford university press (ISBN 0199251967)
6. Durbin,R., Eddy, S.,Krogh and Mitchison, G., Biological sequenceanalysis: Probabilistic models of proteins and nucleic acid, Cambridge university press, 1998. (ISBN 0521629713)
7. Baldi, P. and Brunak, S., Bioinformatics: The machine learning approach, MIT, 1998 (ISBN 026202442X.)
8. Brandon, C.I. and Tooze J., Introduction to protein structure, Garland pub., 1991. (ISBN 0815302703)
9. Lesk, A.M., Introduction to protein architecture: The structural biology of proteins, Oxford university press 2001. (ISBN 0198504748)
10. Creighton, T.E., Protein Structure: A practical approach. Irl. Pr., 1997. (ISBN 0199636184)
11. Schultz, G.E., Principles of protein structure, springer verlag,1978.(ISBN: 0387903348)
12. Sternberg, M (ed)., Protein structure prediction- A practical approach, Oxford university press, London 1996.

Subject code: MPI-P4
Subject: INFORMATION TECHNOLOGY
Practical: 8 hrs. /week

1. Windows Operating system basic commands and utility software exposures
2. Basic operations on MS-offce and Foxpro software.
3. Statistical operations using SPSS packages
4. C- language fundamentals and programming
5. Sequence data retrieval using SRS and Entrez
6. Sequence similarity search using BLAST and FASTA tools
7. Sequence and Structure Analysis using EMBOSS Package.
8. Molecular visualization using visualizing tools- Rasmol,Pymol,Cn3D,Swiss PDB viewer.
9. Protein Target Identification.
10. Selection of Template structures.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MPI-S9
Subject: BIOINFORMATICS
THEORY: **60 Hours (4 hrs. /week)**

1. Bioinformatics basic: Computers, biology and medicine, importance of Unix and Linux systems and its basic commands, data base concepts, protein and nucleic acid database concepts, protein bases, Biological XML DTD's; pattern matching algorithm basics.
2. Computational tools for DNA sequence analysis: GCG: The Wisconsin package of analysis program, web bases interfaces for GCG sequence analysis program.
3. Database and search tools: biological background for sequence analysis. Identification of protein sequence from DNA sequence, searching of database similar sequence. The NCBI; Publicly available tool resources at EBI, resources on the web data base mining tools.
4. DNA sequence analysis: The gene bank sequence data base; submitting DNA sequence to the data base and data base searching, sequence alignment, pairwise alignment, techniques, multiple sequence analysis, multiple sequence alignment, flexible sequence similarity searching with the FAST3 program package, the use of CLUSTALX for the multiple sequence alignment.
5. Submitting DNA protein sequence database: Where and how to submit SEQUIN, genomemcentres; submitting aligned set of sequence updates and internet resources.
6. Protein modeling: Introduction; foecefield methods; energy, buried and exposed resude, side chain and neighbours; fix region, hydrogen bonds, mapping properties onto surfaces; fitting monomers, rms fits of confirms, assigning secondary structures: sequence alignment methods, evaluation, scoring, protein completion, backbone construction and side chain addition, small peptide, methodology, software accessibility, building peptides, protein displayed; substructure manipulation, anneling,
7. Pepdidomimetics: Introduction, classification; conformationally restricted peptides, design pseudopeptides, peptidomimetics and transition state analogs; biologically active template; amino acid replacement; peptidomimetics and rational drug design; CADD techniques in peptidomimetics; development of nonpeptide peptidomimetics,
8. Protein structure prediction: Protein folding and model generation; secondary structure; protein loop searching, loop generating methods, loop analysis; homology modeling,

concept of homology modeling potential application, description methodology, homologous sequence identification; align structure, align model sequence; construction of variables and conserved region, threading technique, topology fingerprint approach for prediction, evaluation of alternate models; structure prediction on a mystery sequence, structure aided sequence technique of structure prediction, structure profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; significant ability; flexy dock, creatine analysis, scoring technique, sequence-sequence scoring.

9. Protein-ligand docking: Introduction; docking problems, methods for protein ligand docking, validation studies and application; screening small molecule database, docking of combinatorial libraries input data, input data, analysis docking results, software accessibility; flexy dock, creating input structures, ligand prepositioning, binding pockets, flexible bonds, torsional space, genetic algorithm, scoring.
10. The virtual library: searching MEDLINE, PubMed, current content, science citation index and current awareness services, electronic journals, grant and finding information.

REFERENCE BOOKS:

1. John,S. and Haywell, W., A guide to chemical basis of drug design, Introduction to the principles of drug design, Wright PSG.
2. Wolff, M.E., Burgers medicinal chemistry and bases of medicinal chemistbliry, vol. III, 5th ed., A Wiley interscience publishers, 1996.
3. Delgado, J.H. and William, A.R (eds).,Wilson and Giswold's, Text book of organic, medicinal and pharmaceutical chemistry, computer assisted drug design, 11th ed. Lippincott publisher, 2004
4. Gudman and gillmans, The pharmacological basis of therapeutics, 10 ed. Pergamon press,2001.
5. Robert, S.M and Price, D.J., Medicinal chemistry- The role of organic chemistry indrug research, Mc-Grawhill, medical publishers.
6. William D.A and Lemke, T.L. Foye's Principles of medicinal chemistry, 5th ed., Lipincott publisher,2002
7. Furniss, B.S., Hannaford, A.J. Smith, B.W.G and Tatchall, A.R. Vogel practical organic chemistry, 5th ed, Addison-Welsey publishers, 1998.
8. Frberick M.A., Current protocol in molecular biology.
9. Tomstrachan and Andrew, P.R, Human molecular genetics.
10. Chrietine orengo, Bioinformatics genes, protein and computer.
11. Geffrey, M. Cooper, The cell- A molecular approach.
12. Nancy S, Templaton D and Lasio, Gene therapy- therapeutic mechanism and strategies.
13. Rajan, S. S. And Balaji, R., Introduction to Bioinformatics, Himalaya Publishing house,Mumbai. 2003.
14. Murthy,C.S.N.,Bioinformatics, Himalaya Publishing House, Mumbai, 2004.

Subject code: MPI-S10
Subject: MOLECULAR BIOLOGY
THEORY: 60 Hours (4 hrs. /week)

1. System and methods of molecular biology: Introduction to genetics engineering and biotechnology, genes and gene expression, bacteria, bacteriophage, yeasts, animal cells; use of mutants, genetics analysis of mutants, genetics of recombination, complementation.
2. DNA replication, transcription and translation: Enzymology of replication,initiation of replication, revers transcriptase, bidirectional replication; transcription signals, pramotor sites, rho and sigma factor,RNA processing;the genetic code,the wobble hypothesis,polycistronic mRNA, overlapping genes, polypeptide synthesis.
3. Mutation: types of mutation, biochemical basis of mutation,mutagenesis,mutator genes,reversion.
4. Plasmids and transposable elements: plasmid DNA and its transfer,plasmid replication,structure of transposable elements and its transcription,genetic phenomenon mediated by transposons.
5. Gene cloning:nucleic and isolation,cloning vectors,salient features and types,biology of bacteriophase lambda,cosmid vectors and their use,cloning methods.
6. Regulation of gene activity in prokaryotes and eukaryotes: principles of regulation, E. coli. Lactose system, tryptophan operon, autregulation, feed back inhibition, gene family, gene dosage, gene amplification, regulation of transcription and processing, transcriptional control, gene rearrangement.
7. DNA –protein interaction: single protein binding to a regulatory DNA site, levels of specificity, single stranded DNA binding protein in E.coli., protein-DNA binding in tobacco mosaic virus, structural and functional studies of ribonuclease.T1, Tet repressor, Tet operator, condensation of chromatin.
8. Genomics: Technology vs. philosophy, DNA, RNA, proteins, the central dogma in molecular biology, splicing, gene structure. Bioinformatics as an essentional part of genomics.

RECOMMENDED BOOKS :

1. Baltimore, D.H. and Berk, A., et. al., Molecular Cell Biology-Scientific American Book, Lodish, New York, 1995.
2. Lewin, B., Gene VII, Oxford University Press,New York,1999.
3. DeVita Jr.,Hellman, S., Rosenberg, S.A(eds)., Cancer: Principle and practice of oncology 6th ed., Lippincott, Williams and Wilkins publication 2001

4. Alberts, B., Bray ,D., Lewis J., Raff, M., Roberts, K. and Watsons, J.D., molecular biology of the cell, 3rd ed., Garland publishing Inc
5. Murthy ,C.S.N., bioinformartics , Himalaya publishing house ,Mumbai,2004.
6. Vedpal, S. M., Padma, S., Mohan and Premlani,R., industrial biotechnology, Oxford and IBH Publishing Co. Pvt. Ltd., New Delhi ,1992.

Subject code: MPI-P9
Subject: BIOINFORMATICS
Practical: 8 hrs. /week

1. Validation and active site prediction of the modeled target structure using SAVS,CASTp and PASS.
2. Identification and generation of ligand molecule from Chemical structure database.
3. Docking the ligand molecule with the protein target using AUTODOCK
4. Creating Databases like SARS PROTEIN , Amino acid and querying using MYSQL
5. Usage of String , Mathematical & Date Functions on MYSQL
6. Understanding the KEYS and references in MYSQL

Subject code: MPI-P10
Subject: MOLECULAR BIOLOGY
Practical: 8 hrs. /week

1. Applications of Analytical techniques –
Ultra-violet and Visible spectroscopy, infra-red spectroscopy.
2. Applications of Chromatographic techniques –
3. Column chromatography, TLC, - HPTLC, HPLC and GC-MS.
4. Identification of chemical compounds by Nuclear Magnetic Resonance (NMR) - spectroscopy.
5. Determination of metals by Flame photometry and Absorption spectrometry.
6. Seperation of proteins by Gel –Electrophoresis.

Semester-III

Subject code: MPI-S13
Subject: SELECTED TOPICS IN PHARMACOINFORMATICS
THEORY: 60 Hours (4 hrs. /week)

1. Drug metabolism and toxicity and metabolic disorder:

Introduction to metabolic errors and metabolic diseases , metabolism in health and diseases, regulatory enzymes for metabolic pathways, metabolic problems as diagnostic criteria ,advanced concept in the organization and control of carbohydrates ,lipid and nitrogen metabolism in eukaryotes ,regulation at cellular levels via metabolite trafficking and control of enzyme activity ,integration of metabolism at the whole body level by hormonal signaling, the molecular basis of inherited metabolic diseases , use of anti metabolites in the chemotherapy molecular graphics and modeling of metabolites and biomolecules , resource for macromolecular modeling and pharmacoinformatics ,pharmacogenetic variations influencing metabolism and its clinical relevance, toxicogenomics, toxicogenetics, microarray expression profiles , gene expression and databases of microarray expression profiles, gene expression biomarkers, toxicology inforamatics.

2. Pharmacoinformatics – The tools

Patterns recognition techniques with examples from spectral patterns and biological sequence patterns, artificial intelligence, logical programming, experts systems, artificial neural network(ANN), genetic algorithms.

Pharmaco informatics- The methodology

a) Pharmacoinformatics: Integration of bioinformatics, chemoinformatics, genomics and proteomics; in silico identification and validation of novel therapeutic targets, 3D database search method, artificial neural network methods, genetic algorithm methods in chemoinformatics, evaluation of diverse compounds subsets from chemical structures databases, recognition of hypothesis, validation of hypothesis using pharmacophore pattern searching methods in chemoinformatics, spectral and crystallographic databases, abinitiogene prediction technique to predict novel gene targets, case studies.

b) In silico combinatorial and high throughput methods: computational methods of library design.

c) Virtual screenings, Lead compounds selection and lead optimization using virtual screening, filtering methods, rapid QSAR methods for virtual screening rapid molecular docking methods for virtual screening; receptor selectivity mapping; testing the lead drug candidates (from chemoinformatics method) for their selectivity across a broad panel of

targets (from bioinformatics methods) ,scoring function and their importance in virtual screening, case studies internet computing in drug discovery.

Pharmacy informatics

Introduction to pharmacy informatics, role of informatics to enhance the services provided by pharmaceutical care gives health information system architecture, health data management, medical coding and classification, medical databases, clinical data collection and aquisation and evaluation methods; privacy and security of clinical data, clinically relevant drug-drug interaction and databases, telemedicine and telehealth, ethics in medical informatics, pharmacy system and automation, drug information systems, electronic records, informatics application in pharmacy, survey and evaluation of online resources.

RECOMMENDED BOOKS :

1. Murthy,C.S.N., bioinformatics, Himalaya Publishing House, Mumbai, 2004.
2. Jogdond, S.N.,medical biotechnology, Himalaya Publishing House, Mumbai,2000.
3. Balasubramnian,D.,Boys,C.F.A.,Dharmalingam, K. J., Green and Kunthala Jayaraman, Concepts in biotechnology, Universities Press Hyderabad, 1996.

Syllabus Prescribed for Degree of Master of Pharmacy in Clinical Pharmacy

Semester-I

Advanced Analytical Techniques (MC-S1 & PC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MCP-S4
Subject: ADVANCED CLINICAL PHARMACY AND PHARMACOTHERAPEUTICS–I
THEORY: 60 Hours (4 hrs. /week)

Pathophysiology and clinical pharmacotherapy of diseases associated with following system;

1. **Cardiovascular system**
   Hypertension, congestive cardiac failure, ischemic heart disease, myocardial infarction, arrhythmias, hyperlipidemias.
2. **Respiratory system**
   Asthma, chronic obstructive airways diseases, drug acting on pulmonary diseases.
3. **Hematological diseases**
   Anemia's deep vein thrombosis, drug induced hematological diseases.
4. **Arthritic diseases**
   Rheumatoid arthritis, osteoarthritis, gout, systemic lupus erythematous.
5. **Gastrointestinal system**
   Peptic ulcer diseases, reflux esophagitis, inflammatory bowel diseases, Hepatitis, jaundice, cirrhosis, diarrhea and constipation, drug induced liver diseases.
6. **Pain management**
   Pain pathways, Analgesics and NSAID'S, neuralgias including herpetic, trigeminal and glossopharyngeal neuralgia.
7. **Immunology**
   Autoimmunity – Definition, classification, mechanism of autoimmune disease, pathogenesis of autoimmunity, immunoglobulin.
8. **Prescribing guidelines for**
   Pediatric patients, geriatric patients, pregnancy and breast feeding.

RECOMMENDED BOOKS :

1. Roger and Walker, Clinical Pharmacy and Therapeutics, Churchill Livingston Publications.
2. Joseph T. Dipiro, Pharmacotherapy: A Path Physiologic Approach.
3. Robinson S. L., Pathologic Basis of Disease, sounders Publication.
4. Green & Harris, Pathology & Therapeutics for Pharmacist: A Basis for Clinical Pharmacy Practice, Chapman & Hall Publication.
5. Hefindal E.T., Clinical Pharmacy & Therapeutics, Williams & Wilkins Publication.
6. Young L. & Kimble K., Applied Therapeutics: The Clinical Use of Drugs, MA (ISBN-033-65881-7).

7. Avery's Drug Treatment, 4th Edition, Adis International Ltd. 1997.
8. Scott L. T., Basic Skills In Interpreting Laboratory Data, American Society of Health System Pharmacist.
9. Practice Standards & Definitions- The Society Of Hospital Pharmacist Australia 1997.
10. Rowland & Tozer, Clinical Pharmacokinetics, Williams & Wilkins Publications.
11. Shargel L., Biopharmaceutics & Applied Pharmacokinetics, Printice & Hall Publications.
12. Relevent Review Article from Recent Medical & pharmaceutical Journals.

Subject code: MCP-P4
Subject: ADVANCED CLINICAL PHARMACY AND PHARMACOTHERAPEUTICS–1
Practical: 8 hrs. /week

Following aspect should be studied in detail in each ward round. Patient medication history in the review, answering drug information questions, patient medication counseling, in ward round. Case presentation should be done in the department. The cases being studied and the follow up studies should be recorded in the practical record books

1. Answering drug information related questions (Queries related to dosage, administration, contraindication, adverse drug reactions, drug interaction, drug used in pregnancy & lactation, drug profile, efficacy & safety)
2. Patient Medication counseling (common diseases like diabetes, asthma, Hypertension, TB, COPD)
3. Case studies related to laboratory investigation (Hematology, thyroid, renal, cardiac enzymes) Patient medication interview, medication review, detection & assessment of adverse reactions & their documentation.
4. The case presentation in the department should include cases of the following diseases.

Diabetes Type I	Schizophrenia
Diabetes Type II	Depression
Hyperthyroidism	Anxiety
Hypothyroidism	Epilepsy
Acute Renal Failure	Parkinsonism
Chronic Renal Failure	

The students should be trained in the following aspects of services provided at the hospitals and should be assessed for their performance on the same. The students are required to submit a record of activities performed which includes the strategies used.

Patient medication interviews
Answering drug information queries
Patient medication counseling
Literature evaluation
Therapeutic drug monitoring
Problem solving in clinical pharmacokinetics
Ward round participation
Medication order review
Detection & Assessment of adverse reactions & their documentation

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MCP-S9
Subject: ADVANCED CLINICAL PHARMACY AND PHARMACOTHERAPEUTICS – II
THEORY: 60 Hours (4 hrs. /week)

Pathophysiology and clinical pharmacotherapy of diseases associated with following system;

1. Renal System: Acute/ chronic renal failure, renal dialysis & transplantation, drug induced renal diseases
2. Central Nervous System: Ischemia, Headache, Epilepsy, Parkinsonism.
3. Endocrine System: Thyroid disease, oral contraceptives, hormone replacement therapy, osteoporosis.
4. Psychiatric diseases: Schizophrenia, depression ,anxiety, sleep disorder, drug induced psychosis
5. Infectious diseases: General guidelines for the rational use of antibiotics, meningitis, respiratory tract infections ,gastroenteritis, bacterial endocarditis septicemia, otitis media, urinary tract infection, tuberculosis, leprosy, malaria, helmenthiasis, HIV and opportunistic infections, fungal infection ,rheumatic fever
6. Neoplasia: General principles of cancer chemotherapy of lung cancer, cytological malignancy, management of nausea and vomiting.
7. Drug and poison information

   Introduction to information resources available
   1. Systematic approach in answering drug information queries.
   2. Critical evaluation of drug information and literature
   3. Preparation of written and verbal reports.
   4. Establishing a drug information center.
   5. Poison information organization and information resources.
   6. Poison management in drug dependence and drug abuse(opiates,cocaine,amphetamines,alcohol,benzodiapines,barbiturates,tobacco) Role of emetics, anti-emetics and respiratory stimulants
8. Clinical Pharmacokinetics: Clinical pharmacokinetics models, physiological determination of drug clearance and volume of distribution, renal and non-renal clearance, organ extraction and models of hepatic clearance ,estimation and determination of bioavailability, multiple dosing, calculation of loading and maintenance dose, dose adjustment in renal failure, hepatic dysfunction, gastric and pediatric patient, therapeutic drug monitoring (general aspects).
9. Research design and conduct of clinical trials: research support including planning and execution of clinical trials, guidelines for good clinical research practice and ethical requirement, various phases of clinical trials, categories of phase IV studies, monitoring and auditing of clinical trials.

RECOMMENDED BOOKS :

1. Roger and Walker, Clinical Pharmacy and Therapeutics, Churchill Livingston Publications.
2. Joseph T. Dipiro, Pharmacotherapy: A Path Physiologic Approach.
3. Robinson S. L., Pathologic Basis of Disease, sounders Publication.
4. Green & Harris, Pathology & Therapeutics for Pharmacist: A Basis for Clinical Pharmacy Practice, Chapman & Hall Publication.
5. Hefindal E.T., Clinical Pharmacy & Therapeutics, Williams & Wilkins Publication.
6. Young L. & Kimble K., Applied Therapeutics: The Clinical Use of Drugs, MA (ISBN-033-65881-7).
7. Avery's Drug Treatment, 4th Edition, Adis International Ltd. 1997.
8. Scott L. T., Basic Skills In Interpreting Laboratory Data, American Society of Health System Pharmacist.
9. Practice Standards & Definitions- The Society Of Hospital Pharmacist Australia 1997.
10. Rowland & Tozer, Clinical Pharmacokinetics, Williams & Wilkins Publications.
11. Shargel L., Biopharmaceutics & Applied Pharmacokinetics, Printice & Hall Publications.
12. Relevent Review Article from Recent Medical & pharmaceutical Journals.

Subject code: MCP-S10
Subject: CLINICAL RESEARCH
THEORY: 60 Hours (4 hrs. /week)

1. **Overview of clinical research**
   Clinical research, the drug development process, phases of clinical research, elements of clinical research and the role of clinical research coordinator in clinical research, the study work area and resources.
2. **FDA regulations and good clinical practice guidelines**
   Code of federal regulations (CFR), ICH GCP guideline, responsibilities of investigators, responsibilities of sponsor, financial disclosure by clinical investigators, electronic signature, the institutional review board, subjects informed consent, regulatory references.
3. **The study: Planning stages and commencement**
   Protocol development, the planning stages of a study, study commencement, keeping up with the study, study termination.
4. **Interactions with the sponsor**
   Sight monitoring visits, resolution of problems identified at site visits, grant – sponsored visits (audits and inspections), telephone monitoring, written correspondence, investigator's meetings, study procedures manual.
5. **Interactions with the institution**
   The principle investigator and subinvestigators, the institutional review board, study logistics, preparing hospital staff.
6. **The role of the study subject**
   The subject, study subject recruitment, obtaining informed consent, assessing subjects for study participation, keeping the subject on the study/ facilitating compliance ,

determining noncompliance, subject leaving the study, what is an evaluable subject?, subject compensation, subject and medical team relationship.

7. **Data management**
   General issues in developing forms for data collection, recording data and completing case report forms, source documents, analyzing the data, reporting the data.
8. **Adverse events**
   Adverse events, assessment of adverse events, recording adverse event data, medical management of adverse events, unblinding the study because of an adverse event, serious adverse events.
9. **Investigational agent management**
   Investigational drug agents in a clinical trial, code breakers, study drug labels, receiving and storing the investigational agent, dispensing the investigational drug agent, instructions to study subjects, study drug accountability, destruction of the investigational drug agent, final disposition.
10. **Inspection of clinical research sites**
    Preparing for an inspection, the data audit, end of the inspection.

RECOMMENDED BOOKS:

1. Avery's Drug Treatment, 4th Edition, Adis International Ltd. 1997
2. Scott L. T., Basic Skills In Interpreting Laboratory Data, American Society of Health System Pharmacist
3. Practice Standards & Definitions- The Society Of Hospital Pharmacist Australia 1997
4. Rowland & Tozer, Clinical Pharmacokinetics, Williams & Wilkins Publications
5. Shargel L., Biopharmaceutics & Applied Pharmacokinetics, Printice & Hall Publications
6. Relevent Review Article from Recent Medical & pharmaceutical Journals.

Subject code: MCP-P9
Subject: ADVANCED CLINICAL PHARMACY AND PHARMACOTHERAPEUTICS–II
Practical: 8 hrs. /week

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Subject code: MCP-P10
Subject: CLINICAL RESEARCH
Practical: 8 hrs. /week

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :
Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Semester-III

Subject code: MCP-S13
Subject: COMMUNITY AND CLINICAL PHARMACY
THEORY: 60 Hours (4 hrs. /week)

Community Pharmacy:

1. The role of community pharmacy and its relationship to other local health care providers
2. Prescribed mediation order – Interpretation & legal requirements communication skills-communications with prescriber and patients, over the counter (OTC) sales.
3. Primary health care on Hospital Pharmacy – Family planning, first aid, participation in primary health care programs, smoking cessation, screening programs.
4. Community Pharmacy Management – Financial Materials, Staff infrastructure requirements, drug information, resources & computers.
5. Code of ethics for community pharmacist
6. Pharmacoepedemiology – Definition & scope, methods (Source of Data, study design, drug utilization studies, meta-analysis) social culture, economic factor influencing drug use. System for monitoring drug effects. Advantages & disadvantages of pharmacoepedemiology.
7. Pharmacoeconomics: Definition & scope, types of economic evaluation, cost models & cost effectiveness analysis.
8. Nutrition: Mal nutrition & deficiency states, enteral & parenteral nutrition.
9. Introduction to clinical pharmacy – Definition, development & scope, introduction to pharmaceutical medicine, the drug development process, new drug discovery, clinical development of drugs, essential clinical trial documents.
10. Introduction to daily activities of a clinical Pharmacist – Drug therapy monitoring (medication chart review, clinical review, pharmacist intervention), ward round participation, adverse drug reaction management & pharmacovigilance, drug information & poison information, medication history, patient counseling, pharmaceutical care, drug utilization (DUE) & review (DUR), Quality assurance of clinical pharmacy services.
11. Patient data analysis – Patient case history, its structure and use in evaluation of drug therapy and understanding, common medical abbreviations & terminologies used in clinical pharmacy, communication skills including patient counseling techniques, medication history, interview presentation of cases, teaching skill, clinical laboratory test used in evaluation of disease state & interpretation of test results like: Hematological, liver function, renal function, thyroid function test associated to cardiac disorder, fluid & electrolyte balance, microbial culture sensitivity test, pulmonary function test.

RECOMMENDED BOOKS :

1. Hassen W.E., Hospital pharmacy, Lec & Febiger Publications.
2. Textbook of Hospital Pharmacy, Allwood M C & Blackwell.
3. Avery's Drug Treatment, 4th Edition, Adis International Ltd. 1997.
4. Scott L. T., Basic Skills in Interpreting Laboratory Data, American Society of Health System Pharmacist.

5. Practice Standards & Definitions- The Society Of Hospital Pharmacist Australia 1997.
6. Rowland & Tozer, Clinical Pharmacokinetics, Williams & Wilkins Publications.
7. Shargel L., Biopharmaceutics & Applied Pharmacokinetics, Printice & Hall Publications.
8. Relevent Review Article from Recent Medical & pharmaceutical Journals.

Syllabus Prescribed for Degree of Master of Pharmacy in Natural Product

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MNP-S4
Subject: INDUSTRIAL PHARMACOGNOSY
THEORY: 60 Hours (4 hrs. /week)

1. Factors influencing production of crude drugs. Plant growth regulators, Disease management of medicinal and aromatic plants.
2. Commercial cultivation technology and post-harvest care of following medicinal plants Ashwagandha, Neem, Liquorice, Aloe, Guggul, Medicinal Yams, Ergot, Belladonna, Senna, Opium, Psyllium, Steroid bearing Solanums, Ammi majus, Ipecac,Henbane, Digitalis, Saffron.

Commercial scale cultivation and processing of following aromatic plants-Lemon grass, Geranium, Basil, Palmarosa, Vetiver, Patchouli, Japanese Mint, Rose, Hops, Jasmine, Sandal, Dill , Celery, Anise, Artemisia.

3. Extraction and Utilization of Biomedicinals:

Occurrence, Methodology for extraction and Chemistry of following-

Sennosides, Digoxin, Ginsenosides, Solasodine, Berberine, Quinine, Scopolamine,

Atropine, Emetine, Ergot alkaloid, Caffeine, Taxol, Withanolides, Podophyllotoxin, Rutin, Hesperidin, Andrographolide, Glycyrrhizin, Cod-liver oil and Shark-liver oil

4. Pharmaceutical aids: Profile for manufacture and commerce of papain, pectin, pharmaceutical gums, starch, absorbent cotton and gelatin.
5. Phytochemical screening of crude drugs: General methods of isolation, purification, identification and estimation of phytoconstituents. Various chromatographic techniques, U.V., TLC, GLC, HPLC and HPTLC, Spectrometry, Fluorimetry and Colorimetry for evaluation.

Preparation of standardized extracts suitable for incorporation in solid dosage forms like tablets, capsules, etc.

6. Herbal formulations: Types of herbal formulations. Recent trends in poly-herbal medicines. Herbal cosmetics and herbal teas. Manufacture, Packaging and approach to quality control of herbal formulations. GMP for herbal drug formulations.

RECOMMENDED BOOKS :

1. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons Limited, New Delhi.
2. Advances in Natural Product Chemistry, extraction and isolation of biologically active compounds. S. Natori et al., Wiley, New York.
3. Phytochemical methods by J.B. Harborne, Chapman and Hall, International Ed., London.
4. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.

5. G.E. Trease and W.C. Evans., Pharmacognosy, W.B. Saunders Co. Ltd., Harcourt Publishers Ltd. UK.
6. Chaudhari R.D., Herbal Drug Industry, Eastern Publication.
7. Quality Control Methods for medicinal plant material, WHO Geneva.
8. Wagner H, Bladt S, 1996. Plant Drug Analysis- A Thin Layer Chromatography Atlas, 2nd Ed., Springer-Verlag, Berlin.
9. Stahl Egon, Thin layer chromatography, 2nd Edition, Springer Publication.
10. Mukherjee PK, 2003. GMP for Indian system of medicine. In GMP for Botanicals. Verpoorte R, Mukherjee PK (Edn.), Business Horizons Limited, New Delhi.
11. Herbal Drug technology by SS Agrawal and M Paridhavi, Orient Longman
12. Indian Herbal Pharmacopoeia, Vol. I- II, SS Handa, RRL Jammu Tawi, and IDMA Mumbai.
13. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
14. Standardization of Botanicals by V. Rajpal, Vol. I and Vol II, Eastern Publishers, New Delhi.
15. Practical Evaluation of Phytopharmaceuticals by K.R. Brain and T.D. Turner, Wright-Scientechnica, Bristol.
16. Houghton P, Mukherjee PK. Evaluation of Herbal Medicinal Product, Pharmaceutical Press, London, 2009

Subject code: MNP-P4
Subject: INDUSTRIAL PHARMACOGNOSY
Practical: 8 hrs. /week

1. Preliminary phytochemical screening of the plant constituents.
2. Extraction of active principles such as alkaloids, glycosides, resins, essential oils, terpenoids, fixed oils, carbohydrates, fats, tannins, steroids, pectins, etc. from natural drugs.
3. Extraction, isolation, purification and identification of important phytoconstituents as follows:

a. Eugenol from clove oil
b. Sennosides from Senna leaves
c. Curcumin from Turmeric
d. Glycyrrhizin from Liquorice
e. Hesperidine from Orange peels
f. Caffeine from Tea
g. Strychnine and Brucine from Nux-Vomica
h. Rutin from Ruta graveolens
i. Aloin from Aloes
j. Piperine from Pepper
k. Quinine from cinchona bark
l. Berberine from Berberis aristata
m. Diosgenin from Dioscorea

4. Determination of lead, arsenic, copper, mercury, etc. from natural drugs or their preparations.

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MNP-S9
Subject: NATURAL PRODUCTS & BIO-ORGANIC CHEMISTRY
THEORY: 60 Hours (4 hrs. /week)

1. Marine natural product: Chemistry and biology of marine natural products, marine chemical ecology, marine biomedicinals and marine toxins from bacteria, micro algae, rhodophyta, chlorophyteporifera, ascidians, corals, nudibrancts. Biosynthesis of marine natural product. Recent developments in natural product chemistry of plant and microbial source.

2. Carbohydrates: Mono, di, oligo-and polysaccharides, separation and isolation, purification, structure determination, linage stereochemistry, biological activity.

3. Glycoproteins, lipoproteins and glycopeptidolipids; Structure and biological activity, isolation, purification, degradation, structure determination.

4. Glycosides and saponins: Classification, separation and isolation, linkages stereochemistry, structure determination, biological activity, study of examples.

5. Alkaloids, steroids and triterpenoids: Classification, methods of isolation, stereochemistry, biological activity, general theory of biogenesis.

6. Coumarins, lignans and flavonoids classification, isolation, stereochemistry, biological activity, biosynthesis.

7. Lipids and autocoids: Classification, identification, biological activity, study examples.

RECOMMENDED BOOKS :

1. Vardemme, E., Biotechnology of Industrial antibiotics.
2. Vapporte and Swendson, Chromatography of Alkaloids.
3. Lala, P.K., Elements of Chromatography.
4. Srivastava, V.K. and Kishore, K., Introduction to Chromatography Theory & Practicals.
5. Knevell, A. N., Jenkine Quantative Pharmaceutical Chemistry.
6. Moual, A. C., Clerk's Isolation & Identification of-drugs.
7. Finar, H., Organic chemistry, Vol II.
8. Guenther, E., The Essential Oil, Vol.I and IV, Van Nostrand Co.
9. Schwartz, J.C.P., Physical Methods in Organic Chemistry.
10. Creger, W., Techniques in Organic Chemistry.
11. Anderson, L. A., Herbal Medicines-Janne Barnes.
12. Kanfinan, P. B., Natural Products from Plants.
13. World Health Organisation, W.H.O., 2000.

14. Toms, G., Marine Pharmacognosy in Chemotaxonomy of the Leguminous Ed. Harborne, Boulter and Tuner, Academic press.
15. Fransworth, N. It S., Some Hallucinogenic and Related Plants.
16. llis, Pergamon, Recent Development in the Chemistry of Natural Phenolic Compounds, 1961.
17. Harborne J.B., Phytochemical methods, Chapman and Hall.
18. Asolkar, Diosgenin and Other Steroidal Drug Precursors.
19. Welnsted, M.I. and Wagman, G.H., Antibiotics, Isolation & Seperation.
20. Butt, W.R., Hormone Chemistry.
21. Gorog, S., Quantitative Analysis of Steroid.
22. Feiry & Feisher, Steroids.
23. Pelletier, S.W., Alkaloids Chemical & Biological.

Subject code: MNP-S10
Subject: STANDARDIZATION OF NATURAL PRODUCTS
THEORY: 60 Hours (4 hrs. /week)

1. Stability testing of natural products, procedures, predictable chemical and galencial changes, technical limitations, testing methods and combination products.

2. Bioavailability and pharmacokinetics aspects for herbal drugs with examples of well known documented clinically used herbal drugs. Phytoequivalence, pharmaceutical equivalence.

3. World Health Organisation guide lines for herbal drugs including standards for pesticide residue/aflatoxins. Current status of regulatory affairs for herbal formulations.

4. Problems encountered in and prospects of discovering new drugs from plants. Natural substances as raw materials in drug synthesis. Biomedicinals of recent discovery.

5. Emerging plant drugs- Anti-hepatotoxic, anti-fertility, antimalarial, anti-hypertensive and antibiotic plants.

6. Current status of anti-cancer, anti-diabetic and immunomodulatory herbal drugs Bio-evaluation of herbal drugs.

7. Saponins and Terpenoids with biological activity of pharmaceutical significance. Recent trends in utilization of vegetable laxatives and vegetable bitters.

8. Natural coloring and sweetening agents.

9. Hallucinogenic, allergic, teratogenic and other toxic plants.

10. Endangered species of medicinal plants.

11. Drug and Pharmaceuticals from marine sources (Marine Pharmacognosy), with special reference to cardiovascular, cytotoxic, antimicrobial and anti-inflammatory compounds. Current status of plants on alternative system of medicines like Chinese, Ayurveda, Homeopathy, Unani and Siddha.

RECOMMENDED BOOKS :

1. Wagner and Black, Plant Drug Analysis.
2. Barn, J. N., Finley, D. J. and Goodwin, R. G., Biological Standardization.
3. Trease and Evans, Pharmacognosy.
4. Tyler, Bready and Robbers, Pharmacognosy.
5. Ramstad, Modem Pharmacognosy.
6. John, Dodds and Lorin, Experiments in Plant Tissue Culture.
7. Handa, S.S. and Kaul, K.I., Suppliments to Cultivation and Utilization of Medicinal Plants.
8. Wealth of India. Raw Material, CSIR, Lucknow.
9. Quality Standards of Indian Medicinal Plants, Vol.1, ICMR, New Delhi.
10. WHO Guidelines for Quality Control of Herbal Plant Material.
11. Indian Pharmacopoeia, 2010
12. Ayurvedic Formulary of India,
13. British Herbal Pharmacopoeia, 1993.
14. Harborne, Comparative Biochemistry of Flavonoids.
15. Turner, R., Screening Methods of pharmacology.
16. Choudhary, R. D., Herbal Drug Industry, 1st Ed., Eastern Publisher, New Delhi, 1996.
17. Mukherjee, P. R., GMP for Botanicals-Regulatory and Quality Issues and Phytomedicines , 1st Ed., Business Horisons, 2003.
18. Pande, H., Herbal Cosmetics, Asia Pacific Business Press, New Delhi.
19. Pande, H., Herbal Perfumes and Cosmetics, National Institute of Industrial Research, New Delhi.
20. PDR for Herbal Medicines, 2nd Ed., Medicinal Economic Company, New Jersey, 2000.
21. Indian Herbal Pharmacopoeia, Vol I and II, RRL IDMA, 1998 and 2000.
22. Rangari, V. D., Pharmacognosy and Phytochemistry.

Subject code: MNP-P9
Subject: NATURAL PRODUCTS & BIO-ORGANIC CHEMISTRY
Practical: 8 hrs. /week

1. Determination of leaf surface data such as stomatal number, stomatal index, palisade ratio, vein-islet number and vein-islet termination number.
2. Experiments based on WHO guidelines for quality control of medicinal plants.
3. Preparation of permanent slides of important medicinal plants.
4. Study of spectroscopy and degradative methods for alkaloids, flavonoids, triterpenoids, sterols, coumarin (2-3 examples)

Subject code: MNP-P10
Subject: STANDARDIZATION OF NATURAL PRODUCTS
Practical: 8 hrs. /week

1. Determination of Anthracene derivatives in senna by spectrophotometric method, Reserpine in Rauwolfia by Photometric method, Carvone content of Umbeliferous fruits, Citral content in Lemongrass oil.
2. Determination of ascorbic acid by UV spectroscopic method in some crude drugs.
3. Paper chromatography and TLC of active principles of natural products.
4. Study of UV and FTIR spectral data of some phytoconstituents.
5. Separation of Solanaceous alkaloids from Belladona leaf by TLC using hyoscine and hyoscyamine as reference compounds.
6. Quantitative estimation of Ephedrine in Ephedra extracts by HPTLC method (only demonstration).
7. Quantitative estimation of Reserpine in Rauwolfia extracts by HPLC method (only demonstration).
8. Study of HPTLC and HPLC fingerprinting of some important phytoconstituents (only demonstration).

Semester-III

Subject code: MNP-S13
Subject: SELECTED TOPICS IN NATURAL PRODUCTS
THEORY: 60 Hours (4 hrs. /week)

1. Herbal formulations (general considerations); Single and composite drug formulation of various types; Ayurvedic formulations (Churn, Avaleh, Satwa, Asawa, Aristha etc); Formulations using herbal extracts/pure phytopharmaceuticals. Study of herbal extracts, Processing, Plant and equipment, Project profile, Standarization of herbal formulations.

2. Study of following pharmacognostic parameters -

Lycopodium spore analysis involving quantitation of discrete structures (starch, stone-cells), linear structures (fibers) and spread out tissues (epidermal area) and fluorescence analysis.

3. Study of following analytical methods (with the sole objective of quantitative analysis of active constituents and if needed, comparison with` reference compounds)

i) Chromatographic methods of analysis (PC, TLC, HPTLC, HPLC & GLC)

ii) Colorimetric and fluorimetric methods

iii) Spectral methods (UV, Visible, IR, H-NMR and Mass)

4. Pesticide residues, heavy metal content and microbial contamination in the formulations. Preparation and standardization of herbal cosmetics. Shampoo, Hair conditioners, Hair dye, Skin care products.

RECOMMENDED BOOKS :

1. Choudhary, R. D., Herbal Drug Industry, 1st Ed., Eastern Publisher, New Delhi, 1996.
2. Verpoorte R. and Mukharjee, P. K., GMP for Botanicala-Regulatory an Quality Issues on Phytomedicine., 1st Ed., Business Horizons, New Delhi, 2003.
3. Pande, H., Herbal Cosmetics, Asia Pacific Business Press, New Delhi.
4. Pande, H., "The Complete Technology Book on Herbal Perfumes and Cosmetics", National Institute of Industrial Research, Delhi.
5. Mukhrjee, P. K, Quality Control of Herbal Drugs, 1st Ed., Business Horizons Pharmaceutical Publisher, New Delhi, 2002.
6. PDR for Herbal Medicines, 2nd Ed., Medicinal Economic Company, New Jersey.
7. Indian Herbal Pharmacopoeia, Vol I & II , RRI, IDMA.
8. Kokate, Purohit, Gokhale, Textbook of Pharrnacognosy, 4th Ed., Nirali Pralcashan, 1996.
9. Rangari, V. D., Text book of Pharmacognosy and Phytochemistry.
10. Wanger and Bladt, Plant Drug Analysis, 2nd Ed.
11. Barn, J.N., Finley D.J. and Goodwin, L.G., Biological Standardization.
12. Ayurvedic Phamacopoeia, Vol. I, H and III, 1999.
13. Herbal Pharmacopoeia, Vol I & II , RRI, IDMA.
14. Silverstein, R.M. and Webster, F.X., Spectrometric Identification of Organic Compounds, John Wiley and Sons Inc.

Syllabus prescribed for Degree of Master of Pharmacy in Pharmaceutical Management

Semester-I

Advanced Analytical Techniques (MC-S1 & MC-P1)	Syllabus is same as prescribed for these papers for M. Pharm semester-I examination in Pharmaceutics
Research Methodology and Biostatistics (MC-S2)	
Drug Regulatory Affairs (MC-S3)	

Subject code: MPM-S4
Subject : PHARMACEUTICAL MANAGEMENT-I (GENERAL AND PERSONNEL)
THEORY: 60 Hours (4 hrs. /week)

1. Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.
2. Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management.Introduction to budgeting, costing, accounting, auditing and budgetary control. Entrepreneurship development.
3. Understanding organizations: Meaning, process, types of organization structures & departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs.
4. Professional Mangers: Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.
5. Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.
6. Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.
7. Motivational aspects: theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

RECOMMENDED BOOKS:

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. David R ,Modern Management by Hempran.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Paul and Blanchard Kenneth,Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Prentice Hall of India, New Delhi
8. Richard. H. Hall, Organization Structure, Process and out comes V th Edition
9. Harry A. Smith. ,Principles and Methods of Pharmacy Management III rd Edition
10.Harold Koontz, Heinz Weihrich, Management "Global Perspective" , Tata Mcgraw Hill.
11. P. C. Tripathi., Personnel Management and Industrial Relations.

Subject code: MPM-P4
Subject: PHARMACEUTICAL MANAGEMENT-I (GENERAL AND PERSONNEL)
Practical: 8 hrs. /week

1. Case studies based on the topics mention in theory

Semester-II

Validation & CGMP (MC-S7)	Syllabus is same as prescribed for these papers for M. Pharm semester-II examination in Pharmaceutics
Biological Evaluation (MC-S8 & MC-P8)	

Subject code: MPM-S9
Subject: PHARMACEUTICAL MANAGEMENT-II (PRODUCTION)
THEORY: 60 Hours (4 hrs. /week)

1. Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D**.**

2. Production planning and control, production processes - mass, job and project; plant location and layout; work study (preliminary idea only), materials management- purchase, inventory control and store keeping.

3. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.

Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections.

Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms.

Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management.

4. Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution.

5. Plant Maintenance Management: Importance of maintenance, objective, classification-corrective, scheduled, preventive, and predictive. Replacement analysis.

6. Documentation and Records: Material identification system codes, Master formula records, Master and Batch production and control records. Equipment cleaning and use of Log book, Record relating to container, closure and labeling, production record review, distribution records, Complaints files.

RECOMMENDED BOOKS:

1. Management by Tripathi P. C. and Reddy P. N.; Tata Mc Graw Hill.
2. Business Organization and Management by Shukla M. C.; S. Chand and Company.
3. Business Organization and Management by Sherlakar S. A.; Himalaya.
4. Personnel Management by Filippo E. B.; McGraw Hill.
5. Organizational Behavior by Rao and Narayan; Konark Publishers.
6. Personnel Management by Tripathi P. C.; S. Chand and Company.
7. Pharmaceutical Production and Management by C.V.S. Subrahmanyam, Vallabh Prakashan.
8. Production and Operations Management by S.N.Chary

Subject code: MPM-S10
Subject: PHARMACEUTICAL MARKETING MANAGEMENT
THEORY: 60 Hours (4 hrs. /week)

1. Marketing: Meaning, concepts, importance and emerging trends; Marketing environment; Industry and competitive analysis, Indian Pharmaceutical Industry; Analysing consumer buying behaviour; industrial buying behaviour, Pharmaceutical market segmentation & targeting. Mix Role of 7 P's (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management,

2. Product Decision: Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

3. Pricing: Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

4. Pharmaceutical marketing channels: Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

5. Promotion: meaning ,methods, determinants of promotional mix, promotional budget; overview-personal selling, advertising, sales promotion and public relations.

6. Strategic marketing planning: Marketing implementation and evaluation.

7. E-Pharma Marketing.

8. Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area.

9. Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales, forcasting.

RECOMMENDED BOOKS:

1) Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2) Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.
3) Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4) Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5) Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6) Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, Indian Context,Macmilan India, New Delhi.
7) Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8) Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.
9. Principle and Practice of Marketing in India by Memoria C. B.
10. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
11. Marketing Hand Book Vol. II , Marketing Management by Edwin – E Bobrow, Mark – D. Bobrow.

Subject code: MPM-P9
Subject: PHARMACEUTICAL MANAGEMENT II (PRODUCTION)
Practical: 8 hrs. /week

1. Case studies based on the topics mention in theory

Subject code: MPM-P10
Subject: PHARMACEUTICAL MARKETING MANAGEMENT
Practical: 8 hrs. /week

1. Case studies based on the topics mention in theory

Semester-III

Subject code: MPM-S13
Subject: PHARMA PRODUCT MANAGEMENT
THEORY: **60 Hours (4 hrs. /week)**

1. Introduction to product management: Definition, role of management and scope of product management.
2. Product planning and development: Meaning of product, classification of pharma products, strategic planning for segmenting, targeting and positioning pharma product, product research'and need gap analysis and health services. Operational pharma product planning including pharma sales program and budgeting, organizing and controlling for pharma product management.
3. New product development process and methods: types of new pharma products, complete product development process, product innovation, new product adoption and diffusion process, opinion leadership.
4. Pharma product mix strategies: product portfolio management strategies, product mix, and product line strategies, decision regarding buying and making new product. Product life cycle, strategies: Domestic pharma product life cycle and international pharma product life cycle; stages and strategies for each stage. R and D management for new product development.
5. Brand, packaging, and other pharma product feature: pharma branding process and strategy, OTC generic and prescription product branding. Packaging and labeling, legal and social consumer reports for different kind of packaging and labeling design control of spurious products.
6. Pharma product pricing issues: Social, economic, legal, ethical issues for pharma product pricing in India. Pricing methods and techniques. Other factors influencing pharma product pricing.
7. Pharma product distribution management: pharma product channel design, single channel v/s multiple channel strategies, roles, and responsibilities of chemist for product promotion and distribution.
8. Pharma product promotion: issues in pharma product promotion, approaches for pharma product promotion, DTC, E-detaing, physician related promotion programmers for increasing acceptance and sales of pharma products.
9. Pharmaceutical Brand Management: Branding and it's potential within pharmaceutical industry: history, meaning, need, importance, branding in pharmaceutical industry, building brand values and brand strategy, timing, patient power, strategic brand management process. The role of advertising in branding pharmaceuticals.

RECOMMENDED BOOKS:

1. Aswathappa, k., Organizational Behavior, Himalaya Publishing House, Revised and Enlarge edition, 1994.
2. Luthans, F., Organizational Behavior, Mc-Graw Hill, International Edition.
3. Rao, S.S.V., Human Resource Management and Industrial Relation, Himalaya Publishing House, I edition 1997.
4. Kumar, K., Human Resource management, I edition, 2001.
5. Harrison, T., The Product Manager's Hand book , Published kogan Page London, paperback Edition 1997.
6. Ahiya, K.,K., Material Management, CBS Publishers and Distributors, 1992.
7. Udupa, N.,Selected Topic in Industrial Pharmacy, Verghese Publishing House, II eddition 1992.
8. Mickey C. Smith, Principles of Pharmaceutical Marketing, Second Edition, Published by Lea Febiger. 1975,
9. Smarta, R, B., Revitalizing the Pharmnaceutical Business, Innovative Marketing Approaches 1st Edition, 1999, Response Books (Sage Publications)

Annexure-I

Elective Subjects:

Group A: Pharmaceutics, Industrial Pharmacy, Biotechnology

1. Advanced biotechnology
2. Advnaces in Fermentation Technology
3. Hospital and Clinical pharmacy
4. Nanotechnology and Biotechnology
5. Pharmaceutical Plant Design and Operations
6. Sterile Product Formulation and Technology

Group B: Pharmaceutical Chemistry

1. Chemistry of Natural Products
2. Chemoinformatics
3. Combinatorial Chemistry
4. Green Chemistry
5. Organic Drug Synthesis
6. Rational Drug Design

Group C: Pharmacology, Clinical Pharmacy

1. Advance Molecular Biology
2. Clinical Research and Development
3. Immunopharmacology
4. Neurobiology
5. Pharmacoepidemiology
6. Safety Pharmacology

Group D: Pharmacognosy, Natural Products

1. Advances in Phytochemistry
2. Herbal Cosmetics
3. Herbal Drug Technology
4. Medicinal Plant Biotechnology
5. Natural Product Management
6. Plant Tissue Culture Techniques

Group E: Quality Assurance, Pharmaceutical Management, Pharmacoinformatics

1. Active Pharmaceutical Ingredients (APIs) Management Technology
2. Human Behaviour in Organization
3. Material Management and Inventory Control
4. Packaging Technology
5. Pharmaceutical Marketing and Market Research
6. Quality Planning and Analysis

Draft Syllabus Prescribed for M. Pharm. (Credit System) - Elective Subjects

GROUP A: PHARMACEUTICS, INDUSTRIAL PHARMACY, BIOTECHNOLOGY

Subject code: MPHE1
Subject: ADVANCED BIOTECHNOLOGY
Theory: **30 Hours (2 hrs./week)**

1. **Biomembrane and Bioenergetics:** Introduction to Biological Membranes: Historical development of the concept of unit membrane. Diversity of membrane composition. Membranes in different organelles. Unified concept of membrane in terms of biological functions.
2. **Molecular Organisation in Biomembranes**: Role of lipids and proteins. Artificial membrane like structures. Liposomes, Stability of bilayer, Semifluidity and temperature transition. Singer-Nicholson model. Asymmetry in membrane constituents. Molecular motion in biomembrane. Hydrophobicity of membranes. Physico chemical probes in membrane studies.
3. **Membrane Functions**: Barrier to prediffusion, specific transport mechanism, passive carrier mediated, active, translocation. Transport of proteins. Molecular mechanism of active transport. REC membrane and glucose transport, lactose transport in bacteria. Membrane proteins and recognition. Insulin and other hormone receptors. Receptors for neurotransmitters, Adenyl cyclase.
4. **Energetics**: Classical thermodynamics, Irreversible thermodynamics, on sagar matrix, coupling open systems, equilibrium aid other equilibrium conditions. Central role of ATP. High energy compounds. Oxidation-reduction enzymes and electron transport chain. Oxidative phosphorylation. Structure of mitochondria- Mitochondrial vesicles. Mitochondria ATPase. Theories of oxidative phosphorylation. Chemiosmotic theory of Mitchell. Uncouplers. Innophores Protein gradient and energy generation. Transmembrane potential. Energy trapping in closed vesicle-natural or artificial.

RECOMMENDED BOOKS:

1. Reddish, Antiseptics, Disinfectants, Fungicides and Chemical and Physical Sterilisation, Lea and Febiger.
2. Rainbow and Rose, Biochemistry of Industrial Microorganisms, Academic Press.
3. MW Miller, 1961. The Pfizer Handbook of Microbial Metabolites. McGraw-Hill, Blakiston Division, New York.
4. Trevan and Others, Biotechnology, The Biological Principles, Tata McGraw Hill Co.
5. Wilman, Cells and Tissues in Cultures, Vol. 3, Academic Press.
6. MJ Pelczar, Jr. ECS Chain, NK Kreig, 2008. Microbiology, McGraw Hill Edition, New York.
7. H W DOELLE, 1975. Bacterial Metabolism (2nd Edition). New York–San Francisco–London 1975, Academic Press.

Subject code: MPHE2
Subject: FERMENTATION TECHNOLOGY
Theory: 30 Hours (2 hrs./week)

1. **Introduction**: General review of microbial products and processes. Bacterial starter cultures, different types of microorganisms used in the industries for the production of various microbial products e.g. bacteria, actinomycetes, fungi, yeast etc.

2. **Screening of Cultures**: Isolation, identification and preservation of culture, Development of strain: introduction, cell division (mitosis/meiosis), Mendelian genetics metabolic controls, mutational selection and classes of mutants, protoplast fusion, Recombination DNA technology.

3. **Theory and design of aerobic fermentation**: Operations involved, importance of each process, value of the products, degree of asepsis required, nature of organism used, choice of equipment and its design, biochemical engineering problems in fermentation technology.

4. **Bioreactors**: Introduction, oxygen transfer, gas liquid mass transfer in microbial growth and effect of mixing and non-mixing on O2 uptake rate, effect of substance concentration, accumulation of product and temperature on growth and respiration rate, effect of temperature on specific death rate and its determination, various types of bioreactors-stirred tank, airlift, fludized, microcarrier, membrane bioreactor, fluid bed and film bed bioreactor, mono chemostat model and effect of recycle concept pf nonideal bioreactor. Design of steriliser, bath sterilisation of media, temperature-time profile and design calculation continuous, sterilisation of media, residence time concept. Types of cultures of micro-organism-batch continuous, semibatch, recycle reactor. Enzyme reactors-theory and limitation, film and floes, immobilised enzymes and cell reactors.

5. **Downstream processing:** physical separation processes-solid-liquid systems, flocculation, coagulations, centrifugation, Equilibrium processes-distillation, drying and crystallisation. Rate processes-chromatography, membrane separation, reverse osmosis.

RECOMMENDED BOOKS:

1. Prescott and Dunn's Industrial Microbiology, 1981. Gerald reed 9Ed), Chapman & Hall; 4 Sub edition.
2. Stanbury and Whitaker, Principles of Fermentation Technology, Pergamon Press.
3. Peppier, Perlman, Microbial Technology, Vol. I and II, Academic Press.
4. Scragg, Biotechnology for Engineers, Biological System in Technological Processes, Ellis Horwood Limited.
5. Dechow, Separation and Purification Techniques in Biotechnology, Noyes Publications.
6. Asenjo, Separation Processes in Biotechnology, Marcel Dekker. Inc.
7. Fermentation Technology in Industries, B. V. Patel Education Trust.

Subject code: MPHE3
Subject: HOSPITAL AND CLINICAL PHARMACY
Theory: 30 Hours (2 hrs. /week)

1. **Pharmacoepidemiology**
   Definition, Origin and evaluation of pharmacoepidemiology, aims and applications, need for pharmacoepidemiology. Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

   Drug utilization review, surveys of drug use, case reports, case series, cross-sectional studies, cohort studies, case control studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

2. **Clinical Pharmacokinetics and therapeutic drug monitoring**
   i) Clinical Pharmacokinetics
   Introduction to clinical pharmacokinetics Nomograms and tabulations in designing dosage regimen, conversion from intravenous to oral dosing, determination of dose and dosing interval, drug dosing in the elderly and pediatrics and obese patients.
   Pharmacokinetic drug interactions, Inhibition and induction of drug metabolism, Inhibition of biliary excretion.

   ii) Therapeutic drug monitoring
   Introduction
   Individualization of drug dosage regimen (variability – genetic, age and weight, disease, interacting drugs). Indications for TDM, Protocol for TDM
   Pharmacokinetic/Pharmacodynamic correlation in drug therapy TDM of drugs use in the following disease conditions: cardiovascular disease, CNS conditions.

   iii) Dosage adjustment in renal and hepatic disease
   Renal impairment. Pharmacokinetic considerations. General approach for dosage adjustment in renal disease. Measurement of glomerular filtration rate and creatinine clearance. Effect of hepatic disease of pharmacokinetics

3. **Clinical Toxicology**
   General principles involved in the management of poisoning
   Antidotes and their clinical applications. Supportive care in clinical toxicology
   Gut decontamination. Elimination enhancement. Toxicokinetics

4. **Clinical symptoms and management of acute poisoning with the following agents:**
   Pesticide poisoning: organophosphorus compounds, carbamates, organochlorines, pyrethroids Opiate overdose, Antidepressants, Barbiturates and benzodiazepines, Alcohol: ethanol, methanol, Paracetamol and salicylates, Non-steroidal anti-inflammatory drugs, Radiation poisoning

5. **Clinical symptoms and management of chronic poisoning with the following agents:**
   Heavy metals: Arsenic, lead, mercury, iron, copper. Food poisoning
6. **Hospital pharmacy – organization and management**
   Organisational structure – staff, infrastructure & work load statistics. Management of materials and finance. Roles & responsibilities of hospital pharmacist
   The budget – Preparation and implementation

7. **Hospital drug policy**
   Pharmacy and therapeutic committee (PTC); Hospital formulary; Hospital committees: Infection committee, Research and Ethical committee

8. **Hospital pharmacy services**
   Procurement & warehousing of drugs and pharmaceuticals
   Inventory control: definition, methods of inventory control, ABC, VED, EOQ, lead time, safety stock.

9. **Drug distribution in the hospital**
   Individual prescription method. Floor stock method. Unit dose drug distribution method. Distribution of Narcotic and other controlled substances. Central sterile supply services – role of pharmacist. Radio pharmaceuticals – handling and packaging.

RECOMMENDED BOOKS:

1. Malcolm Rowland & Thomasn Tozer. Clinical Pharmacakinetics & Concepts and Applications Lippincott Williams & Wilkins 1995
2. Ellenhorns Medical Toxicology – Diagnosis and treatment of poisoning. Mathew J. Ellenhorn.. Williams and Willkins publication, London. Second Edition
3. Hospital Pharmacy by William E. Hassan
4. Brian L. Strom, Stephen E. Kimmel. Textbook of Pharmaco-epidemiology. Wiley Drug Interactions. Stockley I.H. (1996). The Pharmaceutical Press
5. Toxicology - The basic science of poisons, international edition, Curtis D.Klaassen, 6th edition
6. Toxicology – Principles and Applications, Raymond J.M.Niesink, John de.Vries, Mannfred A. Hollinger
7. Drug Interaction Facts, 2003. David S. Tatro.
8. Toxicology - The basic science of poisons, international edition, Curtis D.Klaassen, 6th edition.

Subject code: MPHE4
Subject: NANOTECHNOLOGY AND BIOTECHNOLOGY
Theory: 30 Hours (2 hrs. /week)

1. **Bionanotechnology:** History, opportunities and challenges of bionanotechnology, growth potential of bionanotechnology, significance of nanosize in biotechnology and medicine.

2. **New Drug Delivery:** Conventional delivery of biotechnologicals and its limitations, Biological barriers in delivery of therapeutics, importance of nano-size in site-selective delivery, Targeted delivery of biotechnological using nanoconstructs, Application of nanocarriers in delivery of biotechnologicals, Naño-drug delivery chip.

3. **Bionanocarriers:** Design and fabrications of nanocapsules, nanoliposomes, nanoparticles, nanoemulsion, Nanopore technology, Nano-self assembling systems, Bionanoarrays, Dendrimers, Carbon nanotubes, Nanosomes and Polymersomes, Inorganic nanoparticles (Gold-gold colloids, gold nanofilm, gold nanorods, Titanium and Zinc oxide), structured DNA nanotechnology.

4. **Nanomedicine Nanobiology and Nanobiotechnology:** Synthesis and assembling of nanoparticles/nanostructures using bio-derived templates, Proteins and nanoparticles,

covalent and non-covalent conjugates, Cantilevers array sensors for bioanalysis and diagnostics, Nanowire and nanotube biomolecular sensors for in-vitro diagnosis of cancer and other diseases. Biologically inspired hybrid nanodevices, Nanotube Membranes for Biotechnology, Shelf-assembling of short peptides for nanotechnologicals applications.

5. **Bionanoimaging:** Quantum dots-luminescent semiconductor QD in cell and tissue imaging, Fluroimmunoassay using QD. Ultrasound contrast agents, Magnetic nanoparticles, Nanoparticles in molecular imaging, Nanoforce and imaging-AFM, Molecules, cells, materials and systems design based on nanobiotechnology for use in bioanalytical technology.

6. **Instrumentation and Principles:** Electrophoresis techniques, Laser confocal microscopy, Digital image analysis, Biosensors in diagnostics, Enzyme purification and assay techniques, techniques in cytogenetics: DNA sequencing, DNA microarray, Spectral analysis techniques: Introduction, estimation of proteins, DNA and RNA.

7. **Safety Concern of Bionanotechnologicals:** Inhalation, Contact/dermal delivery, Environmental impact, Explosion hazards.

RECOMMENDED BOOKS:

1. E.S. Papazoglou and A. Parthasarathy, "Bionanotechnology". 1st Ed. Morgan & Claypool.
2. N.H. Malsch. 2005. "Biomedical nanotechnology" CRC Press.
3. D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
4. T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
5. V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology". Wiley-Interscience: Hoboken.
6. S.P. Vyas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and controlled drug delivery" CBS Publishers and Distributors.

Subject code: MPHE5
Subject: PHARMACEUTICAL PLANT DESIGN AND OPERATIONS
Theory: 30 Hours (2 hrs. /week)

1. **Regulatory Aspects:** Introduction, Key stages in drug Approval Process, Example of Requirement, Post-Marketing Evaluation, Procedures for Authorizing Medicinal Products.

2. **Good Manufacturing Practice:** Introduction, GMP Design Requirement, GMP Reviews of Design.

3. **Validation:** Introduction, Preliminary Activities, Validation Master Planning (VMP), Development of Qualification Protocols and Reports, Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), Handover and Process Optimization, Performance Qualification, (PQ), Process Validation (PV), Cleaning

Validation, Computer System Validation, Analytical Method Validation, Change Control and Revalidation.

4. **Primary Production:** Reaction, Key Unit Operation, Production Methods and Considerations, Principles for layout of Bulk Production Facilities, GMP.

5. **Secondary Pharmaceutical Production:** Products and Processes, Principles of layout and Building Design, The Operating Environment, Containment Issues, Packaging Operations, Warehousing and Material Handling, Automated Production Systems, Advanced Packaging Technologies.

6. **Safety, Health and Environment (SHE):** Introduction, SHE Management, System Approach to SHE, Risk Assessment, Pharmaceutical Industry SHE Hazards, Safety, Health and Environment Legislation.

7. **Design of Utilities and Services:** Introduction, Objective, cGMP, Design, Utility and Service System Design, Sizing of System for Batch Production, Solids Transfer, Cleaning System, Effluent Treatment and Waste Minimization, General Engineering Practice Requirements, Installation, In-House Versus Contractors, Planned and Preventive Maintenance.

8. **Laboratory Design:** Introduction, Planning a Laboratory, Furniture Design, Fume Cupboards, Extraction Hoods, Utility Services, Fume Extraction, Air Flow System, Safety and Containment.

9. **Process Development Facilities and Pilot Plant:** Introduction, Primary and secondary Processing, Process Development, Small Scale Pilot Facilities, Chemical Synthesis pilot plants, Physical Manipulation Pilot plant, Final formulation, Filling and packing pilot plats, Safety, Health and Environmental Reviews, Optimization.

10. **Pilot Manufacturing Facilities for the Development and manufacturing of Biopharmaceutical Product:** Introduction, Regulatory, Design and Operating Considerations, Primary Production, Secondary Production, Design of Facilities and Equipment, Process Utilities and Services.

RECOMMENDED BOOKS:

1. Pharmaceutical Manufacturing handbook: Production and processes, Edited by Shayne Cox Gad, John Wiley and Sons, Inc., New Jersey.
2. Pharmaceutical production: An Engineering Guide, Edited by Bill Bennett and Graham Cole, 2003, Published by Institute of Chemical Engineers, Warwickshire, UK.
3. Pharmaceutical production Facilities: Design and Applications, Edited by Graham Cole, second edition, Taylor and Francis, 2003.
4. Good pharmaceutical manufacturing practice: rationale and compliance, John Sharp CRC Press.
5. Modern pharmaceutical industry, Thomas Jacobson, Albert Wertheimer, Jones and Barlett publishers, LONDON , UK.
6. Ethics and Pharmaceutical industry, Michael Santoro, Thomas Gorrie, Cambridge university press, 2005, new York, USA.

Subject code: MPHE6
Subject: STERILE PRODUCTS FORMULATION AND TECHNOLOGY
Theory: 30 Hours (2 hrs. /week)

1. **Biopharmaceutical Factors Influencing Bioavailability:** Physicochemical influences on bioavailability, Physiologic factors influencing drug absorption, Dosage form considerations, Drug absorption and bioavailability from intramuscular injection. Drug absorption from subcutaneous injection, Biopharmaceutics of intrathecal injections, Parenteral administration of peptides and proteins, Parenteral drug delivery systems.

2. **Preformulation Research:** Introduction, Drug substance physicochemical properties, General modes of drug degradation, Preformulation studies for proteins and peptides, Preformulation screening of parenteral packaging components.

3. **SVP and LVP:** Introduction to SVP, Formulation principle, Special types of parenterals (Suspension, Emulsion, Dried Forms), Container effect on formulation, Stability evaluation.Introduction to LVP, Concept of formulation, Formulation development, Solution Quality.

4. **Sustained/Controlled Release Parenterals Drug products:** Biopharmaceutics, Biocompability of polymeric materials, Sustained/controlled release dosage forms: - Aqueous solutions, Aqueous suspensions, Oil solutions, Oil suspensions, Biocompatible carrier, Liposomes, Nanoparticles, Infusion devices, Prodrug.

5. **Design Consideration For Parenteral Production Facility:** Introduction, Site selection, Facility area use planning, Design concepts.

6. **Environmental control:** Introduction, Control of contamination, Environmental contamination control system design, Clean rooms, Personnel contamination control.

7. **Quality Control:** Sterility testing, FDA guidelines on sterility testing, Pyrogen testing, Particulate matter testing, Package integrity testing.

RECOMMENDED BOOKS:

1. K. E. Avis, H. A. Liebermann and Lachman; Pharmaceutical dosage forms: Parenteral Medications: Vol.1, 2, 3, Marcel Dekker.
2. S. J. Turco Sterile Dosage Forms: their preparation and clinical application; 4th Edition. Lee and Febiger.
3. N. K. Jain; Controlled and Novel drug delivery: CBS Publication.
4. J. R. Robinson and H. L. Lee; Controlled drugs delivery: Fundamentals and Applications; Marcel Dekker.
5. S.P. Vyas and R. K. Khar, Controlled drug delivery: concepts and advances; Vallabh Prakashan.
6. M. J. Akers, Parenteral Quality Control. Third Edition. Marcel Dekkers.

GROUP B: PHARMACEUTICAL CHEMISTRY

Subject code: MPCE7
Subject: CHEMISTRY OF NATURAL PRODUCTS
Theory: 30 Hours (2 hrs. /week)

1. **Alkaloids:** General introduction, classification, isolation and purification methods, general methods employed for determining the structure of alkaloids, constitution of morphine, reserpine, atropine and quinine.
2. **Steroids:** Introduction, stereochemistry, nomenclature and structure elucidation of cholesterol, sapogenin and cardiac glycosides.
3. **Amino acids and peptides:** Introduction, synthesis of peptides and amino acids. End group analysis, structural features of Insulin, vasopressin and oxytocin.
4. **Carbohydrates:** Brief introduction, Configuration of monosaccharides, ring structure of monosaccharides, disaccharides – determination of structures of sucrose, maltose and lactose, Polysaccharides – cellulose and starch.
5. **Flavonoids:** Detailed chemical account of rutin and quercetin.
6. **Coumarins:** General methods of isolation and purification and structural determination of Xanthotoxin and psoralene.
7. **Structure elucidation:** Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (^{1}H, ^{13}C).

    i) Carvone, citral; menthol
    ii) Luteolin; kaempferol
    iii) Luteolin-7-O-glucoside
    iv) Nicotine; papaverine
    v) Estrone; progesterone

Note: In teaching unit – 7 the exact shift values need not be given. It is sufficient if the student is taught how many peaks appear for the compound in the NMR and approximately, in which region.

RECOMMENDED BOOKS:

1. I.L. Finar, Organic Chemistry, Vol.2, Stereochemistry and Chemistry of Natural Products 5rd edition, Pearson - Pearson Education.
2. L.F. Fieser and M. Fieser, Steroids, Reinhold Publishing Co., New York.
3. K.B.G. Torsell, Natural Products Chemistry, John Wiley and Sons, New York.
4. J.B. Harborne, Phytochemical Methods, Chapman and Hall, London.
5. Burger's Medicinal Chemistry and Drug Discovery, Vol. I. Principle and Practice, 5th, Edition, John Wiley Sons, New York.
6. Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams and Wilkins.
7. T.L. Lemke, D.A. Williams, V.F. Roche and S.W. Zfto, Foye's Principles of Medicinal Chemistry, 6th edition, Lippincott Williams and Wilkins.
8. M.L. Wickery and B. Wickery, Secondary Plant Metabolism McMillan Press Ltd. London.
9. G.A. Cordell, 1999, The Alkaloids, Vol. 52, Academic Press.

Subject code: MPCE2
Subject: Chemoinformatics
Theory: **30 Hours (2 hrs. /week)**

1. **Representation of chemical compounds**
   Chemical nomenclature, line notations, coding the constitution, processing constitutional information, different ways to represent molecular structure, representation of stereochemistry, representation of 3D structures, molecular surfaces, visualization of molecular models, molecular structure drawing softwares.

2. **Representation of chemical reactions**
   Reaction types, reaction center, chemical reactivity, reaction classification, stereochemistry of reactions.

3. **The data**
   Data acquisition, data preprocessing, preparation of data sets for validation of the model quality, training and test data sets, compilation of test sets.

4. **Databases and data sources in chemistry**
   Basic database theory, search engine, classification of databases, literature databases, tutorial using chemical abstract system, property (numeric) databases, crystallographic databases, structure databases, chemical reaction database, patent databases, chemical information on the internet.

5. **Calculation of physical and chemical data**
   Empirical approaches to the calculation of properties, molecular mechanics, molecular dynamics, quantum mechanics.

6. **Calculation of structure descriptors**
   Structure descriptors and their classification, topological descriptors, 3D descriptors, chirality descriptors, chirality codes, comparative molecular field analysis.

7. **Methods for data analysis**
   Machine learning techniques, Decision tree, chemometrics, neural networks, fuzzy steps and fuzzy logic, genetic algorithms, data mining, visual data mining, expert systems.

8. **Applications**
   Prediction of properties of compounds, LFER, QSPR, structure spectra correlation, chemical reactions and synthesis design, drug design.

RECOMMENDED BOOKS:

1. Johann Gasteiger and Thomas Engel, 2003, Chemoinformatics-A Text Book, Wiley-VCH Verlag GmbH & Co. KGaA.
2. Hans Dieter Holtje, Wolfgang Sippl, Didier Rognan, Gerd Folkers, 2003, Molecular Modeling, Wiley-VCH Verlag GmbH & Co. KGaA
3. Jure Zupan, Johann Gasteiger, 1999, Neural Networks in Chemistry and Drug Design, Wiley-VCH Verlag GmbH & Co. KGaA.
4. http://franklin.chm.colostate.edu/mmac
5. A.R. Leach, Molecular Modeling- Principles and applications, 2nd edition, Pearson Education, Harlow, UK, 2001.
6. D.M. Cvetkovic, M. Doob, H. Sachs, 1995, Spectra of Graphs: Theory and Applications, 3rd edition, Johann Ambrosius Barth Verlag, Heidelberg.

Subject code: MPCE3
Subject: COMBINATORIAL CHEMISTRY
Theory: 30 Hours (2 hrs. /week)

1. Combinatorial chemistry – principles, methods, drug design and combinatorial methodology, possible limitations of combinatorial chemistry.
2. Organic reactions popular in combinatorial chemistry. This includes amide bond formation, amine alkylation, crosscoupling reactions, alkene metathesis, multicomponent reactions and heterocycle synthesis.
3. Solid-phase organic synthesis. The advantages offered by solid-phase synthesis. Methods for resin immobilization, compound cleavage and analytical methods for monitoring reactions.
4. Solution-phase parallel synthesis. Methods employing phase switching such as fluorous tags. The applications of resin-bound reagents and scavengers for simplifying reaction workup.
5. Mixture-based compound libraries. Techniques for extracting information from highly pooled samples, including iterative deconvolution, positional scanning and bead-based screening. Methods for bead encoding.
6. Principles of compound library design. Lipinski's rules and other guidelines for drug like properties. The concept of privileged scaffolds, illustrated by benzodiazepines and arylindoles.
7. Natural product and natural product-like libraries. The differences between synthetic compounds and natural products, and methods for exploiting the latter as a source of molecular diversity.

RECOMMENDED BOOKS:

1. W Bannwarth & B Hinzen, Combinatorial Chemistry, From Theory to Application. Wiley-VCH Verlag GmbH & Co. KGaA., Vol. 26, 2006
2. P A Bartlett & R M Entzeroth, Exploiting Chemical Diversity for Drug Discovery, Royal Society of Chemistry, Vol. 24, 2006.
3. N.K. Terrett, Combinatorial Chemistry, Oxford University Press, Vol. 2, 1998.
4. Anthony W Czarnik, Combinatorial Chemistry: Synthesis and Application, A Wiley-Interscience Publication, 1997
5. Bing Yan, Analytical Methods in Combinatorial Chemistry, Technomic Publication Company, Vol. 6, 2000.
6. Benjamin L. Miller, Dynamic combinatorial Chemistry in drug Discovery, Bioorganic Chemistry and Material Sciences. Vol. 1-10, Hoboken, N.J. John Wiley & Sons Publication, 2010.
7. Gunther Jung, Combinatorial Peptide and Non Peptide Library, Wiley-VCH Verlag GmbH & Co. KGaA., 1996.

Subject code: MPCE4
Subject: GREEN CHEMISTRY
Theory: **30 Hours (2 hrs. /week)**

1. **Introduction**
   The costs of waste, the greening of chemistry and its need, specific health and environmental requirements,

2. **Principles of sustainable and green chemistry**
   Green chemistry and industry, Waste minimization and atom economy, reduction of materials use, reduction of energy requirement, reduction of risk and hazard

3. **Waste minimization in pharmaceutical process development**
   Principles, practice and challenges, focus of process chemistry, safety, increasing complexity, means of purification, choice of starting material, number and order of steps, solvents, reagents, reaction temperature, heavy metals.

4. **Green solvents for chemistry**
   Solvent Usage, Global Effects of Solvent Usage, Chemical Properties of Solvents, Solvent Effects and Green Chemistry, Green Solvents and its definition, green solvents for academic and industrial chemistry, criteria for Selection of Green Solvents, green solvents: ecology and economics.

5. **Extraction of Natural Products with Superheated Water**
   Properties of superheated water, extraction of other plant materials, chromatography with superheated water, process development, extraction with reaction.

6. **Sonochemistry**
   Power ultrasound, apparatus available for sonochemistry, sonochemistry in chemical synthesis, ultrasound in electrochemistry, ultrasound in environmental protection and waste control, enhanced extraction of raw materials from plants, large-scale sonochemistry

RECOMMENDED BOOKS:

1. James Clark & Duncan Macquarie, Handbook of Green Chemistry and Technology, Blackwell Publishing
2. William M. Nelson, Green solvents for Chemistry: Perspectives and Practice, Oxford University Press
3. Anastas, P. T., & Williamson, T. C. Green Chemistry: Frontiers in Benign Chemical Syntheses and Processes. Oxford University Press, Oxford,
4. Repic, O. Process Research and Chemical Development in the Pharmaceutical Industry. John Wiley, New York,
5. Jones, D. G. Chemistry and Industry. Applications of Basic Principles in Research and Process Development. Oxford University Press, Oxford
6. Mason, T. J. Sonochemistry: the Uses of Ultrasound in Chemistry. Royal Society of Chemistry, London.

Subject code: MPCE5
Subject: ORGANIC DRUG SYNTHESIS
Theory: **30 Hours (2 hrs. /week)**

1. **High Throughput Synthesis**
   synthesis strategies; combinatorial synthesis techniques; library design; combinatorial approaches for reaction optimization, assays and screening of libraries.

2. **Chiral Technology**
   Introduction to Chirality and Techniques used in asymmetric synthesis of Diltiazem, Timolol, Ampicillin, Dextrapropoxyphen, Citrenalol, Propranolol, Atenolol, and Naproxen.

3. **Microorganisms in Drug Synthesis and Development**
   Microbial conversions of drugs like steroids, prostaglandin, antibiotics, enzyme immobilization Techniques.

4. Synthesis of agents used in neurodegenerative diseases: like Alzheimer's and Parkinsonism

5. Synthesis of agents used in treatment of AIDS: Life cycle of HIV and Drugs used.

6. **Proteins and Peptide drugs:**
   Chemistry, structure, stability and reactivity of proteins and peptides. Different ways to synthesize proteins and peptides - study of Insulin, Relaxin, Somatostatin, DNAse Interferon

7. **Structure based drug design and synthesis**

RECOMMENDED BOOKS:

1. Burger's Medicinal Chemistry and Drug Discovery, Vol. I. Principle and Practice, 5th, Edition, John Wiley Sons, New York.
2. Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams and Wilkins.
3. T.L. Lemke, D.A. Williams, V.F. Roche and S.W. Zfto, Foye's Principles of Medicinal Chemistry, 6th edition, Lippincott Williams and Wilkins.
4. Daniel Lednicer, 2008, Strategies for Organic Drug synthesis and Design, John Wiley &. Sons New York.
5. Stuart Warren, 2002, Organic Synthesis: The Disconnection Approach, John Wiley & Sons, Ltd.

Subject code: MPCE6
Subject: RATIONAL DRUG DESIGN
Theory: **30 Hours (2 hrs. /week)**

1. DRUG DISCOVERY
   a. Historical Perspective
   b. Drug Discovery studies in Direct Drug Design (Structure based) ND Indirect Drug Design
   c. Target Selection and Lead Identification
      Natural Product Sources
      Fermentation/ microbial sources

Synthetic

d. Introduction to Pharmacogenomics.

2. A general study of co-relation of physicochemical properties and stereochemistry on drug action. Isosterism and bio-isosterism as guides to structural variations, metabolite, antagonism and theory of drug action.

3. An overall treatment of various approaches to drug design including the method of variation, e.g. – Fibonacci search, Topliss tree, Craigs plot, Simplex methods, and Cluster analysis.

4. Quantitative Structure-Activity Relationships (QSAR) with detail coverage of Hansch's Linear method, Free and Wilson methods, mixed approach, principal component analysis and application of above.

5. Drug design based on antagonism and enzyme inhibition.

6. Computer Aided Drug Design, Basic concept of computational chemistry like Quantum Mechanics, molecular mechanics, Force fields, Energy minimization, conformational reaction, Molecular Dynamics. Ligand based drug design based on active site of receptor/enzyme. Indirect Drug Design – Analog approach, Pharmacophore mapping, Template forcing, Excluded volume & shape analysis, artificial intelligence methods.

7. Drug metabolism based drug design: Pro-drug design.

8. Introduction to recent advances in drug design

9. Quantitative structure pharmacokinetic relationship (QSPR), Bioinformatics, Genomic & Proteomics.

RECOMMENDED BOOKS:

1. John Smith & Hywel Williams, Introduction to the Principles of Drug Design, Wright PSG.
2. Burgers Medicinal chemistry-The Basis of Medicinal chemistry by Manfred E. Wolff part-I John Wiley & Sons.
3. Edward. C. Olson, Computer Assisted Drug Design, American Chemical Society..
4. S. M. Roberts and B. J. Price. Medicinal Chemistry – The Role of Organic Chemistry in Drug Research by Principle's of Medicinal Chemistry – Foye.
5. Comprehensive Medicinal Chemistry by Hansch & Leo, Vol. 4.
6. QSAR & Strategies in the design of Bioactive Compound J. K. Seydel Latest after 1984 Deuts che Bibliofech.
7. Propst & Thomas, 1997, Nucleic Acid Targeted Drug Design, Marcel Decker.
8. Pandi veera Pandian, 1997, Structure Based Drug Design, Merck Decker,
9. Burger Alfred, 1997, A Guide to chemical Basis of Drug Design, Wiley Interscience.
10. Patrick Bultinck, 2004, Computational Medicinal Chemistry for Drug Design, 1st edition, Marcel Decker.

GROUP C: PHARMACOLOGY, CLINICAL PHARMACY

Subject code: MPLE1
Subject: ADVANCE MOLECULAR BIOLOGY
Theory: **30 Hours (2 hrs. /week)**

1. Introduction to molecular biology.
2. Background: Mendel and genes; genetic terminology; genetic mapping. Cells and chromosomes. Discovery of the role of DNA; overview of how it fills that role. DNA structures. Protein structure; role of weak bonds. Mutations, an introduction.
3. Transcription. How RNA polymerase recognizes (and distinguishes) genes; promoters, σ (sigma) factors. Interaction of transcription and DNA supercoiling. Elongation and termination.
4. Gene regulation; DNA-protein interactions. Proteins interact with DNA and modulate its structure and function. The Lac operon paradigm, plus a sampling of other regulatory systems. Types of DNA-binding proteins; sequence recognition; DNA-bending.
5. Transcription in eukaryotes. An introduction to the complexity of the transcriptional apparatus in higher organisms.
6. Translation. Formation of initiation complex, prokaryotes and eukaryotes. Genetic code: standard and variations; recoding. The players mRNA, tRNA, activating enzymes, ribosomes, "factors".
7. DNA replication, DNA polymerases. Issues of the replication process: getting started, priming, unwinding the template, working accurately, hanging on, finishing and untangling. The replication apparatus, or replisome. Repair processes; topoisomerases.

RECOMMENDED BOOKS:

1 Harvey Lodish, Arnold Berk, Paul Matsudaira and James Darnel. Molecular Biology, W.H Freeman and company, 2000, 4th edition.
2 Bruce Albert, Molecular Biology of the cell, Garland Science, 2002, 3rd edition.
3 J.D.Watson. Molecular Biology of the Gene, Old spring harbor laboratory press, 2005.
4 B.R.Glick, J.J.Pasternak, Cheryl L. Patten. Molecular Biotechnology-Principles and Application of Recombinant DNA, American Society for Microbiology, Washington, 2006.
5 Jack J. Pasternack, An introduction to human molecular genetics-Mechanism of inherited disease. John Wiley and sons, 2005.
6 A.N.Glazer and H. Nikaido, Microbial biotechnology, Cambridge University press, 2007.
7 F.C. Neidhardt, Escherichia coli and Salmonella, cellular and Molecular Biology, American Society for Microbiology, Washington, 1987.
8 R.C.King. A Dictionary of Genetics, Oxford University press USA. 7th edition.
9 K.Drlica, Understanding DNA and Gene cloning-a guide for curious, Public Health Research Institute. 4th edition.

Subject code: MPLE2
Subject: CLINICAL RESEARCH AND DEVELOPMENT

Theory: **30 Hours (2 hrs. /week)**

1. **Introduction to clinical Trial**
   History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments

2. **Regulatory affairs in clinical trials**
   IND, NDA, ANDA- Parts and contents, Safety monitory boards, FDA in various countries including India

3. **Ethical issues in clinical trials**
   Principle, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report

4. **Clinical trial design**
   Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls

5. **Clinical trial protocol Development**
   Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial

6. **Good Clinical Practice**
   Concept, importance, and GCP guidelines including ICH guidelines

7. **Management of Clinical trials**
   Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials

8. **Bioavailability, bioequivalence and Therapeutic Drug Monitoring**
   Concept, organization, advantages, special issues, applications, bioequivalence

9. **Data analysis issues in Clinical Trials**
   Monitoring of data, computer applications, statistical tests used, interpretation, survival analysis, sub-group analysis, Quality control of clinical trials

RECOMMENDED BOOKS:

1. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, Elsevier
2. Davidson’s Principles of Internal Medicine, Vol-I And II, 14th Edition, Mc Graw-Hill
3. Harrison’s Principle And Practice Of Medicine, 18th Edition, Churchill, Livingston, London
4. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London
5. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics. Tussle, T.G.: Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall, New York

Subject code: MPLE3
Subject: IMMUNOPHARMACOLOGY
Theory: **30 Hours (2 hrs. /week)**

INTRODUCTION

Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity (active and passive). Concept of immunopharmacology and pharmacotheraputics.

A) IMMUNITY

Hematopoiesis and lymphocyte development: an introduction: Introduction: Blood cell development and immunity, Hematopoietic stem cells, lymphocyte development, T cell development, B cell development, NK cell development.

T cell subsets and T cell-mediated immunity: Introduction, Biology of the T lymphocyte immune response, Mechanisms of T cell activation.

Antibody diversity and B lymphocyte-mediated immunity: Antibodies and immunoglobulins, Structure of immunoglobulins, T cell-independent B lymphocyte activation.

Cytokines: Introduction, Differentiation factors, Activation and growth factors of lymphocytes, Mediators of inflammation, Chemokines, Inhibition of cytokines.

Inflammatory mediators and intracellular signaling: Introduction, Eicosanoids, Platelet-activating factor, Innate immune signalling receptors, Cytokines, Chemokines and their intracellular signalling , Kinins, Reactive oxygen species, Amines.

Cancer immunity: Introduction: Expression of targets for the immune system by cancer cells, Immunotherapy of cancer.

B) IMMUNODIAGNOSIS

Antibody detection: Introduction, Basic principle of immunoassays, Antibody structure, Antibody-detection methods.

Immunoassays: Introduction, Basic principles of assay design, Components of immunoassays.

C) IMMUNOTHERAPEUTICS

Vaccines: Introduction, vaccine categories, Pharmacological effects of vaccination new developments.

Plasma-derived immunoglobulins: Introduction, Glycosylation of immunoglobulins, Pharmacokinetics of immunoglobulins, Immunoglobulin preparations for medical use, adverse reactions to IgG therapy.

Anti-allergic drugs: Introduction, Disodium cromoglycate and nedocromil sodium (cromones), Histamine receptor antagonists ,Anti-leukotrienes, Anti-IgE.

Cytotoxic drugs: Background, Azathioprine, Cyclophosphamide, Fludarabine, Methotrexate, Mycophenolic acid

Immunostimulants and Immunosuppressant's.

RECOMMENDED BOOKS:

1. Mary Louis Turgeon "Immunology and Serology in Laboratory Medicines" 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
2. Robbins Pathologic basis of disease, WB Saunders Co (1999) 6th edition.
3. Roger Walker, Clinical Pharmacy and Therapeutics; Second edition, Churchill Livingstone publication
4. Harsh Mohan, "Text book of Pathology" 3rd edition, 1998, Jaypee Brothers N. Delhi (2005) 5th edition.
5. War Roitt, Jonathan Brostoff, David male, "Immunology"3rd edition 1996, Mosby-year book, Europe Ltd, London.
6. D.Satyanarayana, Text book of biochemistry New Central Book Agency (1999) 2nd edition.
7. Lehninger, Principles of biochemistry W.H.Freeman (2005) 4th edition.
8. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London 4th ed., 2007

Subject code: MPLE4
Subject: NEUROBIOLOGY
Theory: **30 Hours (2 hrs. /week)**

1. Organization of the nervous system.
2. Introduction to the neurons, the neuron doctrine, components of neurons, types, organization of a neuron, and functions.
3. Developmental Neurobiology.
4. Glial cells : structure and function, types, glial neuronal relationship, importance of astrocytes in glutamate uptake and blood- brain barrier, role of tanycytes in the hypothalamus.
5. Membrane channels, ionic basis of resting potential and action potential, synaptic plasticity.
6. Neurotransmitters, neurotransmitter receptors, chemical transmission, electrical synapses.
7. Neurobiology of sensory systems : taste, olfaction, vision, auditory preparation.
8. Neuroanatomy of the hypothalamus and neuroendocrine regulation. Central regulation of feeding, appetite, stress, and Circadian rhythms, neurobiology of behavior.
9. Learning and memory.

10. Neurological disorders.

11. Techniques in neuroscience.

RECOMMENDED BOOKS:

1. Zigmond, Bloom, Landis, Roberts, Squire.(2008). Fundamental neuroscience, Academic Press.
2. Eric Kandel, James Schwartz, Thomas Jessell. (2000). Principles of Neural Science. McGraw Hill.
3. A.Guyton, J. Hall. (2011). Textbook of Medical Physiology, 12th edition, Saundersco, London.
4. Dale P. (2007) Neuroscience, 4th edition, Sinaure Associates
5. Current Protocols in Neuroscience. (2010) Springer Publication.

Subject code: MPLE5
Subject: PHARMACOEPIDEMIOLOGY
Theory: 30 Hours (2 hrs. /week)

1. **Definition and scope:** Origin and evaluation of Pharmacoepidemiology need for Pharmacoepidemiology, aims and applications.

2. **Measurement of outcomes in Pharmacoepidemiology:** Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

3. **Concept of risk in pharmacoepidemiology:** Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio.

4. **Research methods in Pharmacoepidemioloy:** Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

5. **Sources of data for pharmacoepidemiological studies:** Ad Hoc data sources and automated data systems.

6. **Selected special applications of pharmacoepidemiology:** Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

RECOMMENDED BOOKS:

1. Textbook of Pharmacoepidemiology. 1st edition. Brian L Strom, Stephen E Kimmel. John Wiley & Sons, Chichester, 2006.
2. Pharmacoepidemiology, 4th edition. Brian L Strom, 2005.
3. Pharmacoepidemiology and Therapeutic Risk Management. Abraham G Hartzema, Hugh H Tilson, K Arnold Chang, 2008.
4. Pharmacoepidemiology: An Introduction, 3rd edition. Abraham G Hartzema, Miquel Porta, Hugh H Tilson, 1998.

5. Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs. Jerry Avorn. Hardcover, 2004.
6. Modern Epidemiology, 3rd edition. Kenneth J Rothman, Sander Greenland, Timothy L Lash. Lippincott Williams & Wilkins, 2008.
7. Epidemiology. An introduction. Kenneth J Rothman, Oxford University Press, 2002.

Subject code: MPLE6
Subject: SAFETY PHARMACOLOGY
Theory: 30 Hours (2 hrs. /week)

1. Definition and scope of safety pharmacology.

2. Regulatory requirements for the new drug safety assessment: ICH, OECD, USFDA, EMEA, Japan, MHW guidelines.

3. Principles and study design of safety evaluation.
   a.Acute toxicity- rodent and non-rodent
   b. Repeated dose studies (sub acute and chronic)
   c. Analysis of safety pharmacological data.

4. Preclinical safety pharmacology: In vitro and in vivo studies including genotoxicity, mutagenicity, carcinogenicity, reproductive and ocular toxicity, Safety testing for dermatological product.

5. Clinical Safety pharmacology: definition, data collection, reporting methods and assessment and analysis of adverse event (AE) monitoring during clinical trials.
6. Pharmacovigilance: Definition, collection of data, reporting, assessment of Post marketing surveillance, periodic safety update reports, Risk-benefit assessment.
7. Safety pharmacology of different body organs and systems

RECOMMENDED BOOKS:

1 Sogliero-Gilbert, G., Drug safety assessment in clinical trials. Statistics, textbooks and monographs. 1993, New York: Dekker.
2 Marx, U. and V. Sandig, Drug testing in vitro : breakthroughs and trends in cell culture technology. 2007, Weinheim: Wiley-VCH
3 Gad, S.C., Safety assessment for pharmaceuticals. 1995, New York: Van Nostrand Reinhold.
4 Turner, J.R., New drug development : design, methodology, and analysis. 2007, Hoboken, N.J.: Wiley-Interscience.
5 Smith, C.G. and J. O'Donnell, The process of new drug discovery and development. 2nd ed. 2006, New York: Informa Healthcare.
6 Bénichou, C., Adverse drug reactions : a practical guide to diagnosis and management.1994, Chichester, West Sussex, England; New York: Wiley.
7 Mann, R.D. and E.B. Andrews, Pharmacovigilance. 2nd ed. 2007, Chichester, England ; Hoboken, NJ: John Wiley & Sons.
8 World Health Organization., WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. 2004, Geneva: World Health Organization.
9 Cobert, B.L., Manual of drug safety and pharmacovigilance. 2007, Sudbury, Mass.: Jones and Bartlett Publishers.
10 Cobert, B.L. and P. Biron, Pharmacovigilance from A to Z : adverse drug event surveillance. 2002, Malden, MA: Blackwell Science.
11 Casarett and Doull's Toxicology: The basic science of poisons 6th edition McGra Hill, Newyork.
12 Helmal Graim and Robert Snyder, Toxicology and risk assessment, a comprehensive introduction. Wiley.

GROUP D: PHARMACOGNOSY, NATURAL PRODUCTS

Subject code: MPGE1
Subject: ADVANCES IN PHYTOCHEMISTRY
Theory: 30 Hours (2 hrs. /week)

1. **Natural products as leads for new drugs:** Approaches to discovery and development of natural products as potential new drugs, selection and optimization of lead compounds for further development with suitable examples from CNS, anticancer, antibiotics and Cardiovascular drugs.

2. **Steriods:** Stereochemistry, SAR, structural modifications and pharmacokinetic properties, Source and structure elucidation of Beta- sitosterol, stigmasterol and diosgenin.

3. **Biogenesis** of cardenolides, bufadienolide, isothiocyanates. General route of biosynthesis of flavonoids, coumarins, and isoprenoids.

4. **Biogenesis of Alkaloids:** Pyridine, Piperidine, Tropane, Quinoline, Isoquinoline, Indole, Phenanthrene types of alkaloids.

5. **Polypeptides and Proteins:** General methods of separation, general methods of degradation and end group analysis, general methods of synthesis of peptides. Sequence analysis, secondary and tertiary structure of proteins; chemistry of Insulin.

RECOMMENDED BOOKS:

1. Natural products chemistry by Nakanishi Golo, Univ Science Books, 1984.
2. Introduction to Molecular Phytochemistry by CHJ Wells (Chapman and Hall).
3. Comparative Phytochemistry, edited by T. Swain, Academic Press, New York, 1966.
4. Phytochemistry, Vol. I to IV, Miller Jan Nostrant Reinhold, Van Nostrand-Reinhold, 1976.
5. Burger's medicinal chemistry, Drug Discovery and development, edited by Alfred Burger, John Wiley and Sons.
6. Modern methods of plant analysis by Peach & M.V. Tracey, Vol. I to VII, Springer, berlin, 1955.
7. Recent advances in Phytochemistry, Vol. I to IV, Scikel Runeckles, Appletaon Century Crofts.
8. Chemistry of Natural Products by SV Bhat, Alpha Science International Ltd., 2005.
9. Natural products – A Laboratory guide by Raphel Ikhan, 2 nd edition, Academic Press.
10. The essential oils by Ernest Guenther and Robert E. Kreiger
11. The Alkaloids, Chemistry and Physiology by Von R. H. F. Manske und H. L. Holmes. Band I. Academic Press Inc., Publishers, New York.

Subject code: MPGE2
Subject: HERBAL COSMETICS
Theory: **30 Hours (2 hrs. /week)**

1. Introduction, classification of cosmetics. Economic aspects and Factors affecting stability of herbal formulations, ICH and other guidelines, methods of stabilizations and methods of stability testing.

2. **Herbal cosmetics for skin:** Manufacturing and formulations aspects of herbal cosmetics for Skin: Powders, creams, lotions, deodorants, suntan preparations and makeup preparations

3. **Herbal cosmetics for Hair:** Manufacturing and formulations aspects for Hair preparations, shampoos, rinses and conditioners, oily scalp hair tonics, hair dressings and depilatories preparations.

4. **Herbal cosmetics for Nail:** Manufacturing and formulations aspects of nail preparations

5. **Analysis of cosmetics:** Nail enamel, shampoos, hair dyes and aerosol preparations

6. **Toxicity methods for cosmetics**

RECOMMENDED BOOKS:

1. Cosmaceuticals and active ingredienrs: Drug vs Cosmetics, 2nd Edition, Cosmetic Science and Technology, Peter Elsner (Ed.), Informa Healthcare.
2. Cosmetic analysis- Selective methods and techniques by P. Borqe, Cosmetic Science and Technology Series, CRC Press, 1985.
3. Herbal cosmetics Handbook by H Panda, Asia Pacific Business Press, New Delhi.
4. Cosmetics- Formulation, Manufacturing and Quality control by PP Sharma, 2nd Ed., Vandana Publications.
5. Harry's Cosmeticology by Ralph Gordon Haqrry, 8th Edition, Chemical Publishing Company, 2000.
6. Indian Herbal Pharmacopoeia, Vol. I- II, SS Handa, RRL Jammu Tawi, and IDMA Mumbai.

Subject code: MPGE3
Subject: HERBAL DRUG TECHNOLOGY
Theory: **30 Hours (2 hrs. /week)**

1. Importance of monographs of medicinal plants as per IP, API, Unani Pharmacopoeia, Homoepathic Pharmacopoeias, Siddha Pharmacopoeia, BHP, Japanese Pharmacopoeia, Chinese Pharmacopoeia, European Pharmacopoeia, USP (dietary supplements), WHO and EMEA guidelines and ESCOP monographs for medicinal products.

2. Natural products used as coloring pigments, excipients, biopolymers, photosensitizing agents, flavors and biofuels.

3. Profiles for commercial cultivation technology/ and post-harvest care of following medicinal plants- Cinchona, Rauwolfia, Pyrethrum, Belladona, Dioscorea, Vinca.

4. Technology for commercial scale cultivation and processing of following aromatic plants- Lemon grass, Geranium, Basil, Palmrosa, Vetiver, Patchouli, Japanese Mint, Rose, Hops, Jasmine, Sandal, Dill, Celery, Anise, Davana.

5. Reverse pharmacology approach to develop herbal drugs/ phytopharmaceuticals from herbs known in Traditional knowledge like Ayurveda / TCM etc. Examples of successful drugs developed in India and abroad, case studies. Emerging regulations like USFDA Guide to Industry for Botanical drugs and how to comply with them.

6. Phytography and phytogeographical distribution of medicinal plants with special reference to India.

RECOMMENDED BOOKS:

1. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons Limited, New Delhi.
2. Indian Herbal Pharmacopoeia, Vol. I-II, SS Handa, RRL Jammu Tawi, and IDMA Mumbai.
3. British pharmacopoeia, 2008. The department of Health, Vol I- IV, British Pharmacopoeia Commission, London.
4. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
5. Quality Control Methods for medicinal plant material, WHO Geneva.
6. Herbal Drug technology by SS Agrawal and M Paridhavi, Orient Longman

Subject code: MPGE4
Subject: MEDICINAL PLANT BIOTECHNOLOGY
Theory: **30 Hours (2 hrs. /week)**

1. **Introduction to genetics & molecular biology:** a. Structural and molecular organization of Cell; b. Genetic Material-DNA, RNA, Protein, Replication, Genetic Code, Regulation of Gene Expression, Structure & Complexity of Genome; c. Cell Cycle, Cell signaling; d. Mutation; e. Recombinant DNA Technology –Principles, Tools, Process & Applications.

2. **Germplasm Conservation:** a. In-situ Conservation; b. In-vitro methods of Conservation.

3. **Applications of Transgenic Plants:** a. Resistance of herbicide; b. Resistance to insect, fungus, & virus; c. Resistance to Physiological stress; d. Production of Phytopharmaceuticals; e. Edible vaccine.

4. **Enzymes:** a. Types & Properties of enzymes; b. Isolation & Purification of enzymes; c. Immobilization of enzymes & its applications; d. Enzyme reactors; e. Detailed study of Plant enzymes– Papain & Bromelain.

5. **DNA bar code development** adopting various techniques and their application to differentiate authentic herb from their other species, and substitutes and adulterants. Applications with examples, limitations of technique, and emerging scenario.

RECOMMENDED BOOKS:

1. Pharmaceutical biotechnology SP Vyas and VK Dixit, CBS Publishers and Distributors, 2001.
2. Advanced methods in plant breeding & biotechnology by David R. Murray. CAB. International Panima book distributors.1991.
3. Plant tissue culture by Dixon IRL Press Oxford Washington DC, 1985.
4. Role of Biotechnology in Medicinal and Aromatic Plants Vol I & II By Irfan A Khan and Atiya Khanum Ukaoz Publications.1998.
5. Plant Chromosome analysis, manipulation and engineering by Arun And Archana Sharma 1st Edition Harwood Academic Publishers 1999.
6. Comprehensive Biotechnology by Murray Moo-Young Vol I- IV Pergamon Press LTD, 1985. Transgenic Plants by R Ranjan Agrobotanica.1999.
7. Medicinal Plant Biotechnology by C.D. Veeresham, C.B.S. Publisher.

Subject code: MPGE5
Subject: Natural Product Management
Theory: **30 Hours (2 hrs. /week)**

1. **Role of Medicinal Plants in National Economy:** Economic growth potential in natural health and cosmetic products. Future economic growth. Development of herbal medicine industry.

2. **Worldwide trade in medicinal plants and derived products:** Demand for medicinal plants and herbal medicine. Trends in worldwide trade of Medicinal plants. International trade. Major importing-exporting regions and countries.

3. **Indian trade in medicinal and aromatic plants:** Export potential of Indian medicinal herbs. Indian medicinal plants used in cosmetics and aromatherapy. Spices and their exports.

4. **Study of infrastructure:** For different types of industries involved in making standardized extracts and various dosage forms including traditional Ayurvedic dosage forms and modern dosage forms.

5. **Global regulatory status of herbal medicines: Patents:** Indian and international patent laws, Recent amendments as applicable to herbal/ natural products and processes Plant breeders right.

6. **Management of natural sources**

RECOMMENDED BOOKS:

1. Textbook of Industrial Pharmacognosy, by A. N. Kalia, CBS Publishers and Distributors. New Delhi.
2. Chaudhari R D, Herbal Drug Industry, Eastern publication.
3. PDR for Herbal Medicines, Second Ed., Medicinal Economic Company, New Jersey.
4. Herbal Drug technology by SS Agrawal and M Paridhavi, Orient Longman.
5. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
6. G.E. Trease and W.C. Evans., Pharmacognosy, W.B. Saunders Co. Ltd., Harcourt Publishers Ltd. UK.

Subject code: MPGE6
Subject: Plant Tissue Culture Techniques
Theory: 30 Hours (2 hrs. /week)

1. **Introduction and Methods employed in plant tissue culture:** Techniques of organ, tissue and free cell culture: a. Excised root culture; b. Excised shoot apices; c. Excised leaf primordia cultures; d. Culture of flowers and floral organs, e. Embryo culture, f. Pollen cultures, g. Callus culture, h. Suspension and continuous culture and i. Culture of isolated cells.

2. The nutrition and Metabolism of plant tissue and organ culture. Growth differentiation and organogenesis in plant tissue and organ culture. Cytogenetics of differentiation in tissue and cell culture. Different parameters used to measure the growth of cultures.

3. **DNA amplification and Tissue culture protoplast:** Somatic hybridization and engineering, Protoplast isolation, protoplast culture and somatic hybridization.

4. **Gene mapping and molecular maps of plant genomes:** Plant chromosome analysis, use of PCR in gene mapping, molecular maps- RFLP, RAPD.

5. **Application of tissue culture in improvement of medicinal plants:** Yield improvement, stress tolerant plants, disease resistant plants, pesticide tolerant plants, synthetic seed production, germplasm storage and cryopreservation for conservation of plants.

6. **Transgenic plants:** Approaches for production of transgenic plants.

RECOMMENDED BOOKS:

1. Cells and Tissues in Culture, Vol. III by E.N. Willman, Academic Press.
2. Plant cell, Tissue and Organ Culture by J. Reinert and Y.P.S. Bajaj, Springer Verlag.
3. Tissue culture and plant science, 1974, by H.E. Street, Academic Press.
4. The cultivation of animal and plant cells, 1954, White P.R., Ronald Press.
5. A handbook of plant culture, 1943, White P.R., Cattell and Co.
6. Modern methods of plant analysis by Peach and Tracey, Vol. II, IV, Springer Verlag.
7. Herbal Drug technology by SS Agrawal and M Paridhavi.
8. Practical Evaluation of Phytopharmaceuticals by Brain and Turner.

GROUP E: QUALITY ASSURANCE, PHARMACEUTICAL MANAGEMENT, PHARMACOINFORMATICS

Subject code: MQAE1
Subject: ACTIVE PHARMACEUTICAL INGREDIENTS (APIS): MANAGEMENT TECHNOLOGY
Theory: 30 Hours (2 hrs. /week)

1. **Introduction to basic pharmaceutical and fine chemical chemistry:** Definitions of basic pharmaceuticals, intermediates, fine chemicals, heavy chemicals. Technology involved in manufacturing of pharmaceuticals. Unit processes in synthesis, biochemical processes in synthesis.

2. **Unit processes:** Study of the following chemical processes (with references to reagents, mechanisms, equipments and manufacture of drugs given below): Acylation, esterification, alkylation, amination, halogenation, hydrolysis, nitration, oxidation and reduction.

3. **Industrial processes & scale up techniques**
   The process design, technology transfer and first manufacture. Industrial manufacturing methods and flow charts of Sulphamethoxazole, Ciprofloxacin, Benzocaine, Adrenaline, Rifampicin, Aspirin and Pentothal sodium.

4. **Bioethics and Bio-Safety**
   Health hazards in manufacturing facility, The forms of Atmospheric contaminants, Chemical mixtures, Detection and sampling, Atmospheric contamination, industrial noise, criteria for hearing damage, Noise measuring instruments, effects of sound and ultrasound, the control of noise, vibration, Radiation Hazards, Radiation detection and measurement, personal protection, eye protection, Types of eye protection equipment. Finger & Arm protection, Foot & leg protection. Environmental protection laws related to industry.

RECOMMENDED BOOKS:

1. Stanley H. Nusim. Active Pharmaceutical Ingredients: Development Manufacturing and Regulation. Taylor and Francis, New York.
2. L. Lachman. The Theory and Practice of Industrial Pharmacy, 3rd Ed., Warghese Publishing House, Mumbai.
3. W.L. McCabe and J.C.Smith. Unit Operations of Chemical Engineering, 5th Ed., McGraw-Hill, Inc., NY.
4. C.L. Dryden, 1973, Outlines of Chemical Technology, 2nd edition, Affiliated East-Eest Press.
5. Groggin P.K. Unit Process in Organic Synthesis, 2nd edition, Mc Graw-Hill, Inc., NY.

Subject code: MQAE2
Subject: HUMAN BEHAVIOR IN ORGANIZATION
Theory: 30 Hours (2 hrs. /week)

1. **Foundations of organizational behavior:** Understanding behavior in organizations, OB model.
2. **Introduction to Individual Motivation Needs, contents and processes;** Maslow's hierarchy of human needs, Herzberg's two factor theory of motivation, Vroom's expectancy theory.
3. **Group processes:**

   Importance of values: Types of values, attitudes and consistency (cognitive dissonance theory)

   Group dynamics and teams.

   Leadership: Trait theories, behavioural theories, Ohio state studies, university of Michigan studies, the managerial grid, contingency theories; Hersey and Bianchard's situational theory and path goal theory.
4. **Transactional analysis.**
5. **Organizational culture:** What is organizational culture, what does cultures do, creating, and sustaining culture, how employees learn culture.
6. **Organizational change:** Forces of change, resistance to change, and approaches to managing organizational change.
7. **Conflict management:** Transitions in conflict thought, functional Vs dysfunctional conflict, the conflict process.

RECOMMENDED BOOKS:

1. Organisational Behaviour, Dr. K. Aswathappa, Published by : Himalaya Publishing House, Revised and Enlarged Edition, 1994
2. Fred Luthans, Organisational Behaviours, Mc-Graw Hill, 8th International Edition.
3. Subba Rao S.V., Human Resource Management and Industrial Relation, Himalaya Publishing House, 1st Edition, 1997.

Subject code: MQAE3
Subject: MATERIAL MANAGEMENT AND INVENTORY CONTROL
Theory: 30 Hours (2 hrs. /week)

1. **Purchasing:** Introduction, purchasing activities, purchasing policies, value analysis, procurement by manufacture, discount and terms of payment, hedging, evaluating purchasing performance.

2. **Materials handling:** Introduction, objectives of material handling, materials handling analysis, guiding principles of material handling, small part handling, packing, transportation, materials handling equipments.

3. **Inventory planning and control:** Introduction, lead time, inventory cushions, recorder point, order quantity, quantity discount, Fifo and Lifo system, materials identification, storage facilities, purging inventories, pilferage protection, symptoms of mismanaged inventories, basic inventory model, inventory model with uncertain demand, inventory control systems, ABC classification of inventory items.

4. **Statistical quality control:** Introduction, frequency distribution, statistical measures, normal distribution, process control, establishing control charts, control charts in use, use of samples, relation of control limits to tolerance limits, control charts computations, control charts of attributes, accepting sampling, operative characteristics curve, average outgoing quality, double and multiple sampling plans, diversified applications of statistical techniques.

5. **Storage:** Storage room management, Shelf stripping and floor marking, marking of merchandise, storage of pharmaceuticals.

RECOMMENDED BOOKS:

1. Effective Industrial Management, J.L.Lundy, Eurasia Publishing House, ND.
2. Hospital Pharmacy, W.E.Hassan, Lea and Febiger, Philadephia.
3. Modern Production/ Operations Management, E.S.Buffa and R.K.Sarin, John Wiley & sons.
4. Production Planning Control and Industrial management, K.C. Jain and L.N. Aggarwal, Khanna Publishers, Delhi.
5. Modern Business Organization and Management, S.A. Sherlekar and V.S. Sherlekar, Himalaya Publishing House.

Subject code: MQAE4
Subject: PACKAGING TECHNOLOGY
Theory: **30 Hours (2 hrs. /week)**

1. **Introduction to pharmaceutical packaging**: Introduction, Some factors influencing pharmaceutical packaging, protection, sterilization.

2. **The packaging function**: Management, development and product shelf life, packaging management, product and pack development, drug substance, shelf life, packaging specifications.

3. **Regulatory aspects of pharmaceutical packaging**: Definition of the pack, product license specifications, data requirements on the package.

4. **Specifications and quality**: material specifications and quality standards, sampling, supplier evaluation, manufacture and qualification controls.

5. **Glass containers**: composition of glass and types, manufacturing process, quality control and quality assurance, bottles and production lines, special pharmaceutical containers.

6. **Plastics**: thermosets, thermoplastics, chemical type evaluation, permeability of plastic to gasses and organic substances, fabrication and moulding processes, sterilization of plastics, WHO guidelines.

7. **Films, foils and laminations**: shrink wrapping, stretch wrapping, combination materials covering flexible and rigid applications, paper, coatings, aluminum foils, lamination and lamination processes, decoration and printing.

8. **Metal containers**: modern packaging metals, types of metal containers, built up containers, aerosols.

9. **Closure and closure systems**: basis of closure system, closure evaluation, assessment and control, prethreaded screw caps, specific closures for containers, non-reclosables, adhesive sealings, closure evaluation.

10. **Sterile products**: sterilization of parenteral products, rubber and elastomers, ampoules and vials, prefilled syringes, auto-injectors, selection of rubber formulation and component design.

11. **Blister, strip and sachet packaging**: blister packs, strip packs, package integrity, sachets, recent developments in blister and strip packaging.

12. **The packaging line**: materials in packaging line, common filling methods, container based filling, labeling and other requirements.

13. **Warehousing, handling and distribution**: hazards in warehousing, handling and distribution, handling, moving and storage methods, load stability, modes of distribution and transport.

14. **Printing and decoration**: decoration, graphic reproduction, mechanical graphic printing, printing machines, recent trends.

RECOMMENDED BOOKS:

1. Pharmaceutical Packaging technology, Edited by: D. A. Dean, E. R. Evans, H. Hall, 2000, Taylor and Francis, New York.
2. Pharmaceutical Packaging handbook, Edward J. Bauer,2003,Informa Healthcare, New York.
3. The Wiley encyclopedia of packaging technology, Kenneth S. Marsh, Aaron L. Brody, Published by Wiley Interscience, New York.
4. Packaging of pharmaceuticals and healthcare products, H Lockhart and F. A. Paine ,Blackaie academic and professional, Chapman and Hall UK, 1996.
5. Fundamentals of packaging technology, Walter Soroka, Edition2, Institute of Packaging Professionals, 1999, The University of Virginia.

Subject code: MQAE5
Subject: PHARMACEUTICAL MARKETING AND MARKET RESEARCH
Theory: 30 Hours (2 hrs. /week)

1. Indian Pharmaceutical Industry- An overview
2. The Pharmaceutical Market
3. Nine P's
4. Marketing New Products
5. Marketing Planning
6. Modern Marketing
    a. The field of marketing
    b. Career in Marketing
    c. The changing marketing environment
    d. Strategic planning and forecasting
    e. Marketing research and Information
7. Marketing in Special Field
    a. Services marketing by For-Profit and Nonprofit Organization
    b. International Marketing
8. Managing the sales force

RECOMMENDED BOOKS:

1. Subba Rao, Pharmaceutical Marketing in India, Published by Asian Institute of Pharmaceutical Marketing, Hydrabad.
2. William J. Stanton, Michael J. Etzel, Bruce J. Walker, Fundamentals of Marketing, McGRAW-HILL International Edition, Marketing and Advertising series.
3. Philip Kotler, Marketing Management, Prentice-Hall of India Private Limited, New Delhi
4. Walker, Boyd and Larreche, Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.
5. Dhruv Grewal and Michael Levy, Marketing, Tata MC Graw Hill
6. Arun Kumar and N Menakshi, Marketing Management, Vikas Publishing, India
7. Shanker, Ravi, Service Marketing, Excell Books, New Delhi
8. Memoria C. B., Principle and Practice of Marketing in India
9. Mickey Smith, Principles of Pharmaceutical Marketing, C.B.S. Publications.

Subject code: MQAE6
Subject: QUALITY PLANNING AND ANALYSIS
Theory: 30 Hours (2 hrs. /week)

1. **Basic concepts of Quality**
   Definition of Quality, The Quality function, Managing for Quality, Perspective on Quality- Internal versus External

2. **Quality Improvement and Cost Reduction**
   Sporadic and chronic quality problems, Need for quality improvement & cost reduction, Causes of poor quality and high cost, Remedy to prove effectiveness for improving quality, Resistance to change.

3. **Control of Quality**
   Definition of Control, Self control, The control subject for Quality, Units of measure

Setting a goal for the control subject, The sensor, Measuring actual performance, Interpreting the difference between actual performance and goal, Taking action on the difference, Continuous process regulation.

4. **Developing Quality culture**
   Technology and cultures, Theories of motivation, Create and maintain awareness of Quality, Provide evidence of management and empowerment, Time to change the culture.

5. **Manufacturing**
   Importance of manufacturing planning for quality, Initial planning for Quality, Concept of controllability, self control, Defining quality responsibilities, Self inspection Automated manufacturing, Overall review of manufacturing planning, Process quality audits, Quality and production floor culture

6. **Statistical Process control**
   Definition and importance of SPC, Quality measurement in manufacturing, Statistical control charts-general, Advantages of statistical control, Process capability, Estimating inherent or potential capability from a control chart analysis, Measuring process control and Quality improvement

7. **Inspection, test and Measurement**
   The terminology of inspection, Conformance to specification and fitness for use, Disposition of non conforming product, Inspection planning, Automated inspection, How much inspection is necessary?, Inspection accuracy, Errors of measurement, Economics of Inspection.

8. **Quality assurance general concepts**
   Definition of Quality Assurance, Concept of Quality Assurance, Quality Audit- The concept, Structuring the audit programme, Planning and performance of audit, Human relations in auditing, Audit reporting, Essential elements of quality audit programme Quality surveys, Product audit, Sampling for audit, Reporting the results of audit

RECOMMENDED BOOKS:

1. Quality Planning and Analysis, 5th ed., J.M.Juran and F.M.Gryna, Tata Mc-Graw Hill, India

2. Improving Quality through planned experimentation by Meon, Tata Mc-Graw Hill, India

3. Statistical Quality control by Grant, Tata Mc-Graw Hill, India

4. Juran's Quality Handbook, 5th ed, J.M.Juran, Tata Mc-Graw Hill, India.

Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur

M. Pharm. Syllabus

Credit-grade based performance and assessment system (CGPA)

Features of the Credit System

With effect from Academic Session 2012- 2013

Scheme of Absorption & Matchable Subjects

OLD SYLLABUS		NEW SYLLABUS	
Subject Code	**Name of Subject**	**Subject Code**	**Name of Subject**
CP-1	Biostatistics	MC-S2	Research Methodology and Biostatistics
CP-2	Product Development and Formulation	MPHE6	Sterile Product Formulation and Technology
Pharmaceutics			
PH-1	Advanced Physical Pharmacy	MPH-S4	Advanced Pharmaceutics
PH-2	Biopharmaceutics and Pharmacokinetics	MPH-S13	Biopharmaceutics and Pharmacokinetics
PH-3	Pharmaceutical Dosage Form Technology	MPH-S9	Product Development and Formulation
PH-4	Selected Topics in Pharmaceutics	MPH-S10	Novel Drug Delivery Systems
PH-5	Practicals In Pharmaceutics	MPH-P4	Advanced Pharmaceutics
Pharmaceutical Chemistry			
PC-1	Advanced Pharmaceutical Chemistry-I	MPC-S9	Advanced Pharmaceutical Chemistry- II
PC-2	Advanced Pharmaceutical Chemistry-II	MPC-S10	Advanced Pharmaceutical Chemistry-III
PC-3	Advanced Pharmaceutical Chemistry-III	MC-S1	Advanced Analytical Techniques
PC-4	Selected Topics in Pharmaceutical Chemistry	MPC-S13	Advanced Pharmaceutical Chemistry-IV
PC-5	Practicals in Pharmaceutical Chemistry	MPC-P9	Advanced Pharmaceutical Chemistry-II
Pharmacology			
PL-1	Advanced Physiology and Pathophysiology	MPL-S4	Advanced Physiology and Pathophysiology
PL-2	Advanced Systemic Pharmacology	MPL-S9	Advanced Systemic Pharmacology
PL-3	Biological Evaluation Methods and Toxicology	MC-S8	Biological Evaluation
PL-4	Selected Topics in Pharmacology	MPL-S13	Molecular Pharmacology and Toxicology
PL-5	Practicals in Pharmacology	MPL-P9	Advanced Systemic Pharmacology
Pharmacognosy			
PG-1	Advance Pharmacognosy and Tissue Culture	MPGE6	Plant Tissue Culture Techniques
PG-2	Plant Biochemistry and Biogenesis	MPGE1	Advances in Phytochemistry
PG-3	Comparative Phytochemistry and Taxonomy	MPGE3	Herbal Drug Technology
PG-4	Selected Topics in Pharmacognosy	MPG-S13	Selected Topics in Pharmacognosy
PG-5	Practicals in Pharmacognosy	MPG-P4	Advanced Pharmacognosy and Phytochemistry
Quality Assurance			
QA-1	Cosmetic Preparation & Evaluation	MQA-S9	Quality Assurance of Cosmeceuticals
QA-2	Quality Management	MQA-S13	Quality Management
QA-3	Modern Analytical Techniques	MC-S1	Advanced Analytical Techniques
QA-4	New Drug Delivery System	MQA-S10	Novel Drug Delivery Systems
QA-5	Practicals in Quality Assurance	MC-P1	Advanced Analytical Techniques

2016

THE MASTER OF PHARMACY (M. PHARM.)

COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA NO. 362, DATED DECEMBER 11, 2014)

SCHEME AND SYLLABUS

PHARMACY COUNCIL OF INDIA
Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.

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भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग III—खण्ड 4
PART III—Section 4
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 362] नई दिल्ली, बृहस्पतिवार, दिसम्बर 11, 2014/अग्रहायण 20, 1936
No. 362] NEW DELHI, THURSDAY, DECEMBER 11, 2014/AGRAHAYANA 20, 1936

PHARMACY COUNCIL OF INDIA
NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations; namely–

CHAPTER –I:REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.)Degree Program – Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Phamacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semestershall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours.Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments,Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits

are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

The specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 11.

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 3: Course of study for M. Pharm. (Industrial Pharmacy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MIP101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP102T	Pharmaceutical Formulation Development	4	4	4	100
MIP103T	Novel drug delivery systems	4	4	4	100
MIP104T	Intellectual Property Rights	4	4	4	100
MIP105P	Industrial Pharmacy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP202T	Scale up and Technology Transfer	4	4	4	100
MIP203T	Pharmaceutical Production Technology	4	4	4	100
MIP204T	Entrepreneurship Management	4	4	4	100
MIP205P	Industrial Pharmacy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 4: Course of study for M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC1012T	Advanced Organic Chemistry –I	4	4	4	100
MPC103T	Advanced Medicinal chemistry	4	4	4	100
MPC104T	Chemistry of Natural Products	4	4	4	100
MPC105P	Pharmaceutical Chemistry Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry –II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 5: Course of study for M. Pharm. (Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105P	Pharmaceutical Analysis Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 6: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MQA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 7: Course of study for M. Pharm. (Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
MRA 101T	Good Regulatory Practices	4	4	4	100
MRA 102T	Documentation and Regulatory Writing	4	4	4	100
MRA 103T	Clinical Research Regulations	4	4	4	100
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	4	4	100
MRA 105P	Regulatory Affairs Practical I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA 202T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
MRA 203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA 204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA 205P	Regulatory Affairs Practical II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 8: Course of study for M. Pharm. (Pharmaceutical Biotechnology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPB 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPB 102T	Microbial And Cellular Biology	4	4	4	100
MPB 103T	Bioprocess Engineering and Technology	4	4	4	100
MPB 104T	Advanced Pharmaceutical Biotechnology	4	4	4	100
MPB 105P	Pharmaceutical Biotechnology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPB 201T	Proteins and protein Formulation	4	4	4	100
MPB 202T	Immunotechnology	4	4	4	100
MPB 203T	Bioinformatics and Computer Technology	4	4	4	100
MPB 204T	Biological Evaluation of Drug Therapy	4	4	4	100
MPB 205P	Pharmaceutical Biotechnology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 9: Course of study for M. Pharm. (Pharmacy Practice)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
	Semester I				
MPP 101T	Clinical Pharmacy Practice	4	4	4	100
MPP 102T	Pharmacotherapeutics-I	4	4	4	100
MPP 103T	Hospital & Community Pharmacy	4	4	4	100
MPP 104T	Clinical Research	4	4	4	100
MPP 105P	Pharmacy Practice Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
	Semester II				
MPP 201T	Principles of Quality Use of Medicines	4	4	4	100
MPP 102T	Pharmacotherapeutics II	4	4	4	100
MPP 203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MPP 204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
MPP 205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 10: Course of study for (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPL 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL 102T	Advanced Pharmacology-I	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL 104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL 105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL 201T	Advanced Pharmacology II	4	4	4	100
MPL 202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL 203T	Principles of Drug Discovery	4	4	4	100
MPL 204T	Experimental Pharmacology practical- II	4	4	4	100
MPL 205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 11: Course of study for M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPG101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced Pharmacognosy-1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG102T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 12: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

* Non University Exam

Table – 13: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
Total		35	20

Table – 14: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Table – 15: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held Outside India

International Journal: The Editorial Board Outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Programme Committee shall be as follows: A teacher at the cadre of Professor shall be the Chairperson; One Teacher from eachM.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.

ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.

iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

iv. Communicating its recommendation to the Head of the institution on academic matters.

v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 16.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to IVshall beconducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables – 1616 : Schemes for internal assessments and end semester (Pharmaceutics– MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
	SEMESTER I							
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH 102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH 104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH 105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
	Total							650
	SEMESTER II							
MPH 201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH	Cosmetic	10	15	1 Hr	25	75	3 Hrs	100

204T	and Cosmeceuticals							
MPH 205P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	–	–	–	–	–	–	100
Total								650

Tables – 1717 : Schemes for internal assessments and end semester (Industrial Pharmacy– MIP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MIP101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MIP102T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3 Hrs	100
MIP103T	Novel drug delivery systems	10	15	1 Hr	25	75	3 Hrs	100
MIP104T	Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MIP105P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	–	–	100
Total								650
SEMESTER II								
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	10	15	1 Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	10	15	1 Hr	25	75	3 Hrs	100

MIP205P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	–	–	–	–	–	–	100
Total								650

(Pharmaceutical Chemistry-MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPC101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPC102T	Advanced Organic Chemistry -I	10	15	1 Hr	25	75	3 Hrs	100
MPC103T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC104T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
MPC105P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	–	100
		Total						650
SEMESTER II								
MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC202T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
MPC203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC205P	Pharmaceutic	20	30	6 Hrs	50	100	6	150

	al Chemistry Practical II						Hrs	
-	Seminar /Assignment	–	–	–	–	–	–	100
Total								650

Tables – 19: Schemes for internal assessments and end semester examinations (Pharmaceutical Analysis-MPA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA103T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MPA104T	Food	10	15	1 Hr	25	75	3 Hrs	100
MPA105P	Pharmaceutical Analysis-I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPA203T	Quality Control and Quality	10	15	1 Hr	25	75	3 Hrs	100

	Assurance							
MPA204T	Herbal and Cosmetic analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA205P	Pharmaceuti cal Analysis–II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	–	-	100
Total								650

Tables – 20: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance– MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MQA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MQA102T	Quality Management System	10	15	1 Hr	25	75	3 Hrs	100
MQA103T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MQA104T	Product Development and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MQA105P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	–	-	-	-	-	-	100
Total								650
SEMESTER II								
MQA201T	Hazards and Safety Management	10	15	1 Hr	25	75	3 Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MQA203T	Audits and Regulatory Compliance	10	15	1 Hr	25	75	3 Hrs	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	75	3 Hrs	100
MQA205P	Pharmaceutical Quality Assurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	–	-	-	-	-	-	100
Total								650

Tables – 21: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs–MRA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MRA101T	Good Pharmaceutical Practices	10	15	1 Hr	25	75	3 Hrs	100
MRA102T	Documentation and Regulatory Writing	10	15	1 Hr	25	75	3 Hrs	100
MRA103T	Clinical Research Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MRA105T	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	–	–	–	–	–	–	100
Total								650
SEMESTER II								
MRA201T	Regulatory Aspects of Drugs & Cosmetics	10	15	1 Hr	25	75	3 Hrs	100

MRA202T	Regulatory Aspects of Herbal & Biologicals	10	15	1 Hr	25	75	3 Hrs	100
MRA203T	Regulatory Aspects of Medical Devices	10	15	1 Hr	25	75	3 Hrs	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	10	15	1 Hr	25	75	3 Hrs	100
MRA205P	Pharmaceutical Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 22: Schemes for internal assessments and end semester examinations (Pharmaceutical Biotechnology–MPB)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPB101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPB102T	Microbial And Cellular Biology	10	15	1 Hr	25	75	3 Hrs	100
MPB103T	Bioprocess Engineering and Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB104T	Advanced Pharmaceutical Biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB105P	Pharmaceutical Biotechnology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPB201T	Proteins and protein Formulation	10	15	1 Hr	25	75	3 Hrs	100
MPB202T	Immunotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB203T	Bioinformatics and Computer Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB204T	Biological Evaluation of Drug Therapy	10	15	1 Hr	25	75	3 Hrs	100
MPB205P	Pharmaceutical Biotechnology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 23: Schemes for internal assessments and end semester examinations (Pharmacy Practice-MPP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPP101T	Clinical Pharmacy Practice	10	15	1 Hr	25	75	3 Hrs	100
MPP102T	Pharmacotherapeutics-I	10	15	1 Hr	25	75	3 Hrs	100
MPP103T	Hospital & Community Pharmacy	10	15	1 Hr	25	75	3 Hrs	100
MPP104T	Clinical Research	10	15	1 Hr	25	75	3 Hrs	100
MPP105P	Pharmacy Practice Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPP201T	Principles of Quality Use of Medicines	10	15	1 Hr	25	75	3 Hrs	100
MPP102T	Pharmacotherapeutics II	10	15	1 Hr	25	75	3 Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1 Hr	25	75	3 Hrs	100
MPP205P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 24: Schemes for internal assessments and end semester examinations (Pharmacology-MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL105P	Experimental Pharmacology – I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Clinical research and pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Experimental Pharmacology – II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 25: Schemes for internal assessments and end semester examinations (Pharmacognosy-MPG)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPG101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Advanced Pharmacognosy-1	10	15	1 Hr	25	75	3 Hrs	100
MPG103T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG104T	Industrial Pharmacognostical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG105P	Pharmacognosy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPG201T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3 Hrs	100
MPG203T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG204T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG205P	Pharmacognosy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 26: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 27: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 28	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 28: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm.programme if he/she secures at least 50% marks in that particular courseincluding internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table – 29: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and IIsemesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.The letter grades and their corresponding grade points are given in Table – 30.

Table – 30: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtainedin all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * ZERO}{C_1 + C_2 + C_3 + C_4}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed statusin case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA

shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C_1, C_2, C_3,.... is the total number of credits for semester I,II,III,…. and S_1,S_2, S_3,....is the SGPA of semester I,II,III,…. .

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of. 7.50 and above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation I Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

PHARMACEUTICS(MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

Chemicals and Excipients

The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

THEORY 60 HOURS

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. 11 Hrs

   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 11 Hrs

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	11 Hrs
4	Chromatography:Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11 Hrs
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	11 Hrs
6	Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods - Part B - J W Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEMS
(MPH 102T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

Upon completion of the course, student shall be able to understand

The various approaches for development of novel drug delivery systems.

The criteria for selection of drugs and polymers for the development of delivering system

The formulation and evaluation of Novel drug delivery systems..

THEORY 60 Hrs

1.	Sustained Release(SR) and Co ntrolled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	10 Hrs
2	Rate Controlled DrugDelivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10 Hrs
3	Gastro-Retentive Drug Delivery Systems: Principle, concepts 10 Hrsadvantagesanddisadvantages,ModulationofGItransittime approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	
4	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs

5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS
(MPH 103T)

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

Upon completion of the course, student shall be able to understand

The elements of preformulation studies.

The Active Pharmaceutical Ingredients and Generic drug Product development

Industrial Management and GMP Considerations.

Optimization Techniques & Pilot Plant Scale Up Techniques

Stability Testing, sterilization process & packaging of dosage forms.

THEORY 60 HRS

1. a. Preformation Concepts – Drug Excipient interactions – 10 different methods, kinetics of stability, Stability testing. Theories of Hrs dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

   b. Optimization techniques in Pharmaceutical Formulation: 10 Concept and parameters of optimization, Optimization techniques Hrs in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation

2 Validation : Introduction to Pharmaceutical Validation, Scope & 10 merits of Validation, Validation and calibration of Master plan, Hrs ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

3 cGMP & Industrial Management: Objectives and policies of 10 current good manufacturing practices, layout of buildings, Hrs services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

4	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10 Hrs
5	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10 Hrs

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS
(MPH 104T)

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

To know the approval process of

To know the chemistry, manufacturing controls and their regulatory importance

To learn the documentation requirements

for To learn the importance and

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

The Concepts of innovator and generic drugs, drug development process

The Regulatory guidance's and guidelines for filing and approval process

Preparation of Dossiers and their submission to regulatory agencies in different countries

Post approval regulatory requirements for actives and drug products

Submission of global documents in CTD/ eCTD formats

Clinical trials requirements for approvals for conducting clinical trials Pharmacovigilence and process of monitoring in clinical trials.

THEORY 60 Hrs

1. a.Documentation in Pharmaceutical industry: Master 12 formula record, DMF (Drug Master File), distribution records. Hrs Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in -vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

   b.Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH – Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3	Non clinical drug development: Global submission of IND, NDA,ANDA.Investigationofmedicinalproductsdossier,dossier (IMPD) and investigator brochure (IB).	12 Hrs
4	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS - I
(MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)

(MPH 201T)

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

The various approaches for development of novel drug delivery systems.

The criteria for selection of drugs and polymers for the development of NTDS

The formulation and evaluation of novel drug delivery systems.

THEORY 60 Hrs

1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. 12 Hrs
2. Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation. 12 Hrs
3. Micro Capsules / Micro Spheres: Types, preparation and evaluation,MonoclonalAntibodies;preparationandapplication, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. 12 Hrs
4. Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. 12 Hrs
5. Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future. 12 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery – concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able understand,

The basic concepts in biopharmaceutics and pharmacokinetics.

The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

The critical evaluation of biopharmaceutic studies involving drug product equivalency.

The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY 60 Hrs

1. Drug Absorption from the Gastrointestinal Tract: 12 Hrs

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model: Permeability–Solubility–Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight–Junction Complex.

2	Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing,meeting dissolution requirements,problems of variable control in dissolution testingperformance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drug product.	12 Hrs
3	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:two compartment – model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max}. Drug interactions: introduction, the effect of protein-binding interactions,the effect of tissue-binding interactions,cytochrome p450-based drug interactions,drug interactions linked to transporters.	12 Hrs
4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hrs
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hrs

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT
(MPH 203T)

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

History of Computers in Pharmaceutical Research and Development Computational Modeling of Drug Disposition

Computers in Preclinical Development

Optimization Techniques in Pharmaceutical Formulation Computers in Market Analysis

Computers in Clinical Development

Artificial Intelligence (AI) and Robotics

Computational fluid dynamics(CFD)

	THEORY	60 Hrs
1.	a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD – examples of application.	12 Hrs
2	Computational Modeling Of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	12 Hrs

3	Computer-aidedformulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	12 Hrs
4	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro-in vivo correlation, Biowaiver considerations b. Computer Simulations in Pharmacokineticsand Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems	12 Hrs
5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS
(MPH 204T)

Scope

This course is designed to impart knowledge and skills necessary forthefundamental need for cosmetic and cosmeceutical products.

Objectives

Upon completion of the course, the students shall be able to understand

Key ingredients used in cosmetics and cosmeceuticals.

Key building blocks for various formulations.

Current technologies in the market

Various key ingredients and basic science to develop cosmetics and cosmeceuticals

Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

THEORY 60 Hrs

1. Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties. 12 Hrs

2 Cosmetics - Biological aspects : Structure of skin relating to 12 Hrsproblemslikedryskin,acne,pigmentation,pricklyheat,wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

3 Formulation Building blocks: Building blocks for different 12 product formulations of cosmetics/cosmeceuticals. Surfactants – Hrs Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4 Design of cosmeceutical products: Sun protection, sunscreens 12 Hrsclassificationandregulatoryaspects.Addressingdryskin,acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

5 Herbal Cosmetics : Herbal ingredients used in Hair care, skin 12 care and oral care. Review of guidelines for herbal cosmetics by Hrs private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics – Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II
(MPH 205P)

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

INDUSTRIALPHARMACY(MIP) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MIP 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

THEORY 60 HOURS

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. (11 Hrs)

   IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

   Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. (11 Hrs)

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy — 11 Hrs

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: — 11 Hrs
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography

5 Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: — 11 Hrs
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. Immunological Assays: Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays. — 5 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis– Modern methods – Part B – J W Munson,3 Volume 11, Marcel Dekker Series

PHARMACEUTICAL FORMULATION DEVELOPMENT
(MIP 102T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

Objectives

On completion of this course it is expected that students will be able to understand-

The scheduled activities in a Pharmaceutical firm.

The pre formulation studies of pilot batches of pharmaceutical industry. The significance of dissolution and product stability

THEORY 60 Hrs

1. Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination. 12 Hrs

2 Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development. 12 Hrs

3 Solubility: Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. 12 Hrs

4 Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in-vitro and in-vivo correlations, levels of correlations. 12 Hrs

5 Product Stability: Degradation kinetics, mechanisms, stability 12 testing of drugs and pharmaceuticals, factors influencing-media Hrs effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice Of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nded., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3 rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999. 13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I - III.
18. Wells J. I. Pharmaceutical Preformulation : The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

NOVEL DRUG DELIVERY SYSTEMS
(MIP 103T)

Scope

This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.

Objective

On completion of this course it is expected that students will be able to understand,

The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.

To formulate and evaluate various novel drug delivery systems

THEORY 60 Hrs

1. Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release. 12 Hrs

   Carriers for Drug Delivery: Polymers / co-polymers- introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

2 Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems 12 Hrs

3 Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. 08 Hrs

4 Sub Micron Cosmeceuticals: Biology, formulation science and regulatory aspects. 04 Hrs evaluation of various cosmetics for skin, hair, nail, eye etc and it's

5	Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.	12 Hrs
6	Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.	
7	Biotechnology in Drug Delivery Systems: Brief review of 06 major areas- recombinant DNA technology, monoclonal antibodies, gene therapy.	Hrs
8	New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	06 Hrs

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

INTELLECTUAL PROPERTY RIGHTS
(MIP 104T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

Objectives

On completion of this course it is expected that students will be able to understand,

Assist in Regulatory Audit process.

Establish regulatory guidelines for drug and drug products

The Regulatory requirements for contract research organization

THEORY		60 Hrs
1.	Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.	12 Hrs
2	Role of GATT, TRIPS, and WIPO	12 Hrs
3	Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.	12 Hrs
4	Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA	12 Hrs
5	Regulatory requirements for contract research organization. Regulations for Biosimilars.	12 Hrs

REFERENCES :

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

INDUSTRIAL PHARMACY PRACTICAL - I
(MIP 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation..
9. Stability studies of drugs in dosage forms at 25 ^{o}C, 60% RH and 40 $_{o}$C, 75% RH.
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).
11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
16. Electrophoresis of protein solution.
17. Preparation and evaluation of Liposome delivery system.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP 201T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

Objectives

On completion of this course it is expected that students will be able to understand,

The basic concepts in Biopharmaceutics and pharmacokinetics.

The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

To critically evaluate Biopharmaceutics studies involving drug product equivalency.

To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY 60 Hrs

1. Drug Absorption From The Gastrointestinal Tract: 12 Hrs

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH-partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

2 Biopharmaceutic Considerations in Drug Product Design 12 HrsandInVitroDrugProductPerformance:Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the

	Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: In Vitro–In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.		
3	Pharmacokinetics:Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis - Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.	12 Hrs	
4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.	12 Hrs	
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic-pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.	12 Hrs	

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B.J aiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen,pharmaceutical press, RPS Publishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

SCALE UP AND TECHNOLOGY TRANSFER
(MIP 202T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Objectives:

On completion of this course it is expected that students will be able to understand,

Manage the scale up process in pharmaceutical industry. Assist in technology transfer.

To establish safety guidelines, which prevent industrial hazards.

THEORY 60 Hrs

1. Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations. 12 Hrs

   Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

2 Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification. 12 Hrs

3 Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation. 12 Hrs

4 Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control. 12 Hrs

5	Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.	12 Hrs

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan,Dehli.

PHARMACEUTICAL PRODUCTION TECHNOLOGY
(MIP 203T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

Objectives

On completion of this course it is expected that students will be able to understand,

Handle the scheduled activities in a Pharmaceutical firm.

Manage the production of large batches of pharmaceutical formulations.

THEORY 60 Hrs

1. Improved Tablet Production: Tablet production process, unit operationimprovements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. 12 Hrs

   Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

2. Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. 12 Hrs

3. Lyophilization & Spray drying Technology:Principles, process, freeze-drying and spray drying equipments. 12 Hrs

4. Capsule Production:Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered. 12 Hrs

   Disperse S ystems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.

5	Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI.	12 Hrs

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

ENTREPRENEURSHIP MANAGEMENT
(MIP 204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Objectives:

On completion of this course it is expected that students will be able to understand,

The Role of enterprise in national and global economy
Dynamics of motivation and concepts of entrepreneurship
Demands and challenges of Growth Strategies And Networking

THEORY 60 Hrs

1. Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management. 12 Hrs

2 Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency –Concepts. Developing Entrepreneurial competencies – requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role. 12 Hrs

3 Launching And Organising An Enterprise: Environment scanning–Information,sources,schemesofassistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation – finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation. 12 Hrs

4 Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study. 12 Hrs

5	Preparing Project Proposal To Start On New Enterprise Project work – Feasibility report; Planning, resource mobilisation and implementation.	12 Hrs

REFERENCES

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

INDUSTRIAL PHARMACY PRACTICAL - II
(MIP 205P)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.
13. Preparation and evaluation of a freeze dried formulation.
14. Preparation and evaluation of a spray dried formulation.

PHARMACEUTICALCHEMISTRY(MPC)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPC 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

THEORY 60 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory,Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 10 Hrs

   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 10 Hrs

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 Hrs

4 Chromatography:Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs

a) Thin Layer chromatography
b) High Performance Thin Layer Chromatography
c) Ion exchange chromatography
d) Column chromatography
e) Gas chromatography
f) High Performance Liquid chromatography
g) Ultra High Performance Liquid chromatography
h) Affinity chromatography
i) Gel Chromatography

5 a.Electrophoresis:Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b.X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6 a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs

b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation

and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis – Modern Methods – Part B – J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED ORGANIC CHEMISTRY - I
(MPC 102T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be to understand

The principles and applications of reterosynthesis

The mechanism & applications of various named reactions

The concept of disconnection to develop synthetic routes for small target molecule.

The various catalysts used in organic reactions

The chemistry of heterocyclic compounds

THEORY 60 Hrs

1. Basic Aspects of Organic Chemistry: 12 Hrs

   1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
   2. Types of reaction mechanisms and methods of determining them,
   3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations. Addition reactions
      a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
      b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
      c) Rearrangement reaction

2 Study of mechanism and synthetic applications of following named Reactions: 12 Hrs

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

3 Synthetic Reagents & Applications: 12 Hrs

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups

a. Role of protection in organic synthesis
b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
c. Protection for the Carbonyl Group: Acetals and Ketals
d. Protection for the Carboxyl Group: amides and hydrazides, esters
e. Protection for the Amino Group and Amino acids: carbamates and amides

4 Heterocyclic Chemistry: 12 Hrs

Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine,Theophylline , Mercaptopurine and Thioguanine.

5 Synthon approach and retrosynthesis applications 12 Hrs

i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA)
ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds
iii. Strategies for synthesis of three, four, five and six-membered ring.

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis – The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis – Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

ADVANCED MEDICINAL CHEMISTRY
(MPC 103T)

Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

THEORY 60 Hrs

1. Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. 12 Hrs

   Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

2 Prodrug Design and Analog design: 12 Hrs

   a) Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

   b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

   c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs,

alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3 a) Medicinal chemistry aspects of the following class of drugs 12 Hrs

Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:
a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

4 Rational Design of Enzyme Inhibitors 12 Hrs

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

5 Peptidomimetics 12 Hrs

Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS
(MPC 104T)

Scope

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives

At completion of this course it is expected that students will be able to understand-

Different types of natural compounds and their chemistry and medicinal importance

The importance of natural compounds as lead molecules for new drug discovery

The concept of rDNA technology tool for new drug discovery

General methods of structural elucidation of compounds of natural origin

Isolation, purification and characterization of simple chemical constituents from natural source

THEORY 60 Hrs

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs 12 Hrs
   a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
   b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
   c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
   d) Neuromuscular Blocking Drugs: Curare alkaloids
   e) Anti-malarial drugs and Analogues
   f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)

2 a) Alkaloids 12 Hrs

General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

b) Flavonoids

Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

c) Steroids

General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

3 a) Terpenoids 12 Hrs

Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (β carotene).

b) Vitamins

Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

4 a). Recombinant DNA technology and drug discovery 12 Hrs

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

b). Active constituent of certain crude drugs used in Indigenous system Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.

5 Structural Characterization of natural compounds 12 Hrs

Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

PHARMACEUTICAL CHEMISTRY PRACTICAL - I
(MPC 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography
2. Claisen-schimidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents

ADVANCED SPECTRAL ANALYSIS
(MPC 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

At completion of this course it is expected that students will be able to understand-

Interpretation of the NMR, Mass and IR spectra of various organic compounds

Theoretical and practical skills of the hyphenated instruments Identification of organic compounds

THEORY 60Hrs

1. UV and IR spectroscopy: 12 Hrs

Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones.

ATR-IR, IR Interpretation of organic compounds.

2 NMR spectroscopy: 12 Hrs

1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

3 Mass Spectroscopy 12 Hrs

Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

4 Chromatography: 12 Hrs

Principle, Instrumentation and Applications of the following : a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography

5 a). Thermal methods of analysis 12 Hrs

Introduction, principle, instrumentation and application of DSC, DTA and TGA.

b). Raman Spectroscopy

Introduction, Principle, Instrumentation and Applications.

c). Radio immuno assay

Biological standardization , bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC – P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis– Modern methods – Part B – J W Munson, Volume 11, Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY - II
(MPC 202T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall able to understand

The principles and applications of Green chemistry The concept of peptide chemistry.

The various catalysts used in organic reactions

The concept of stereochemistry and asymmetric synthesis.

THEORY 60 Hrs

1. Green Chemistry: 12 Hrs
   a. Introduction, principles of green chemistry
   b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
   c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
   d. Continuous flow reactors: Working principle, advantages and synthetic applications.
2. Chemistry of peptides 12 Hrs
   a. Coupling reactions in peptide synthesis
   b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
   c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
   d. Side reactions in peptide synthesis: Deletion peptides, side

reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

3 Photochemical Reactions 12 Hrs

Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.

Pericyclic reactions

Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples

4 Catalysis: 12 Hrs

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
f. Phase transfer catalysis - theory and applications

5 Stereochemistry & Asymmetric Synthesis 12 Hrs

a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.
b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

REFERENCES

1. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.
2. “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston,NewYork.
3. “Organic Chemistry” Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

COMPUTER AIDED DRUG DESIGN
(MPC 203T)

Scope

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screening protocols

Theory — 60 Hrs

1. Introduction to Computer Aided Drug Design (CADD) — 12 Hrs

   History, different techniques and applications.

   Quantitative Structure Activity Relationships: Basics

   History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

2 Quantitative Structure Activity Relationships: Applications — 12 Hrs

   Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.

   3D-QSAR approaches and contour map analysis.

   Statistical methods used in QSAR analysis and importance of statistical parameters.

3 Molecular Modeling and Docking — 12 Hrs

   a) Molecular and Quantum Mechanics in drug design.
   b) Energy Minimization Methods: comparison between global

minimum conformation and bioactive conformation

c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

4 Molecular Properties and Drug Design 12 Hrs

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.

c) Homology modeling and generation of 3D-structure of protein.

5 Pharmacophore Mapping and Virtual Screening 12 Hrs

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques

Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.

7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

PHARMACEUTICAL PROCESS CHEMISTRY
(MPC 204T)

Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives

At completion of this course it is expected that students will be able to understand

The strategies of scale up process of apis and intermediates

The various unit operations and various reactions in process chemistry

THEORY 60 Hrs

1. Process chemistry 12 Hrs

Introduction, Synthetic strategy

Stages of scale up process: Bench, pilot and large scale process.

In-process control and validation of large scale process.

Case studies of some scale up process of APIs.

Impurities in API, types and their sources including genotoxic impurities

2 Unit operations 12 Hrs

a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
c) Distillation: azeotropic and steam distillation
d) Evaporation: Types of evaporators, factors affecting evaporation.
e) Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

3 Unit Processes - I 12 Hrs

a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,

b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.

c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2, sodium hypochlorite, Oxygen gas, ozonolysis.

4 Unit Processes - II 12 Hrs

a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.

b) Fermentation: Aerobic and anaerobic fermentation. Production of

i. Antibiotics; Penicillin and Streptomycin,
ii. Vitamins: B2 and B12
iii. Statins: Lovastatin, Simvastatin

c) Reaction progress kinetic analysis

i. Streamlining reaction steps, route selection,
ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

5 Industrial Safety 12 Hrs

a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)

b) Fire hazards, types of fire & fire extinguishers

c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

PHARMACEUTICAL CHEMISTRY PRACTICALS – II
(MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
   a) Oxidation
   b) Reduction/hydrogenation
   c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene from p-toluidine.
13. $NaBH_4$ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares
    Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

PHARMACEUTICALANALYSIS(MPA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

	THEORY	60 Hrs
1.	a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	10 Hrs
2	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10 Hrs
3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass	10

Spectroscopy, Different types of ionization like electron impact, Hrs chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

4 Chromatography: Principle, apparatus, instrumentation, 10 chromatographic parameters, factors affecting resolution, isolation Hrs of drug from excipients, data interpretation and applications of the following:

a. Thin Layer chromatography
b. High Performance Thin Layer Chromatography
c. Ion exchange chromatography
d. Column chromatography
e. Gas chromatography
f. High Performance Liquid chromatography
g. Ultra High Performance Liquid chromatography
h. Affinity chromatography
i. Gel Chromatography

5 a. Electrophoresis: Principle, Instrumentation, Working 10 conditions, factors affecting separation and applications of the Hrs following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

6 Potentiometry: Principle, working, Ion selective Electrodes and 10 Application of potentiometry. Hrs

Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation

and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis – Modern Methods – Part B – J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACEUTICAL ANALYSIS
(MPA 102T)

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall able to know,

Appropriate analytical skills required for the analytical method development.

Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.

Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY 60 Hrs

1. Impurity and stability studies: 10 Hrs

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

Impurities in new drug products:

Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents:

General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

2 Elemental impurities: 10 Hrs

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis

	Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.	
3	Impurity profiling and degradent characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products	10 Hrs
4	Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.	10 Hrs
5	Biological tests and assays of the following: a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)	10 Hrs
6	Immunoassays (IA) Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.	10 Hrs

REFERENCES

1. Vogel's textbook of quantitative chemical analysis – Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis – K A Connors, 3rd Edition, John Wiley & Sons, 1982.

4. Pharmaceutical Analysis – Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis– Modern methods – J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs – D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids – Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

PHARMACEUTICAL VALIDATION
(MPA 103T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

Upon completion of the subject student shall be able to

Explain the aspect of validation

Carryout validation of manufacturing processes

Apply the knowledge of validation to instruments and equipments Validate the manufacturing facilities

THEORY 60 Hrs

1.	Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.	12 Hrs
2	Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.	12 Hrs
3	Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).	12 Hrs
4	Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.	12 Hrs

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.

5	General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property -patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	12 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

FOOD ANALYSIS
(MPA 104T)

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

Food constituents
Food additives
Finished food products
Pesticides in food

And also student shall have the knowledge on food regulations and legislations

THEORY 60 Hrs

1. Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates 12 Hrs

   Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

2 Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods. 12 Hrs

   Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

3 Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents. 12 Hrs

   Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic

dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

4	General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar.	12 Hrs
5	Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.	12 Hrs

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

PHARMACEUTICAL ANALYSIS PRACTICALS - II
(MPA 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Imupurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

ADVANCED INSTRUMENTAL ANALYSIS
(MPA 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives

After completion of course student is able to know,

interpretation of the NMR, Mass and IR spectra of various organic compounds

theoretical and practical skills of the hyphenated instruments identification of organic compounds

THEORY 60 Hrs

1. HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC. 12 Hrs

2 Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. 12 Hrs

Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

3 Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications. 12 Hrs

Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method

development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

4 Mass spectrometry: Principle, theory, instrumentation of mass 12 spectrometry, different types of ionization like electron impact, Hrs chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.

5 NMR spectroscopy: Quantum numbers and their role in NMR, 12 HrsPrinciple,Instrumentation,SolventrequirementinNMR,

Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods - Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

MODERN BIO-ANALYTICAL TECHNIQUES
(MPA 202T)

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

Upon completion of the course, the student shall be able to understand
Extraction of drugs from biological samples
Separation of drugs from biological samples using different techniques Guidelines for BA/BE studies.

THEORY 60 Hrs

1. Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid – Liquid extraction and Solid phase extraction and other novel sample preparation approach. Bioanalytical method validation: USFDA and EMEA guidelines. — 12 Hrs

2 Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. — 12 Hrs

3 Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics. — 12 Hrs

4 Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of — 12 Hrs

cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

5 Metabolite identification: 12 Hrs

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met -ID. Regulatory perspectives.

In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:

Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley - Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods - Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development - Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals - John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology - Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations - Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

QUALITY CONTROL AND QUALITY ASSURANCE
(MPA 203T)

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

At the completion of this subject it is expected that the student shall be able to know

the cGMP aspects in a pharmaceutical industry
to appreciate the importance of documentation
to understand the scope of quality certifications applicable to Pharmaceutical industries
to understand the responsibilities of QA & QC departments

THEORY 60 hrs

1. Concept and Evolution of Quality Control and Quality Assurance 12 Hrs

   Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

   Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

2. cGMP guidelines according to schedule M, USFDA (inclusive 12 of CDER and CBER) Pharmaceutical Inspection Convention Hrs

   (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

3. Analysis of raw materials, finished products, packaging 12 materials, in process quality control (IPQC), Developing Hrs specification (ICH Q6 and Q3)

Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

4. Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. 12 Hrs

5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. 12 Hrs

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V – General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management

9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 – With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

HERBAL AND COSMETIC ANALYSIS
(MPA 204T)

Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

Determination of herbal remedies and regulations

Analysis of natural products and monographs

Determination of Herbal drug-drug interaction

Principles of performance evaluation of cosmetic products.

THEORY 60 Hrs

1. Herbal remedies- Toxicity and Regulations: Herbals vs 12 Conventional drugs, Efficacy of herbal medicine products, Hrs Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

2 Adulteration and Deterioration: Introduction, types of 12 adulteration/substitution of herbal drugs, Causes and Measure of Hrs adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.

Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

3 Testing of natural products and drugs: Effect of herbal 12 medicine on clinical laboratory testing, Adulterant Screening using Hrs modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.

Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic

Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

4 Herbal drug-drug interaction: WHO and AYUSH guidelines for 12 safety monitoring of natural medicine, Spontaneous reporting Hrs schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

5 Evaluation of cosmetic products: Determination of acid value, 12 Hrsestervalue,saponificationvalue,iodinevalue,peroxidevalue,

rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

PHARMACEUTICAL ANALYSIS PRACTICALS - I
(MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

PHARMACEUTICALQUALITYASSURANCE(MQA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

THEORY 60 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. (12 Hrs)

   b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. (12 Hrs)

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	12 Hrs
4	Chromatography:Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: Thin Layer chromatography High Performance Thin Layer Chromatography Ion exchange chromatography Column chromatography Gas chromatography High Performance Liquid chromatography Ultra High Performance Liquid chromatography Affinity chromatography Gel Chromatography	12 Hrs
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	12 Hrs
6	a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation	12 Hrs

and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis – Modern Methods – Part B – J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

QUALITY MANAGEMENT SYSTEMS
(MQA 102T)

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives

At completion of this course it is expected that students will be able to understand-

The importance of quality ISO
management systems Tools
for quality improvement
Analysis of issues in quality
Quality evaluation of pharmaceuticals
Stability testing of drug and drug substances
Statistical approaches for quality

THEORY 60 Hrs

1. Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality 12 Hrs

   Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality

   Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.

   Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.

2	Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.	12 Hrs
3	Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection. Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints – evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	12 Hrs
4	Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	12 Hrs
5	Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts – concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	8 Hrs
6	Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	4 Hrs

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE
(MQA 103T)

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

Upon completion of this course the student should be able to

Understand the cGMP aspects in a pharmaceutical industry To appreciate the importance of documentation

To understand the scope of quality certifications applicable to Pharmaceutical industries

To understand the responsibilities of QA & QC departments.

THEORY 60 Hrs

1. Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines. — 12 Hrs

2 cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. — 12 Hrs

3 Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. — 12 Hrs

In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

4 Documentation in pharmaceutical industry: Three tier 12 documentation, Policy, Procedures and Work instructions, and Hrs records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents.
Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.

5 Manufacturing operations and controls: Sanitation of 12 manufacturing premises, mix-ups and cross contamination, Hrs processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.
Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's - P P Sharma, Vandana Publications, Agra, 1991.

5. The International Pharmacopoeia – vol I, II, III, IV & V – General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 – With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives

Upon completion of this course the student should be able to

To understand the new product development process

To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D

To elucidate necessary information to transfer technology of existing products between various manufacturing places

THEORY 60 Hrs

1. Principles of Drug discovery and development: Introduction, 12 HrsClinicalresearchprocess.Developmentandinformationalcontent

for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

2 Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development. 12 Hrs

3 Pilot plant scale up: Concept, Significance, design, layout of 12 Hrspilotplantscaleupstudy,operations,largescalemanufacturing

techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

4 Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. 12 Hrs

Quality control test: Containers, closures and secondary packing materials.

5 Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. 12 Hrs

Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

QUALITY ASSURANCE PRACTICAL - I
(MQA 105P)

PRACTICALS

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on
   - Total Quality
   - Management Six Sigma
   - Change Management/ Change control.
   - Deviations, Out of Specifications (OOS)
   - Out of Trend (OOT)
   - Corrective & Preventive Actions
   - (CAPA) Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of Pka and Log p of drugs.

HAZARDS AND SAFETY MANAGEMENT
(MQA 201T)

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

Understand about environmental problems among learners.

Impart basic knowledge about the environment and its allied problems.

Develop an attitude of concern for the industry environment.

Ensure safety standards in pharmaceutical industry

Provide comprehensive knowledge on the safety management

Empower an ideas to clear mechanism and management in different kinds of hazard management system

Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

THEORY 60Hrs

1. Multidisciplinary nature of environmental studies: Natural 12 Resources, Renewable and non-renewable resources, Natural Hrs resources and associated problems,
a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources
Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

2 Air based hazards: Sources, Types of Hazards, Air circulation 12 maintenance industry for sterile area and non sterile area, Hrs Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

3 Chemical based hazards: Sources of chemical hazards, 12 Hazards of Organic synthesis, sulphonating hazard, Organic Hrs solvent hazard, Control measures for chemical hazards,

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

4 Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion-electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers. 12 Hrs

5 Hazard and risk management: Self-protective measures against workplacehazards.Criticaltrainingforriskmanagement,Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools
Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services. 12 Hrs

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

PHARMACEUTICAL VALIDATION
(MQA 202T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

At completion of this course, it is expected that students will be able to understand

The concepts of calibration, qualification and validation
The qualification of various equipments and instruments
Process validation of different dosage forms
Validation of analytical method for estimation of drugs
Cleaning validation of equipments employed in the manufacture of pharmaceuticals

THEORY 60 Hrs

1. Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. 10 Hrs

   Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status-Calibration Preventive Maintenance, Change management).

2 Qualification of manufacturing equipment:Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression Hrs (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.

Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

3	Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.	10 Hrs
4	Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.	10 Hrs
5	Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP	10 Hrs
6	General Principles of Intellectual Property: Concepts of IntellectualProperty(IP),IntellectualPropertyProtection(IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property -patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications- provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics- positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	10 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco,
5. (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

AUDITS AND REGULATORY COMPLIANCE
(MPA 203T)

Scope

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives

Upon completion of this course the student should be able to

To understand the importance of auditing
To understand the methodology of auditing To carry out the audit process
To prepare the auditing report
To prepare the check list for auditing

THEORY 60 Hrs

1. Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies — 12 Hrs

2 Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries. — 12 Hrs

3 Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging. — 12 Hrs

4 Auditingof Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials. — 12 Hrs

5 Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP. 12 Hrs

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

PHARMACEUTICAL MANUFACTURING TECHNOLOGY
(MQA 204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives

At completion of this course it is expected that students will be able to understand,

The common practice in the pharmaceutical industry developments, plant layout and production planning

Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.

Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

THEORY 60 Hrs

1. Pharmaceutical industry developments: Legal requirements 12 HrsandLicensesforAPIandformulationindustry,Plantlocation-Factors influencing.

Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.

Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

2 Aseptic process technology: Manufacturing, manufacturing 12 flowcharts, in process-quality control tests for following sterile Hrs dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).

Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),

Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.

3 Non sterile manufacturing process technology: 12 Manufacturing, manufacturing flowcharts, in process-quality Hrs control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).

Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

4 Containers and closures for pharmaceuticals: Types, 12 performance, assuring quality of glass; types of plastics used, Hrs Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

5 Quality by design (QbD) and process analytical technology (PAT): 12 Hrs
Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

QUALITY ASSURANCE PRACTICAL – II PRACTICALS (MQA 205P)

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO_2 using Colorimetric method
7. Qualification of following Pharma equipment
   a.Autoclave
   b.Hot air oven
   c.Powder Mixer (Dry)
   d.Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

PHARMACEUTICALREGULATORY AFFAIRS(MRA)

GOOD REGULATORY PRACTICES (MRA 101T)

Scope

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Objectives

At completion of this course it is expected that students will be able to understand,

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits and inspections.

THEORY 60 Hrs

1. Current Good Manufacturing Practices: Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs. 12 Hrs

2 Good Laboratory Practices: Introduction, USFDA GLP 12 Regulations (Subpart A to Subpart K), Controlling the GLP Hrs inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India(QCI) Standards

3 Good Automated Laboratory Practices: Introduction to GALP, 12 Principles of GALP, GALP Requirements, SOPs of GALP, Hrs Training Documentation,21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

4	Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards	12 Hrs
5	Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.	12 Hrs

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

DOCUMENTATION AND REGULATORY WRITING
(MRA 102T)

Scope

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives

Upon completion of the course the student shall be able to,

Know the various documents pertaining to drugs in pharmaceutical industry

Understand the basics of regulatory compilation

Create and assemble the regulation submission as per the requirements of agencies

Follow up the submissions and post approval document requirements

THEORY 60 Hrs

1. Documentation in pharmaceutical industry: Exploratory 12 Product Development Brief (EPDB) for Drug substance and Drug Hrs product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

2 Dossier preparation and submission: Introduction and 12 overview of dossiers, contents and organization of dossier, Hrs binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

3 Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485. 12 Hrs

4 Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA). 12 Hrs

5 Product life cycle management: Prior Approval Supplement 12 (PAS), Post Approval Changes [SUPAC], Changes Being Hrs Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS
(MRA 103T)

Scope

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives

Upon completion of the course, the student shall be able to (know, do and appreciate)

- History, origin and ethics of clinical and biomedical research and evaluation
- Clinical drug, medical device development process and different types and phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research

Theory — 60 Hrs

1. Clinical Drug Development Process — 12 Hrs

Different types of Clinical Studies

Phases of clinical trials, Clinical Trial protocol Phase 0 studies

Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points

Phase II studies (proof of concept or principle studies to establish efficacy)

Phase III studies (Multi ethnicity, global clinical trial, registration studies)

Phase IV studies (Post Marketing Studies; PSUR)

Clinical Investigation and Evaluation of Medical Devices & IVDs

Different Types of Studies

Key Concepts of Medical Device Clinical Evaluation

Key concepts of Clinical Investigation

2 Ethics in Clinical Research: 12 Hrs

Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki

Origin of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines.

The ethics of randomized clinical trials

The role of placebo in clinical trials

Ethics of clinical research in special population

Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data

Data safety monitoring boards.

Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research

Ethical principles governing informed consent process

Patient Information Sheet and Informed Consent Form

The informed consent process and documentation

3 Regulations governing Clinical Trials 12 Hrs

India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance

USA: Regulations to conduct drug studies in USA (FDA)

NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)

NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)

ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)

FDA Guidance for Industry – Acceptance of Foreign Clinical Studies

FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

4	Clinical Research Related Guidelines Good Clinical Practice Guidelines (ICH GCP E6) Indian GCP Guidelines ICMR Ethical Guidelines for Biomedical Research CDSCO guidelines GHTF study group 5 guidance documents Regulatory Guidance on Efficacy and Safety ICH Guidance's E4 – Dose Response Information to support Drug Registration E7 – Studies in support of General Population: Geriatrics E8 – General Considerations of Clinical Trials E10 – Choice of Control Groups and Related Issues in Clinical Trials, E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population General biostatics principle applied in clinical research	12 Hrs
5	USA & EU Guidance USA: FDA Guidance CFR 21Part 50: Protection of Human Subjects CFR 21Part 54: Financial Disclosure by Clinical Investigators CFR 21Part 312: IND Application CFR 21Part 314: Application for FDA Approval to Market a New Drug CFR 21Part 320: Bioavailability and bioequivalence requirements CFR 21Part 812: Investigational Device Exemptions CFR 21Part 822: Post-market surveillance FDA Safety Reporting Requirements for INDs and BA/BE Studies FDA Med Watch Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment European Union: EMA Guidance EU Directives 2001 EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use EU Annual Safety Report (ASR) Volume 9A – Pharmacovigilance for Medicinal Products for Human Use EU MDD with respect to clinical research ISO 14155	12 Hrs

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www. ich.org/products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application:
6. http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmetic ActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
7. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
8. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
9. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in /ethical_guidelines.pdf

REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

(MRA 104T)

Scope

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives

Upon the completion of the course the student shall be able to:

Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.

Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

THEORY 60 Hrs

1. Biologicals & Herbals, and Food & Nutraceuticals 12 Hrs

Acts and Rules (with latest amendments):

1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA
2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

2	Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals Format and contents of Regulatory dossier filing Clinical trial/ investigations	12 Hrs
3	Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards	12 Hrs
4	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO Guidelines for Drug testing in animals/Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research	12 Hrs
5	Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs	12 Hrs

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)

6. ICH E6 Guideline — Good Clinical Practice‖ by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

REGULATORY AFFAIRS PRACTICAL - I
(MRA 105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER II

REGULATORY ASPECTS OF DRUGS & COSMETICS

(MRA 201T)

Scope

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countriesIt prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Objectives

Upon completion of the course, the student shall be able to know

process of drug discovery and development and generic product development

regulatory approval process and registration procedures for API and drug products in US, EU

Cosmetics regulations in regulated and semi-regulated countries

A comparative study of India with other global regulated markets

Theory 60 Hrs

1. USA & CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada. 12 Hrs

2 European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, 12 Hrs

Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

3 Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan — 12 Hrs

4 Emerging Market: Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) — 12 Hrs

WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) – General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)

5 Brazil, ASEAN, CIS and GCC Countries: — 12 Hrs

ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

CIS (Commonwealth Independent States): Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE

Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

REFERENCES :

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe

It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

Objectives

Upon the completion of the course the student shall be able to :

Know the regulatory Requirements for Biologics and Vaccines

Understand the regulation for newly developed biologics and biosimilars

Know the pre-clinical and clinical development considerations of biologics

Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

Theory 60 Hrs

1. India : Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP. — 12 Hrs

2 USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics — 12 Hrs

3 European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical — 12 Hrs

and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU

4	Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US anc. European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)	12 Hrs
5	Herbal Products: Quality, safety and legislation for herbal products in India, USA and European Union.	12 Hrs

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatory Information (Biologics)

REGULATORY ASPECTS OF MEDICAL DEVICES
(MRA 203T)

Scope

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Objectives

Upon completion of the course, the student shall be able to know

basics of medical devices and IVDs, process of development, ethical and quality considerations

harmonization initiatives for approval and marketing of medical devices and IVDs

regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN

clinical evaluation and investigation of medical devices and IVDs

Theory 60 Hrs

1. Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices. IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN). 12 Hrs

2 Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device 12 Hrs

3	USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.	12 Hrs
4	European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.	12 Hrs
5	ASEAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.	12 Hrs

REFERENCES

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Scope

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe.

It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

Objectives

Upon completion of the course, the student shall be able to

Know the regulatory Requirements for nutraceuticals

Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

Theory 60 Hrs

1.	Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.	12 Hrs
2	Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.	12 Hrs
3	India : Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.	12 Hrs
4	USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S	12 Hrs

5	European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.	12 Hrs

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL - II
(MRA 205P)

1. Case studies on
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

PHARMACEUTICALBIOTECHNOLOGY(MPB)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPB 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

THEORY 60 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. 12 Hrs

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

b. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

c. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 12 Hrs

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	12 Hrs
4	Chromatography:Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	12 Hrs
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder diffration technique, Types of crystals and applications of X-ray diffraction.	12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore.
3. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern methods - Part B - J W Munson, Volume 11, Marcel Dekker Series

MICROBIAL AND CELLULAR BIOLOGY
(MPB 102T)

Scope

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objective

At the completion of this course it is expected that the students will get an understanding about the following aspects;

Importance of Microorganisms in Industry
Central dogma of molecular biology
Structure and function of cell and cell communication
Cell culture technology and its applications in pharmaceutical industries.
Microbial pathogenesis and correlating it to rational use of antimicrobial agents.

THEORY 60Hrs

1. Microbiology 12 Hrs

Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actionomycetes and virus – structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms – examples and applications

2 Molecular Biology: Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and translation. 12 Hrs

Gene regulation

Gene copy number, transcriptional control and translational control.

RNA processing

Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of plasmids– types purification and application. Phage genetics, geneticorganization, phage mutation and lysogeny.

3	Cell structure and function Cell organelles, cytoskeleton & cell movements, basic aspectsof cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics,secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Celljunctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – thelife and death of cells in tissues. Cell Cycle and Cytoskeleton Cell Division and its Regulation, G-Protein CoupledReceptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, IntermediateFilaments. Apoptosis and Oncogenes Programmed Cell Death, Tumor cells, carcinogens & repair. Differentiation and Developmental Biology Fertilization, Events of Fertilization, In vitro Fertilization, Embryonic Germ Cells, Stem Cells and its Application.	12 Hrs
4	Principles of microbial nutrition Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures. Growth of animal cells in culture General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. In-vitro screening techniques- cytotoxicity, anti-tumor, anti-viral assays.	12 Hrs
5	Microbial pathology Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.	12 Hrs

REFERENCES

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore,Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

BIOPROCESS ENGINEERING AND TECHNOLOGY
(MPB 103T)

Scope

This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

Objective

At the completion of this subject it is expected that students will be able to,

Understand basics and design of fermentation technology

Scale up and scale down processing of fermentation technology

Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.

Regulation governing the manufacturing of biological products

Understand and conduct fermentation process kinetics.

THEORY 60 Hrs

1. Introduction to fermentation technology 12 Hrs

Basic principles of fermentation

Study of the design and operation of bioreactor

Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.

Types of bioreactor

CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application

Computer control of fermentation process

System configuration and application

2 Mass transfer 12 Hrs

Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co-efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.

Rheology

Rheological properties of fermentation system and their importance in bioprocessing.

3 Scale up of fermentation process 12 Hrs

Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.

Cultivation and immobilized culture system

Cultivation system – batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.

Introduction to immobilization

Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.

4 Scale down of fermentation process 12 Hrs

Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.

Isolation and screening

Primary and secondary, maintenance of stockculture, strain improvement for increased yield.

5 Bioprocessing of the industrially important microbial metabolites 12 Hrs

a) Organic solvents – Alcohol and Glycerol
b) Organic acids – Citric acids, Lactic acids,
c) Amino acids – Glutamic acids, Lysine, Cyclic AMP and GMP
d) Antibiotics – Penicillin, Streptomycin, Griseofulvin,
e) Vitamins – B12, Riboflavin and Vitamin C

Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids

Regulation governing the manufacturing of biological products .

REFERENCES

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.
5. H. Patel, Industrial microbiology, Macmillan India Limited.

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY
(MPB 104T)

Scope

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

Objective

At the completion of this subject it is expected that students will be able to

Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.

Identify appropriate sources of enzymes.

Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.

Understand the overview of pharmacogenomics.

Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

THEORY 60 Hrs

1. Enzyme Technology 12 Hrs

Classification, general properties of enzymes, dynamics of enzymatic activity,sources of enzymes, extraction and purification, pharmaceutical,therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase,amylase and trypsin.

2 Genetic Engineering 12 Hrs

Techniques of gene manipulation, cloning strategies,procedures, cloning vectors expression vectors, recombinant selection andscreening, expression in E.coli and yeast.

Site directed mutagenesis, polymerase chain reaction, and analysis of DNAsequences.

Gene library and cDNA

Applications of the above technique in the production of,

Regulatory proteins	- Interferon, Interleukins
Blood products	- Erythropoietin
Vaccines	- Hepatitis-B
Hormones	- Insulin

3	Therapeutic peptides Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration. Transgenic animals Production of useful proteins in transgenic animals and gene therapy. Human Genome The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes	12 Hrs
4	Signal transduction Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases. Oncogenes Introduction, definition, various oncogenes and their proteins.	12 Hrs
5	Microbial Biotransformation Biotransformation for the synthesis of chiral drugs and steroids. Microbial Biodegradation Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein, Applications of microbes in environmental monitoring. Biosensors Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.	12 Hrs

REFERENCES

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose

6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman.

PHARMACEUTICAL BIOTECHNOLOGY
PRACTICAL - I (MPB 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

PROTEINS AND PROTEIN FORMULATIONS
(MPB 201T)

Scope

This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

Objective

At the completion of this course it is expected that students will be able to understand,

Various methods of purification of proteins Peptides in drug development
Protein identification and characterization
Protein based formulations
Sequencing proteins

THEORY 60 Hrs

1. Protein engineering — 12 Hrs

Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution.

2 Peptidomimetics — 12 Hrs

Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

3 Proteomics — 12 Hrs

Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags.

2-Dimensional gel electrophoresis
Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments

4	Protein formulation Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, Neon-spears, Neon-particulate system, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.	12 Hrs
5	Methods of protein sequencing Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.	12 Hrs

REFERENCES

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book, Amersham pharmacia biotech
3. EngelbertBuxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA,Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.

IMMUNOTECHNOLOGY
(MPB 202T)

Scope

This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology – based techniques will be used for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

Objective

After this course, the students will be able to:-

Understand the techniques like immunodiagnostic tests, Characterization of lymphocytes, purification of antigens and antibody, etc.

Access health problems with immunological background;

Develop approaches for the immune intervention of diseases

THEORY 60 Hrs

1. Fundamental aspects of immunology 12 Hrs

Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure.

Types of immune responses, anatomy of immune response.

Overview of innate and adaptive Immunity.

Humoral Immunity

B – Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.

Cell mediated Immunity

Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis

2 Immune Regulation and Tolerance 12 Hrs

Complement activation and types and their biological functions, cytokines and their role in immune response.

Hypersensitivity

Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment

Autoimmune diseases

3 Vaccine technology 12 Hrs

Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics.

Stem cell technology

Stem cell technology and applications to immunology

4 Hybridoma Technology 12 Hrs

Hybridoma techniques – fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.

5 Immunological Disorder 12 Hrs

Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.

Immunodiagnosis

Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction.

REFERENCES

1. J. Kubey, Immunology – an Introduction.
2. S.C. Rastogi, Immunodiagonstics, New Age International.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology.

BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB 203T)

Scope

This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objectives

Upon completion of this course it is expected that the students will be able to understand,

- Use of computers in developing a new drugs
- Biological concepts for bioinformatics
- Proteins and their diversity
- Various gene finding methods
- Searching the biological databases Target searching
- Various methods of drug designing

THEORY 60 Hrs

1. Introduction to Bioinformatics 12 Hrs

Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics,

Biological Database

Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.

2 Sequence analysis 12 Hrs

Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.

3 Protein informatics 12 Hrs

Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R &

S fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.

Protein structure prediction

Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring.

Docking

Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.

4	Diversity of Genomes	12 Hrs

Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications- Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression.

Completed Genomes

Bacterium, Nematode, Plant and Human

Evolution of Genomes

Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome-General Account

Phylogenetic analysis

Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.

5	Target searching and Drug Designing Target and lead, timeline for drug development, target discovery, target modulators, In-silico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.	12 Hrs

REFERENCES

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics- Concepts Skill and Applications, CBS Publishers and Distributors
3. T. E. Creighton, Protein Structure and Molecular Properties, W. H.Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

BIOLOGICAL EVALUATION OF DRUG THERAPY
(MPB 204T)

Scope

This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

Objective

At the completion of this subject it is expected that students will be able to,

Understand about the general concept of standardization of biological.

Understand the importance of transgenic animals and knockout animals.

Understand the biological medicines in development of various diseases.

Learn the biological evaluation of drugs in vitro and in vivo

THEORY 60 Hrs

1. Biological Standardization 12 Hrs

General principles, Scope and limitation of bio-assay, bioassay of some official drugs.

Preclinical drug evaluation

Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity.

Guidelines for toxicity studies

Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

2 Pyrogens 12 Hrs

Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.

Microbiological assay

Assay of antibiotics and vitamins.

Biological evaluation of drugs

Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study).

3	Biologic Medicines in Development for various diseases - By Therapeutic Category Genetic Disorders Eye related Disorders Digestive Disorders Diabetes/Related Conditions Cardiovascular Disease Cancer/Related Conditions Blood Disorders Autoimmune Disorders Infectious Diseases Neurologic Disorders Skin Diseases Organe Transplantation Biologic Medicines in Development for various diseases – by Product Category Antisense Vaccines Recombinant Hormones/Proteins Monoclonal Antibodies (mAb) Interferons Growth Factors Gene Therapy RNA Interference	12 Hrs
4	Regulatory aspects : drugs, biologics and medical devices An introduction to the regulations and documents necessary for approval of a medical product. Regulatory consideration Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices. New Drug Applications for Global Pharmaceutical Product Approvals	12 Hrs
5	Bioavailability Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio-availability.	12 Hrs

Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals.

Pharmacokinetics

Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.

REFERENCES

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.
6. Screening methods in pharmacology (vol I & II), R.A. Turner.

PHARMACEUTICAL BIOTECHNOLOGY
PRACTICAL - II (MPB 205P)

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
14. Introduction to PCR – working of PCR, Programming.
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

PHARMACYPRACTICE(MPP)

CLINICAL PHARMACY PRACTICE (MPP 101T)

Scope

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Objectives

Upon completion of this course it is expected that students shall be able to :

Understand the elements of pharmaceutical care and provide comprehensive patient care services

Interpret the laboratory results to aid the clinical diagnosis of various disorders

Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

THEORY 60 Hrs

1. Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care — 12 Hrs

   Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)

2 Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services. — 12 Hrs

3 Patient Data Analysis: — 12 Hrs

Patient Data & Practice Skills: Patient's case history – its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services.

	Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests	
4	Lab DataInterpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests	12 Hrs
5	Medicines & Poison Information Services Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre. Poison Information Service: Definition, need, organization and functions of poison information centre.	12 Hrs

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions – The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I
(MPP 102T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY 60 Hrs

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

1. Cardiovascular system: Hypertension, Congestive cardiac 12 failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias. Hrs

2 Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases 12 Hrs

Endocrine system: Diabetes, Thyroid diseases

3 Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis 12 Hrs

4 Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease 12 Hrs

Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders

5	Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis		12 Hrs
	Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders		
	Ophthalmology: Conjunctivitis, Glaucoma		

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-- McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

HOSPITAL & COMMUNITY PHARMACY
(MPP 103T)

Scope

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

THEORY 60 Hrs

1. Introduction to Hospitals – Definition, classification, organizational structure 12 Hrs

   Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management

   Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH

2. Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management 12 Hrs

3. Education and training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. 12 Hrs

   Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers.

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

4	Prescription – Legal requirements & interpretation, prescription related problems Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy, OTC medication: Rational use of over the counter medications Medication counseling and use of patient information leaflets Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence Patient referrals to the doctors ADR monitoring in community pharmacies	12 Hrs
5	Health Promotion – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care National Health Programs– Role of Community Pharmacist in Malaria and TB control programs Home Medicines review program – Definition, objectives, Guidelines, method and outcomes Research in community pharmacy Practice	12 Hrs

REFERENCES

1. Hospital Pharmacy – Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy – Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH
(MPP 104T)

Scope

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives

Upon completion of this course it is expected that students shall be able to:

Know the new drug development process.

Understand the regulatory and ethical requirements.

Appreciate and conduct the clinical trials activities

Know safety monitoring and reporting in clinical trials Manage the trial coordination process

THEORY 60 Hrs

1. Drug development process: Introduction, various approaches to drug discovery, Investigational new drug application submission Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] – its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting. 12 Hrs

2 Types and Designs used in Clinical Research: Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) 12 Hrs

Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

3	Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Hrs Consent Form, Case report forms, Contracts and agreements, Dairy Cards Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission	12 Hrs
4	Investigational Product: Procurement and Storage of investigation product Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up Clinical Trial Monitoring and Close out: Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.	
5	Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management Data Management Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.	12 Hrs

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I
(MPP 105P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

PRINCIPLES OF QUALITY USE OF MEDICINES
(MPP 201T)

Scope:

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

THEORY 60 Hrs

1. Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing. — 12 Hrs

2. Concepts in QUM — 12 Hrs
   Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings
   Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list
   Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.

3. QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. — 12 Hrs
   QUM in special population: Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.

4 Regulatory aspects of QUM in India: Regulation including 12 scheduling, Regulation of complementary medicines, Regulation Hrs of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.

5 Medication errors: Definition, categorization and causes of 12 Hrsmedicationerrors,Detectionandpreventionofmedicationerrors,

Role of pharmacist in monitoring and management of medication errors

Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

REFERENCES:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors
6. Online:
   http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
   http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
   http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS II
(MPP 202T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effect/s)

	THEORY	60 Hrs
1.	Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.	12 Hrs
2	Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease	12 Hrs
3	Infectious diseases: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.	12 Hrs
4	Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.	12 Hrs

5	Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care	12 Hrs	

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-- McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING
(MPP 203T)

Scope

This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
  - Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
  - Recommend dosage adjustment for patients with renal/ hepatic impairment
  - Recommend dosage adjustment for paediatrics and geriatrics Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
  - Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
  - Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

THEORY 60 Hrs

1. Introduction to Clinical pharmacokinetics: Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses — 12 Hrs

   Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

2	Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.	12 Hrs
3	Non Linier Mixed Effects Modelling: The Structural or Base 12 Model, Modeling Random Effects, Modeling Covariate Hrs Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.	
4	Altered Pharmacokinetics: Drug dosing in the elderly, Drug 12 Hrsdosinginthepaediatrics,Drugdosingintheobesepatients,Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure.	
5	Therapeutic Drug monitoring: Introduction, Individualization of 12 drug dosage regimen (Variability – Genetic, age, weight, disease Hrs and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem.	

REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. lippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. lippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. lippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP 204T)

Scope

This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Objectives

Upon completion of this course it is expected that students shall be able to:

Understand the various epidemiological methods and their applications

Understand the fundamental principles of Pharmacoeconomics.

Identify and determine relevant cost and consequences associated with pharmacy products and services.

Perform the key Pharmacoeconomics analysis methods

Understand the Pharmacoeconomic decision analysis methods and its applications.

Describe current Pharmacoeconomic methods and issues.

Understand the applications of Pharmacoeconomics to various pharmacy settings.

THEORY 60 Hrs

1. Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio — 12 Hrs

2 Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event — 12 Hrs

monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

3 Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. 12 Hrs

Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs.

Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

4 Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA). 12 Hrs

5 Definition, Steps involved, Applications, Advantages and disadvantages of the following: 12 Hrs

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures.

Definition, Steps involved, Applications of the following:

Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.

REFERENCES

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.

5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - II
(MPP 205P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics–II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about,

Chemicals and Excipients

The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

THEORY 60 Hrs

1. UV-Visiblespectroscopy: Introduction, Theory,Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 10 Hrs

   IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

   Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 10 Hrs

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: j) Thin Layer chromatography k) High Performance Thin Layer Chromatography l) Ion exchange chromatography m) Column chromatography n) Gas chromatography o) High Performance Liquid chromatography p) Ultra High Performance Liquid chromatography q) Affinity chromatography r) Gel Chromatography	10 Hrs
5	Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	10 Hrs
6	Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	10 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis – Modern Methods – Part B – J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY - I
(MPL 102T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives

Upon completion of the course the student shall be able to :

Discuss the pathophysiology and pharmacotherapy of certain diseases
Explain the mechanism of drug actions at cellular and molecular level
Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY 60 Hrs

1. General Pharmacology 12 Hrs

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

2 Neurotransmission 12 Hrs

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting

neuromuscular junction

3	Central nervous system Pharmacology General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.	12 Hrs
4	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs	12 Hrs
5	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	12 Hrs

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.

10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I
(MPL 103T)

Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Objectives

Upon completion of the course the student shall be able to,

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

THEORY 60 Hrs

1. Laboratory Animals 12

Common laboratory animals: Description, handling and Hrs applications of different species and strains of animals.

Transgenic animals: Production, maintenance and applications
Anaesthesia and euthanasia of experimental animals.
Maintenance and breeding of laboratory animals.
CPCSEA guidelines to conduct experiments on animals

Good laboratory practice.
Bioassay-Principle, scope and limitations and methods

2 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and

depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

3	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.	12 Hrs

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti - emetic, anti-diarrheal and laxatives.

4	Preclinicalscreeningofnew substances forthe pharmacological activity using in vivo, in vitro, and other possible animal alternative models.	12 Hrs

Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

5	Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.	12 Hrs

limmunomodulators, Immunosuppressants and immunostimulants

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

Limitations of animal experimentation and alternate animal experiments.

Extrapolation of in vitro data to preclinical and preclinical to humans

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

CELLULAR AND MOLECULAR PHARMACOLOGY
(MPL 104T)

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

THEORY — 60 Hrs

1. Cell biology — 12 Hrs

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

Cell cycles and its regulation.

Cell death- events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

2 Cell signaling — 12 Hrs

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3	Principles and applications of genomic and proteomic tools 12 DNA electrophoresis, PCR (reverse transcription and real time), Hrs Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	
4	Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice	12 Hrs
5	a. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars	12 Hrs

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGICAL PRACTICAL - I
(MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds – Robert M Silverstein,
6. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis – Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

ADVANCED PHARMACOLOGY - II
(MPL 201T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Objectives

Upon completion of the course the student shall be able to:

Explain the mechanism of drug actions at cellular and molecular level
Discuss the Pathophysiology and pharmacotherapy of certain diseases
Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

	THEORY	60 Hrs
1.	Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation	12 Hrs
2	Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.	12 Hrs
3	Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants	12 Hrs

4	GIT Pharmacology Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer	12 Hrs
5	Free radicals Pharmacology Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12 Hrs

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II
(MPL 202T)

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

Upon completion of the course, the student shall be able to,

Explain the various types of toxicity studies.

Appreciate the importance of ethical and regulatory requirements for toxicity studies.

Demonstrate the practical skills required to conduct the preclinical toxicity studies.

	THEORY	60 Hrs
1.	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	12 Hrs
2	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	12 Hrs
3	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12 Hrs
4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.	12 Hrs

Safety pharmacology studies- origin, concepts and importance of safety pharmacology.
Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12 Hrs

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp-handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY
(MPL 203T)

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

Upon completion of the course, the student shall be able to,

Explain the various stages of drug discovery.

Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery

Explain various targets for drug discovery.

Explain various lead seeking method and lead optimization

Appreciate the importance of the role of computer aided drug design in drug discovery

THEORY 60 Hrs

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. 12 Hrs

   Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

2 Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. 12 Hrs

   Protein structure

   Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

3 Rational Drug Design 12 Hrs

   Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

	Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,	
4	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.	12 Hrs
5	QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design	12 Hrs

REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MPL 204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

THEORY 60 Hrs

1. Regulatory Perspectives of Clinical Trials: 12 Hrs

   Origin and Principles of International Conference on Harmonization – Good Clinical Practice (ICH-GCP) guidelines

   Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR

   Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

2 Clinical Trials: Types and Design 12 Hrs

   Experimental Study- RCT and Non RCT,

   Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team

   Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

3	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	12 Hrs
4	Basic aspects,terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	12 Hrs
5	Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	12 Hrs
6	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	12 Hrs

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOLOGICAL PRACTICAL - II
(MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA_2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

PHARMACOGNOSY (MPG)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

THEORY 60 Hrs

1. UV-Visiblespectroscopy: Introduction, Theory,Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. 12 Hrs

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.1 12 Hrs

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography	10 Hrs
5	Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	10 Hrs
6	Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and	10 Hrs

cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis – Modern Methods – Part B – J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

ADVANCED PHARMACOGNOSY - I
(MPG 102T)

SCOPE

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

advances in the cultivation and production of drugs

various phyto-pharmaceuticals and their source, its utilization and medicinal value.

various nutraceuticals/herbs and their health benefits Drugs of marine origin

Pharmacovigilance of drugs of natural origin

THEORY 60 Hrs

1. Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In-situ conservation of medicinal plants. 12 Hrs

2 Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution. 12 Hrs

3 Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric. 12 Hrs

4 Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following. 12 Hrs

a) Carotenoids – i) α and β – Carotene ii) Xanthophyll (Lutein)
b) Limonoids – i) d–Limonene ii) α – Terpineol
c) Saponins – i) Shatavarins
d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids– Ellagic acid
f) Vitamins
g) Tocotrienols and Tocopherols
h) Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol
i) Miscellaneous

5 Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug–drug and bio drug–food interactions with suitable examples. 12 Hrs

REFERENCES (Latest Editions of)

1. Pharmacognosy – G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
2. Pharmacognosy–Tyler, Brady, Robbers
3. Modem Methods of Plant Analysis– Peach & M.V. Tracey, Vol. I&II
4. Text Book of Pharmacognosy by T.E. Wallis
5. Marine Natural Products–Vol.I to IV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
9. Chemistry of Marine Natural Products– Paul J. Schewer 1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.

14.Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15.Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles-Appleton Century crofts.
16.Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17.Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

PHYTOCHEMISTRY
(MPG 103T)

SCOPE

Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify and extract and the phyto-constituents

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery

phytochemical fingerprinting and structure elucidation of phytoconstituents.

THEORY 60 Hrs

1. Biosynthetic pathways and Radio tracing techniques: Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs: 12 Hrs
   a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vinca alkoloids.
   b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin.
   c) Steroids: Hecogenin, guggulosterone and withanolides
   d) Coumarin: Umbelliferone.
   e) Terpenoids: Cucurbitacins

2 Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules. 12 Hrs

3 Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave 12 Hrs

assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

4	Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents.	12 Hrs
5	Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) a. Carvone, Citral, Menthol b. Luteolin, Kaempferol c. Nicotine, Caffeine iv) Glycyrrhizin.	12 Hrs

REFERENCES (Latest Editions of)

1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999.

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY
(MPG 104T)

SCOPE

To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

OBJECTIVES

By the end of the course the student shall be able to know,

the requirements for setting up the herbal/natural drug industry.

the guidelines for quality of herbal/natural medicines and regulatory issues.

the patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY 60 Hrs

1. Herbal drug industry: Infrastructure of herbal drug industry 12 Hrsinvolvedinproductionofstandardizedextractsandvarious dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale -up techniques, case studies of herbal extracts. Formulation and production management of herbals.

2 Regulatory requirements for setting herbal drug industry: 12 Global marketing management. Indian and international patent Hrs law as applicable herbal drugs and natural products.
Export - Import (EXIM) policy, TRIPS.
Quality assurance in herbal/natural drug products.
Concepts of TQM, GMP, GLP, ISO-9000.

3 Monographs of herbal drugs: General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

4 Testing of natural products and drugs: Herbal medicines – 12 clinical laboratory testing. Stability testing of natural products, Hrs protocols.

5 Patents:Indian and international patent laws, proposed 12 amendments as applicable to herbal/natural products and Hrs process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.

REFERENCES (Latest Editions of)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals – Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H.Wagner and S.Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.
11. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,
12. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), Eastern Publisher, New Delhi.

PHARMACOGNOSY PRACTICAL - I

(MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography
4. Estimation of sodium/potassium by flame photometry
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
6. Methods of extraction
7. Phytochemical screening
8. Demonstration of HPLC- estimation of glycerrhizin
9. Monograph analysis of clove oil
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts
12. Formulation of different dosage forms and their standardisation.

MEDICINAL PLANT BIOTECHNOLOGY
(MPG 201T)

SCOPE

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

OBJECTIVES

Upon completion of the course, the student shall be able to,

Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.

Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

THEORY 60 Hrs

1. Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology. 12 Hrs

2 Different tissue culture techniques: Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. 15 Hrs

3 Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites. 15 Hrs

4 Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic 13 Hrs

plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

5	Fermentation technology: Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest.	05 Hrs

REFERENCES (Latest Editions of)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.

ADVANCED PHARMACOGNOSY - II
(MPG 202T)

SCOPE

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

validation of herbal remedies

methods of detection of adulteration and evaluation techniques for the herbal drugs

methods of screening of herbals for various biological properties

THEORY 60 Hrs

1. Herbal remedies – Toxicity and Regulations: Herbals vs 12 Conventional drugs, Efficacy of Herbal medicine products, Hrs Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.

2 Adulteration and Deterioration: Introduction, Types of 12 Adulteration/ Substitution of Herbal drugs, Causes and Measures Hrs of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations.

3 Ethnobotany and Ethnopharmacology: Ethnobotany in herbal 12 drug evaluation, Impact of Ethnobotany in traditional medicine, Hrs New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.

4 Analytical Profiles of herbal drugs: Andrographis paniculata, 12 Boswellia serata, Coleus forskholii, Curcuma longa, Embelica Hrs officinalis, Psoralea corylifolia.

5 Biological screening of herbal drugs: Introduction and Need for 12 Phyto-Pharmacological Screening, New Strategies for evaluating Hrs

Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.

REFERENCES (Latest Editions of)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal.

INDIAN SYSTEMS OF MEDICINE
(MPG 203T)

SCOPE

To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

OBJECTIVES

After completion of the course, student is able to

To understand the basic principles of various Indian systems of medicine

To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

THEORY 60 Hrs

1. Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine 12 Hrs

Different dosage forms of the ISM.

Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality.

Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).

2 Naturopathy, Yoga and Aromatherapy practices 12 Hrs

a) Naturopathy – Introduction, basic principles and treatment modalities.

b) Yoga – Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.

c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.

3 Formulation development of various systems of medicine 12 Hrs

Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization,

Shelf life and Stability studies of ISM formulations.

4	Schedule T – Good Manufacturing Practice of Indian systems of medicine Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records. Quality assurance in ISM formulation industry – GAP, GMP and GLP. Preparation of documents for new drug application and export registration. Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias.	12 Hrs
5	TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU	12 Hrs

REFERENCES (Latest Editions of)

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacy : An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, bRITISH Herbal Medicine Association, UK.
9. GMP for Botanicals – Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
12. Clinical Dietitics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
13. Yoga – The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.

HERBAL COSMETICS
(MPG 204T)

SCOPE

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

OBJECTIVES

After completion of the course, student shall be able to,

understand the basic principles of various herbal/natural cosmetic preparations

current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

THEORY 60 Hrs

1. Introduction: Herbal/natural cosmetics, Classification & Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: – License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics. 12 Hrs

2 Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation. 12 Hrs

3 Herbal Cosmetics : Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following : Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails. 12 Hrs

4 Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants. 12 Hrs

5	Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act.	12 Hrs

REFERENCES (Latest Editions of)

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics – Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatheraphy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

HERBAL COSMETICS PRACTICALS
(MPG 205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization technique
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde contents of volatile oils
8. Estimation of total phenolic content in herbal raw materials
9. Estimation of total alkaloid content in herbal raw materials
10. Estimation of total flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General R esearch Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

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