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1. **Sumit Arora, Shobha Ubgade, Alok Ubgade**; "Recent Techniques in Isolation of Nutraceuticals from Plants" in "Nutraceutical Delivery Systems" edited by Pankaj Dangre and Debarshi Kar Mahapatra, published by Apple Academic Press, (CRC Press, Taylor and Francis Group) Toronto; August 2022. Hard ISBN: 9781774637166 E-Book ISBN: 9781003189671
2. **Vaishali Kilor, Nidhi Sapkal, Shobha Ubgade, Abhay Ittadwar** "Microemulsions for Improvement in Bioavailability of Potential Nutraceuticals" in "Nutraceutical Delivery Systems" edited by Pankaj Dangre and Debarshi Kar Mahapatra, published by Apple Academic Press, (CRC Press, Taylor and Francis Group) Toronto; August 2022. Hard ISBN: 9781774637166 E-Book ISBN: 9781003189671
3. Shoqufto Khan, **Vaishali Kilor**, Dilesh Singhavi, Kundan Patil. "Progress in nanotechnology-based targeted cancer treatment' in book Photophysics and Nanophysics in Therapeutics. Elsevier, 2022, ISBN: 9780323898393.
4. Vipin V. Dhote, **Vaishali A. Kilor**, Muthu Kumaradoss Mohan Maruga Raja, Ashish Singhai, Avinash Singh Mandloi, Aman B. Upoganlowar. "Effect of Tinospora cordifolia on neuroinflammation" in book -Treatments, Nutraceuticals, Supplements, and Herbal Medicine in Neurological Disorders. Academic Press, 2023, ISBN: 9780323900522

RESEARCH/REVIEW ARTICLE

1. Farheen Bano Khan, **Vaishali Kilor, Nidhi Sapkal**, Priya Dule. Formulation development of mouth dissolving printed film of ketorolac and in vitro evaluation. **International Journal of Applied Pharmaceutics**, 2022, 14(5), 128–136. **Scopus, UGC**
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- Kajal Bais, Kanchan Attargade, Nidhi sapkal, Sumit Arora and Abhay Ittadwar. In-silico evaluation of hesperidin derivatives as vasoprotective agents. 108th Indian Science Congress- 2023. Abstract number for ISC: PP115
- Pradnya Gondane and Nidhi Sapkal. Synthesis and Preliminary Characterization, Evaluation of Loratadine Ionic Salts" presented in 72nd Indian Pharmaceutical Congress, Nagpur held on 20-22 January, 2023.
- Shobha Ubgade. Bioenhancement of drug molecules using nanotherapeutics: potential of nanosuspension as a non-specific approach presentation in 72nd Indian Pharmaceutical Congress, Nagpur held on 20-22 January, 2023.
- Kajal Bais, Kanchan Attargade, and Nidhi sapkal. Mechanism of action of hesperidin and diosmin in varicose vein activity presentation in 72nd Indian Pharmaceutical Congress, Nagpur held on 20-22 January, 2023.
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- Dipti Pirwani, T.M. Rasala, Kajal J. Bhede, A.M. Ittadwar. Environment and Infectious Diseases: Emergence and outbreaks. presentation in 72nd Indian Pharmaceutical Congress, Nagpur held on 20-22 January, 2023.
- Kajal J. Bhede, Dipti Pirwani, T.M. Rasala, A.M. Ittadwar. Formulation and Development of Omega Fatty Acid nutraceutical Beads. presentation in 72nd Indian Pharmaceutical Congress, Nagpur held on 20-22 January, 2023.
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- Krishnakant B. Bhelkar, Keshav S. Moharir, Vinita V. Kale. PREPARATION AND PROCESS OPTIMIZATION OF SUPERABSORBENT HYDROGEL FROM NATURAL POLYMER. Presentation in 72nd Indian Pharmaceutical Congress, Nagpur held on 20-22 January, 2023.

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- Adiba Khan, Mitali Bodhankar. Guar gum based ondansetron microspheres for irritable bowel syndrome. Presentation in 72nd Indian Pharmaceutical Congress, Nagpur held on 20-22 January, 2023.
- Nikita Pal, Mitali Bodhankar. Formulation and evaluation of proliposomal gel for acne vulgaris. Presentation in 72nd Indian Pharmaceutical Congress, Nagpur held on 20-22 January, 2023.

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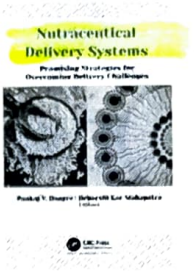
Chapter



Recent Techniques in Isolation of Nutraceuticals from Plants

By Sumit Arora (/search?contributorName=Sumit Arora&contributorRole=author&redirectFromPDP=true&context=ubx), Shobha Ubgade (/search?contributorName=Shobha Ubgade&contributorRole=author&redirectFromPDP=true&context=ubx), Alok Ubgade (/search?contributorName=Alok Ubgade&contributorRole=author&redirectFromPDP=true&context=ubx)

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ABSTRACT

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Photophysics and Nanophysics in Therapeutics
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Chapter 12 - Progress in nanotechnology-based targeted cancer treatment

Shagufta Khan [a], Vaishali Kilor [b], Dilesh Singhavi [a], Kundan Patil [c]

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Abstract

Cancer is the leading cause of death around the world. According to the WHO about 13 million people will die by 2030 due to cancer. This scary forecast has compelled scientists to search for the strategies that could revolutionize the cancer diagnosis and treatment. Many drugs have shown good therapeutic activity but they have failed clinically because of their physicochemical properties and pharmacokinetic behavior. The major drawback of conventional cancer therapy is nonspecific distribution to tissues, resulting in suboptimal concentration at the target site and substantial adverse effects due to the cytotoxicity of normal cells. In the recent years, there have been steady rise in the nanotechnology based research with many successful nanocarriers on market like Doxil, Myocet, DaunoXome, and Onco-TCS which have resulted into a significantly reduced morbidity, improved lifestyle and life expectancy. The improvement in cancer treatment with these drug loaded nanocarriers is attributed to the presence of drug specifically within the cancerous cells. With many more products in pipeline, scientists are optimistic that nanotechnology will completely revolutionize the diagnosis and treatment of cancer. This chapter attempts to throw light on the progress in nanotechnology based diagnosis and treatment of most prevalent types of cancer.

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Chapter 32 - Effect of *Tinospora cordifolia* on neuroinflammation

Vipin V. Dhote [a], Vaishali A. Kilor [b], Muthu Kumaradoss Mohan Maruga Raja [c], Ashish Singhai [a], Avinash Singh Mandloi [a], Aman B. Upaganlawar [d]

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Abstract

Neuroinflammation, regulated by neuroimmune cells, influences multiple pathophysiological conditions. Microglia and astrocyte activation presents distinct functional phenotypes: the M1 (proinflammatory) and M2 (proreparatory). The implication of activated microglia in Alzheimer's disease (AD), Parkinson's disease (PD), and ischemia warrants further deliberations on the role of neuroinflammation in the development of therapeutic strategies. *Tinospora cordifolia* exhibit inhibition of neuroinflammation and exert neuroprotective effect on preclinical and clinical investigations. The pharmacological outcomes of phytoconstituents are restricted by limited solubility, fast metabolism, poor permeability, plasma protein binding, and the lack of stability within them. Here we discussed the role of neuroinflammation in CNS-related disorders and systemic disease. The chapter highlighted the developmental challenges that can be overcome by adopting novel approaches to deliver phytoconstituents of medicinal herbs into the CNS. We also shared an insight on recommendations and concerns of the drug regulatory authorities to provide approval for herbal formulation.

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Original Article

FORMULATION DEVELOPMENT OF MOUTH DISSOLVING PRINTED FILM OF KETOROLAC AND *IN VITRO* EVALUATION

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ABSTRACT

Objective: The present research work was carried out to prepare Ketorolac printed Oral Thin Films using a pneumatic pressure printer. In this research, we attempted to prepare a non-contact printing system by using pneumatic pressure-based printer that incorporates printing of active pharmaceutical ingredients onto a medical-grade Orodispersible film for developing personalized medication.

Methods: In the present work Ketorolac Trometamol was used as a model drug. Placebo substrate was developed by using cellulosic polymers like HPMC, MCC, Neusilin, and starch to impart paper-like properties that are desirable for printing. It was evaluated for various physicochemical properties like disintegration time, mechanical strength, folding endurance, surface properties, etc. Polymers and plasticizers were evaluated for the development of drug loaded Printing ink. The drug-printed films were characterized for physicochemical properties and *in vitro* drug dissolution.

Results: Various film-forming polymers were evaluated for the development of printing substrates. The F3 substrate had desired mechanical properties i.e. the thickness of 0.157±0.003, the tensile strength of 0.331±0.016, disintegration within 60 seconds, and this substrate also maintained its integrity after the printing of the drug ink. The HPMC-based ink (I4) with polyethylene glycol for modulating flow properties of ink in the concentration of 1.40%w/v was selected among various ink formulations. The drug release from the printed films was 98±1.94% in 1 h.

Conclusion: Through this new drug printing technology the limitation of low drug dose loading associated with ink-jet and flexographic printing can be solved by increasing the drug loading ranges from micrograms to milligrams by a single pass of the print head.

Keywords: Ketorolac printed OTF, 2D printing, HPMC ink, Pneumatic-based printer

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INTRODUCTION

Printing of medicine on an oral thin film (OTF) is an emerging technology that is not yet fully established. It has multiple advantages compared to other conventional manufacturing processes of OTF. Firstly, printing active pharmaceutical ingredients (APIs) is potentially an enabling technology to produce personalized medicine [1]. Personalization is crucial, for drugs that require careful dose adjustments, such as low therapeutic index drugs, and potent drugs. The OTF disintegrates within seconds when placed on the tongue intentional swallowing is not essential for effective treatment [2]. Therefore, OTF is an ideal oral dosage form for drug delivery in children and the elderly. Solvent casting is the most common method for the preparation of oral thin films. During solvent casting, the API is stressed by the solvent used, the high shear mixing process, and subsequent drying. Unstable APIs can be affected by mixing and drying. Achieving a uniform distribution of APIs throughout the film can be difficult, especially when using potent drugs at low doses and characteristics of coating mass i.e., Viscosity or density is affected by the properties and quantity of APIs processed. Therefore, the formulation of coated mass often needs to be adjusted for each new active substance and each new dose and waste containing API is also generated by this method. So in this perspective, manufacturing Orodispersible films by printing APIs onto placebo substrates can overcome these constraints, increasing the production yield and quality.

(Gaisford, 2011) Evaluate the use of thermal ink-jetting the printing drugs onto oral films. Hewlett-Packard printer was modified the drug solution was replaced by ink. They used potato starch-based film for the deposition of Salbutamol solution. The printer used in this work was operated most successfully when the viscosity of the feed solution was between 1.1 and 1.5 $mm^2 s^{-1}$, corresponding to glycerine concentrations of 10–20%v/v [4]. The dose deposition was achieved with a single pass of the print head on multiple passes of the printhead the dose deposition was always lower because of shearing forces eroding the existing dose during paper handling. (Georgios K. Eleftheriadis 1 ID, 2018) Applied ink-jetting for the printing of diclofenac sodium, a nonsteroidal anti-inflammatory drug, commonly used to treat pain and inflammation onto an edible sugar sheet [5]. They found that drug solution can be deposited up to 9 passes of the print head. (Yasmin Thabet, 2018) Applied the piezoelectric inkjet printing technique for the printing of enalapril maleate ink during continuous OTF production. Macrogol, methanol, and water-based inks were printed on OTF. No enalapril maleate crystallization was found in water-based ink [6]. The same approach was also applied to print enalapril maleate ink on hydrochlorothiazide (HCT) containing OTFs to prepare a fixed-dose combination. (Jana Pardeikea, 2011) Printed the nanosuspensions of Folic acid. Printing of the folic acid nanosuspensions was performed using an inkjet-based micro-dosing dispenser head at a frequency of 200Hz and voltage of 100V and impulse width of 25µs. Despite the potential advantages, there are still technical limitations for printing medicine that have not yet been overcome most critically, inkjet printing of APIs has been restricted to low viscosity fluids. Inkjet printing of viscous liquids can be attained by using heated piezoelectric-based inkjet systems but the heat-sensitive drugs cannot be printed through a heated print head because this results in degradation of API [7]. Alternatively, contact printing techniques such as flexographic printing, which are common in industrial roll-to-roll printing, have been used. However, contact with the board can lead to mutual contamination and damage to the board [3, 8]. Moreover, such printing techniques can lead to excessive waste of ink, and their implementation on an industrial scale involves a high cost of capital. Therefore, to avoid the challenges associated with the above-mentioned printing techniques in this current study we focus on the use of extrusion-based printing. Although several 2D printers were available on the market these all utilize a drug ink of water-like consistency and the main printing principle is based on inkjet printing or flexographic printing. So, in this research work, we used a 3D pneumatic-pressure extrusion-based printer for 2D printing on

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A Brief Review on Lysozyme's Pharmacology and Drug-Carrying Capacity

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ABSTRACT:

In recent years, the repurposing of drugs has been one of the exciting work areas for pharmaceutical scientists worldwide. We have prepared a review on Lysozyme, which will help scientists in this area review its properties. Lysozyme is an endogenous enzymatic peptide present in almost every living thing. It has wide therapeutic uses, including antibacterial, antiviral, anti-inflammatory, and immunomodulatory effects. It is showing prominent uses in various diseases, alone or along with other drugs. It is also used as a drug carrier for kidney targeting. It is categorized as generally referred to as safe by USFDA and EC. It is available on the market as oral formulations. Its traditional production by chicken egg is now a day swapped by recombinant production technologies, including transgenic animals. It has a great potential to be studied for various other activities. This review will help the researchers in selecting the medicament for further scientific evaluations.

KEYWORDS: Lysozyme, Antibacterial activity, Muramidase, Chicken egg lysozyme, Drug carrier, Transgenic production.

1. INTRODUCTION:

Lysozyme (Lyz) is a significant inborn host safeguard protein, which is also called muramidase or N-acetylmuramide glycohydrolase. They are widely distributed and present in almost all developed living things, including single-cell organisms like bacteria. It is an inherent part of the immune system, which provides excellent antimicrobial, antiviral, antitumor, and immunomodulatory actions. It is an antimicrobial protein that has a host defensive property. The antimicrobial capacity of Lyz is combined with a significant immunomodulatory role since it can cause alterations in inborn immunity. Lyz can be obtained from various sources such as birds, plants, rodents, insects, viruses, and mammals. Rich quantities of Lyz are present in various bodily secretions such as tears, salivation, milk, and bodily fluid. It is likewise present in cytoplasmic granules of the macrophages and the polymorphonuclear neutrophils. Out of all these sources, hen eggs and animal milk are used commercially to obtain it. Due to technological advances, recombination is also used to get the bulk quantity of it. The Lyz obtained from a human is more dynamic than that obtained from the hen egg white.

Lyz is also utilized to develop valuable materials by catalysis; al and other applications. Lyz can be administered in the body via variou and sprays, respectively. It is also available in powder for injection form f focuses on compiling recent research done in the Lyz field to help the rese l presents a graphical view of this review article.

Figure 1: A brief review of Lysozyme's pharmacology and drug-carrying

2. HISTORY:

a. Discovery:

Sir Alexander Fleming found lyz in the year 1928. It was first seen during some examination made on a patient experiencing intense coryza. The patient's nasal discharge was cultured each day on plates made up of blood agar, and for the initial three days of infection, there was no bacterial development except for an intermittent staphylococcal state. From that point, Fleming's remarkable bacteriolytic agent became known.[1] For, past 90 years, this exceptional protein has gotten the interest of researchers due to its various properties. The hen Lyz was the first protein in which all the 20 usual amino acids are

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Exploring the phytoconstituents targeting TNF-α as potential lead compounds to treat inflammatory diseases: an *in-silico* approach

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ABSTRACT

Objective To explore the anti-inflammatory phytoconstituents from various plant sources as tumour necrosis factor-α (TNF-α)-inhibitor, a mediator involved in the inflammatory disorder, by *in silico* molecular docking.

Methods Based on previous findings, we performed the *in silico* assessment of anti-inflammatory phytoconstituents from different medicinal plants to understand their binding patterns against TNF-α (PDB ID: 6OP0) using AutoDock Vina. Molecular docking was performed by setting a grid box (25 × 25 × 25) Å centered at [– 12.817 × (– 1.618) × 19.009] Å with 0.375 Å of grid spacing. Furthermore, Discovery Studio Client 2020 program was utilized to assess two- and three-dimensional (2D and 3D) hydrogen-bond interactions concerning an amino acid of target and ligand. Physicochemical properties were reported using the Lipinski's rule and SwissADME database to support the *in silico* findings.

Results From the selected medicinal plants, more than 200 phytocompounds were screened against TNF-α protein with binding scores in the range of – 12.3 to – 2.5 kcal/mol. Amongst them, emodin, aloe-emodin, pongamol, purpuritenin, semiglabrin, ellagic acid, imperatorin, α-tocopherol, and octanorcucurbitacin A showed good binding affinity as – 10.6, – 10.0, – 10.5, – 10.1, – 11.2, – 10.3, – 10.1, – 10.1, and – 10.0 kcal/mol, respectively. Also, the absorption, distribution, metabolism, excretion, and toxicology (ADMET) profiles were well within acceptable limits.

Conclusion Based on our preliminary findings, we conclude that the selected phytoconstituents have the potential to be good anti-inflammatory candidates by inhibiting the TNF-α target. These compounds can be further optimized and validated as new therapeutic components to develop more effective and safe anti-inflammatory drugs.

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Original Article

FORMULATION AND EVALUATION OF SUPERABSORBENT HYDROGEL FROM NATURAL POLYMER

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ABSTRACT

Objective: The objective of the present study was to synthesize the hydrogel from natural polymer and evaluation of its physical and chemical properties.

Methods: Hydrogel was synthesized using graft co-polymerization technique from wheat starch, by crosslinking with acrylic acid. The product was purified, dried and micronized. It was then evaluated for water absorption and retention property at varying pH, FTIR, PXRD and Thermal analysis, microscopic, micromeritic and stability studies etc. Furthermore, the effect of NaOH treatment on prepared hydrogel material was studied.

Results: Result of the studies revealed that superabsorbent hydrogel (SAH) product shows good water absorption capacity of 120g/g at neutral pH. Maximum water absorption capacity was at pH 9 which is 146.28g/g. Product shows good thermal stability, less cohesiveness and is amorphous in nature. In hygroscopicity study weight gain by SAH was 6.65% only while for unpurified SAH and NaOH treated SAH, it was 10.5% and 23.42% respectively. NaOH treatment shows a decrease in water absorption capacity by more than 40% also there is change in surface morphology of the product. Additionally, hygroscopicity was more and degradation rate was faster for NaOH treated hydrogel.

Conclusion: Crosslinking with acrylic acid can form superabsorbent hydrogel material from the natural polymer such as wheat starch. The product shows excellent water absorption and retention capacity. pH affects water absorption capacity and shows maximum at pH 9 and at lower and higher pH it decreases to a significant level. There was decline in water absorption capacity and increase in hygroscopicity, when NaOH treatment is given to the SAH powder.

Keywords: Hydrogel, Superabsorbent, Graft co-polymerization, Crosslinking, Natural polymer, Water absorption, Starch

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INTRODUCTION

Hydrogels are the hydrophilic cross-linked polymer matrix that can retain a significant amount of water within their structures and swell without dissolving in water [1]. The hydrogels that can absorb very large amount of water and retain it even under pressure are called superabsorbent hydrogels [2]. After absorbing large amount of water, they become soft, transparent or translucent and mostly remains biocompatible [3]. Natural products like hyaluronic acid, fibrin and collagen, derivatives of natural materials such as chitosan and alginate possess the properties of hydrogel [4]. Likewise, mucilage containing plant products viz. Garden crest seeds, sweet basil seeds and Psyllium husk also show hydrogel like action when come in contact with water [5]. Preparation of this compound in laboratories from different substances is the present area of research in the field of polymer science.

Hydrogels are having applications in agriculture [6–8], drug delivery [9–11], tissue engineering [12–14], contact lenses [15, 16] and water purification [17, 18]. Dry hydrogel material mixed into the soil which in turn absorbs and retains more water that keeps plants hydrated even in time of drought. Hydrogel's biocompatibility and protective nature which causes encapsulation of hydrophilic drug molecule are excellent drug carriers in drug delivery. Contact lenses prepared from silicon hydrogel shows increased oxygen permeability with water content providing optimal comfort and eye health [19]. They are also found useful in early scaffold formation to repair damaged tissues of the body. In water purification, hydrogel was found useful to remove heavy metals like nickel and mercury. Recently, the global issue of oil spillage in the oceans is resolved by preparing hydrogel [20].

Hydrogel is prepared using Physical gel and Chemical gel method. In the former method, the hydrogel is prepared with some external activation technique and is having noncovalent interactions, whereas the latter method is mostly permanent, do not need any activation technique and formed by cross-linking network formed with covalent bonds. Methods of physical gel include crystallization, stereo complex formation, hydrophobized polysaccharides, ionic interactions and protein interaction whereas chemical hydrogel are formed via crosslinking by radical polymerization, addition and condensation polymerization, gamma and electron beam polymerization. Based on the method of preparation, hydrogels are classified as Homopolymeric hydrogels [21], Copolymeric hydrogels [22] and Multipolymer interpenetrating polymeric hydrogel (IPN) [23]. They may be amorphous, semicrystalline or crystalline. Moreover, on the basis of electric charges imposed on it, they are nonionic, ionic, amphoteric or zwitterionic (like polybetaines).

Recently, hydrogels are researched in order to improve its properties like water absorbency and its applicability in drug delivery. Starch used is available in abundance and cost effective also the method of graft copolymerization does not need any costly instrumentation or reactants. Since all chemicals used are having excellent water solubility, it is easy to remove any unused reactants by simply soaking product in excess water quantity. Hence in the present study, hydrogel was prepared from natural polymer wheat starch by crosslinking with acrylic acid. Evaluation of prepared hydrogels for various parameters like gel fraction, water absorption capacity at various pH conditions, hygroscopicity, surface morphology and micromeritic properties was undertaken.

MATERIALS AND METHODS

Chemicals

The starch was sourced from homemade wheat powder. Other chemicals and their respective manufacturers are: Sodium hydroxide (Research Lab Fine Chem. Industries Mumbai, urea and ammonium persulphate (Powder Pack Chem, Mumbai), N,N-methylenebisacrylamide and acrylic acid (Loba Chemie Pvt. Ltd.). Distilled water was used as a solvent. All the chemicals used were of AR grade.

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Original Article

SUSTAINABLE SYNTHESIS AND CHARACTERIZATION OF TUNABLE AND MULTIPURPOSE NANOCELLULOSE FROM FRESHWATER AQUATIC WEED AS PHARMACEUTICAL EXCIPIENT

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ABSTRACT

Objective: The main objective of this work was to understand the basic properties of crystalline nanocellulose (CNC) that can be useful as a novel excipient in pharmaceutical formulations. This covers the isolation and preparation of nanocellulose followed by characterization.

Methods: Cellulose was isolated from aquatic weed by autoclaving and bleaching. Cellulose to CNC conversion involved gluconic acid treatments at different concentrations (40%, 50% and 60%) followed by centrifugation and neutralization. CNC was further characterized by Differential Scanning Calorimetry (DSC) and Thermo gravimetric Analysis (TGA), Field Emission Scanning Electron Microscopy (FE-SEM) and Atomic Force Microscopy (AFM) for surface morphology, elemental analysis by Energy Dispersive Spectroscopy (EDS), Fourier Transform Infrared Spectroscopy (FTIR), crystallinity index by X-Ray Diffraction (XRD), and optical microscopy.

Results: Acid concentration affects the moisture uptake, particle size, and yield of CNC. CNC size ranged from 350 nm to 900 nm with a crystallinity index 80% to 85%. Moisture uptake was 6.38±0.12% at 33% relative humidity. DSC and TGA established thermal stability over 200 °C. Nanocellulose has shown Angle of repose (28.81°), Carrs index (12.32), zeta potential (33mV) values and heavy metals within pharmacopoeial limits.

Conclusion: CNC from water hyacinth was prepared successfully by sustainable process. CNC physico-chemical characterization revealed the stable nature of CNC, suitable to be used as an excipient in pharmaceutical formulations.

Keywords: Nanocellulose, Excipient, Drug delivery, Characterization, Water hyacinth

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INTRODUCTION

The progress in drug delivery systems in last couple of decades has seen giant leap from conceptualization to actual utility in terms of excipient and adjuvant research. Be it synthetic drug, biologicals, biosimilars, and natural extractives; pharmaceutical excipients have the lion's share to make the drug exhibit its pharmacological actions at the correct time, correct location, in correct manner and with minimum unwanted effects. The quest for newer excipients and drug carriers is not only restricted to novel drug delivery systems but also, they are in demand for conventional pharmaceutical formulations [1]. The correct answer to the question why we at all need novel pharmaceutical excipients lies in the fact that they impart stability to the API (active pharmaceutical ingredients), improve dissolution rate, help to deliver the drug at target location, improve taste, enhance aesthetic value, prolong the drug release, maintain immunogenicity in vaccines, and impart ease of handling via their tunable physico-chemical properties. These excipients truly exert 'behind the scenes' role, with latest example as the incorporation of lipid membranes in mRNA vaccine for COVID-19 developed by Moderna and Pfizer/BioNTech as an effective means of career system [2].

In this context, novel excipients are being continuously searched and developed with an eye on nanomaterials owing to their several advantages such as high surface area, high drug loading capacity, target specific drug delivery, predictable drug release kinetics, and possible customizable approaches in their applications. In recent years, the focus has shifted more towards bionanomaterials, that too of biodegradable nature. While several factors are involved in selection of suitable bionanomaterials in drug delivery systems, current trend highlights exploration of natural polymers and their composite structures. Some of these include chitosan, sodium alginate, pectin, cellulose, gelatin, natural gums, dextran, agarose, proteins, peptides, clays like bentonite, etc. These natural nanoparticulate drug carriers can be broadly classified as organic, inorganic and metal oxides. Among all of these biodegradable, biocompatible, inexpensive bionanocarriers, cellulose is most abundant on the earth having noteworthy inherent mechanical, chemical, structural and biological properties [3]. In addition, nanocellulose properties are tunable, it is recyclable, promising sustainable alternative to current biodegradable and natural nanoparticles in several aspects of drug delivery systems. Being "green material", it has been the mainstay area of extensive research for last few years in the field of drug delivery and biomedical applications [4]. Based on the sources and method to obtain it, nanocellulose can be classified as Crystalline Nanocellulose (CNC), Crystalline Nanofibers (CNF) and Bacterial Nanocellulose (BNC) [5]. The application of each of them changes with perspective of their preparation method and ensuing physico-chemical properties [6].

Numerous sources to obtain nanocellulose have been reported such as sugarcane bagasse, kenaf, cotton, sugar beet, wheat straw, bamboo, tunicates, algae, eucalyptus, garlic skin, to quote a few among many that span among plant, animal, bacterial and civil waste origin [7]. Several excellent reviews are available that throw light on sources, extraction and isolation processes of nanocellulose. For conversion of cellulose to nanocellulose, hydrophobic and amorphous lignin as well as hemicellulose regions must be broken by overcoming the phenolic group and xylan-glucomannan bonds respectively present in them [8]. The harsh conditions are required stepwise that include alkali treatment such as 4% to 10% NaOH (w/v) for removal of amorphous hemicellulose for varying time and temperature conditions reported by several researchers. Similarly, removal of lignin needs strong acidic treatment primarily reported as sulphuric acid, phosphoric acid, hydrochloric acid at 30% to 65% concentration level running for several minutes to few hours at ambient temperatures 40 °C to 120 °C. Sizeable works also mention use of bleaching agents H_2O_2 and acidified sodium chlorite as means of delignification [9]. In a process to obtain CNF from raw cellulose, 2,2,6,6-Tetramethylpiperidine-1-oxyl radical (TEMPO), a strong oxidizing agent is used as catalyst often rated as hazardous environment material [10]. Taking into consideration adverse environmental impact of these harsh chemicals and excess quantity of water required at each step of neutralization, modern methods such as use of ultrasonication, ionic liquids and deep eutectic solvents (DES). However, each of these modern methods pose limitation/s; either has higher cost element, being environmentally toxic or require higher input of energy in various ways [10].

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2D-QSAR Modeling of Chalcone Analogues as Angiotensin Converting Enzyme Inhibitor

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Abstract: Targeting angiotensin-converting enzyme (ACE) comes out to be an effective mechanism for controlling hypertension. Two-dimensional quantitative structural activity relationship models were generated to predict the ACE inhibitory activity of chalcone analogs. The genetic algorithm- multiple linear regression models (GA-MLR) approach was used to generate highly predictive models using straightforwardly interpretable Py_Estate, Alvadesc, and Padel descriptors. Application of Intelligent consensus modeling confirms that model-2 is statistically robust (R^2_{tr} = 0.66, Q^2_{LOO} = 0.5621) with good external predictivity (Concordance Correlation Coefficient, CCC_{ex} = 0.9109, Q^2-F^1 = 0.85818, Q^2-F^2 = 0.85782 and Q^2-F^3 = 0.88489). Novel analogs designed according to the synthetic route considering structural requirements indicated by the model were found to be satisfactory and could be considered for synthesis and subsequent screening.

Keywords: angiotensin-converting enzyme; chalcone; 2D-QSAR; consensus modeling; validation.

1. Introduction

Hypertension is a widespread illness in adults all over the world, and it is one of the leading causes of cardiovascular and renal disorders [1,2] Angiotensin-converting enzyme (ACE) inhibition has come out to be an effective mechanism in controlling hypertension [3]. Angiotensin-converting enzyme inhibitors (ACEIs) regulate the biosynthesis of a vital chemical known as angiotensin II thereby decreasing salts concentration, dilating arteries, and controlling hypertension. ACE and Angiotensin II are considered essential points of regulation in the Renin-Angiotensin-Aldosterone System (RAAS); deregulation of any of them is accountable for cardiovascular and renal diseases [4–7]. The RAAS is widely known for its importance in cardiovascular physiology, water-electrolyte balance, and cell function. Excessive activation of this system is a major contributor to hypertension. ACE is the essential regulation locus of RAAS to combat hypertension. ACE is a dipeptidyl carboxypeptidase that removes the carboxy-terminal dipeptide of angiotensin I, inactivating the vasodepressor bradykinin and activating the strong vasoconstrictor. Growth-promoting chemical angiotensin

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J Biomol Struct Dyn. 2023 May 2:1-20. doi: 10.1080/07391102.2023.2203261. Online ahead of print.

In silico study to recognize novel angiotensin-converting-enzyme-I inhibitors by 2D-QSAR and constraint-based molecular simulations

Sapan Shah [1], Dinesh Chaple [1], Vijay H Masand [2], Magdi E A Zaki [3], Sami A Al-Hussain [3], Ashish Shah [4], Sumit Arora [5], Rahul Jawarkar [6], Mohammad Tauqeer [7]

Affiliations
PMID: 37128759 DOI: 10.1080/07391102.2023.2203261

Abstract

Cardiovascular diseases (CVD) such as heart failure, stroke, and hypertension affect 64.3 million people worldwide and are responsible for 30% of all deaths. Primary inhibition of the angiotensin-converting enzyme (ACE) is significant in the management of CVD. In the present study, the genetic algorithm-multiple linear regressions (GA-MLR) method is used to generate highly predictive and statistically significant (R^2 = 0.70-0.75, Q^2_{LOO}=0.67-0.73, Q^2_{LMO}=0.66-0.72, CCC_{ex}=0.70-0.78) quantitative structure-activity relationships (QSAR) models conferring to OECD requirements using a dataset of 255 structurally diverse and experimentally validated ACE inhibitors. The models contain simply illustratable Padel, Estate, and PyDescriptors that correlate structural scaffold requisite for ACE inhibition. Also, constraint-based molecular docking reveals an interaction profile between ligands and enzymes which is then correlated with the essential structural features associated with the QSAR models. The QSAR-based virtual screening was utilized to find novel lead molecules from a designed database of 102 thiadiazole derivatives. The Applicability domain (AD), Molecular Docking, Molecular dynamics, and ADMET analysis suggest two compound D24 and D40 are inflexibly linked to the protein binding site and follows drug-likeness properties.Communicated by Ramaswamy H. Sarma.

Keywords: Cardiovascular diseases; QSAR; angiotensin-converting enzyme inhibitors; molecular docking; structural features; validation.

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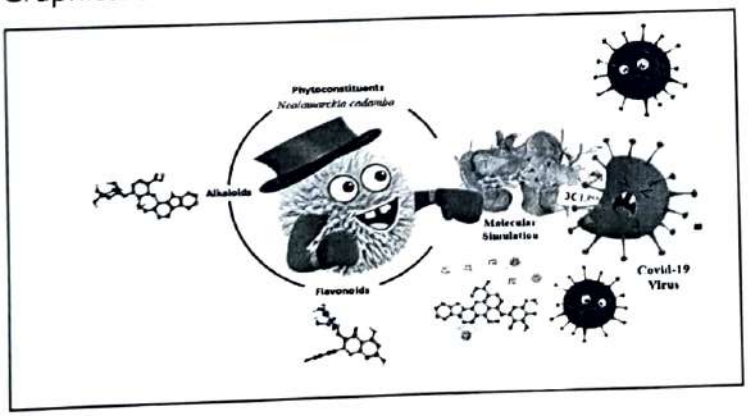
Investigation of *Neolamarckia cadamba* Phytoconstituents Against SARS-CoV-2 3CL Pro: An In-Silico Approach

Sumit Arora [a], Kalpana Tirpude [b], Pallavi Rushiya [b], Nidhi Sapkal [c], Subhash Yende [d] Abhay Ittadwar [e], and Sapan Shah [f]

In present study, the inhibitory potential of *Neolamarckia cadamba* phytoconstituents was investigated against SARS-CoV-2 3CL protease (3CL pro) (PDB ID: 6M2N). Molecular docking was analyzed using AutoDock Vina software by setting the grid parameter as X= -33.163, Y= -65.074 and Z= 41.434 with dimensions of the grid box 25 × 25 × 25 Å. Remdesivir was taken as the standard for comparative analysis along with inhibitor 5, 6, 7-trihydroxy-2-phenyl-4H-chromen-4-one. Furthermore, the exploration of 2 D Hydrogen-bond interactions was performed by Biovia Discovery Studio 4.5 program to identify the interactions between an amino acid of target and ligand followed by assessment of physicochemical properties using Lipinski's rule and Swiss ADME database. The decent bonding scores of secondary metabolites owing to hydrogen bonding with catalytic residues suggest the effectiveness of these phytochemicals towards 3CLpro. The results are further consolidated positively by Lipinski's rule and Swiss ADME prediction. Thus reasonably, observations with docking studies suggest possibility of phytochemicals from *Neolamarckia cadamba* to inhibit the 3CLpro and consequently would be explored further as agents for preventing COVID-19.

Graphical abstract



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1. Introduction

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Development and evaluation of novel famotidine-loaded fast dissolving sublingual film using the quality-by-design approach

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Abstract

The present study deals with the development and evaluation of a novel famotidine (FMD) loaded fast-dissolving sublingual film based on quality-by-design approach using a solvent casting technique. Initially, quality target product profile (QTPP) was set to build quality in patient-centric products. The risk assessment and risk management were performed using Ishikawa diagram and failure mode effect analysis (FMEA). A central composite design (CCD) was employed in order to assess the effect of the formulation variables such as HPMC K-15 and PEG-400 on their responses such as content uniformity, folding endurance, and thickness. The developed optimized sublingual film was characterized by Fourier-transform infrared spectroscopy (FTIR) and differential scanning calorimetry (DSC) for its intermolecular interactions. The morphology of the optimized film was studied by scanning electron microscopy (SEM) in which the drug particles appeared spherical. The developed film showed stability for 3 months according to the International Conference on Harmonization (ICH) Q1A (R2) guidelines. A dissolution study showed enhanced dissolution for the optimized sublingual film as compared to the buccal and oral film. The permeation study of the optimized film showed the highest permeation within 30min. *In vivo* study using rabbit as model animal exhibited the improved bioavailability of the drug i.e. 2.05 folds. The drug reached systemic circulation within 15min to improve bioavailability significantly. Thus, the fast dissolving sublingual film containing FMD potentially overcomes the biopharmaceutical challenges and can be a better alternative system for the administration of FMD for the treatment of peptic ulcers.

Graphical abstract

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RESEARCH ARTICLE

Novel Antidiabetic Polyherbal Formulation for Synergistic Therapeutic Effects in Streptozotocin (STZ)-Induced Diabetic Rats

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ABSTRACT

Worldwide demand for new anti-diabetic drugs from plant sources has increased as diabetes mellitus has become a global epidemic. In the era of herbal medicines, polyherbal formulations offer higher therapeutic efficacy than single plants due to synergistic effects. Therefore, the objective was to develop a novel anti-diabetic polyherbal formulation containing mixtures of three plants: *Azadirachta indica* leaves, *Tinospora cordifolia* stem and *Ocimum sanctum* leaves extracts. The eight different plant formulations (F1 to F8) were formulated while F1 to F3 contained a single plant extract. Hyperglycemia was developed in rodents by ingestion of streptozotocin. The experimental animals' serum sugar level, body weight and lipid profile were determined. In the diabetic rats treated orally with F1 to F8, the blood glucose level decreased significantly compared to the diabetic control group. Similar effects were also observed in the diabetic rats treated with glibenclamide. In addition, F1 to F8 controlled lipid level, namely total cholesterol (CHL), triglycerides (TGL), low-density lipoprotein (LDL), and high-density lipoprotein (HDL) levels in rodents. The findings suggested that F7 showed higher anti-diabetic and antihyperlipidemic efficiency when equated to the other formulations. It was also found that the formulations (F1 to F3) containing a single plant extract exhibited lower therapeutic efficacy than the polyherbal formulations (F4 to F8). The results suggest that the higher therapeutic efficacy of the polyherbal formulation is due to the synergistic effect of the different phytoconstituents in the plant mixtures.

Keywords: Anti-diabetic, Antihyperlipidemic, Diabetes, Polyherbal formulations, Streptozotocin.

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Conflict of interest: None

INTRODUCTION

Hyperglycemia is the primary symptom of diabetes, which a lack of insulin action can cause, decreased insulin production, or both. Diabetes is a complex endocrine and metabolic disease that can manifest in a variety of ways. Insulin dysfunction can arise from either a deficiency of pancreatic cells that secrete insulin (diabetes mellitus type 1 (T2DM)) or an insufficient response to insulin (T2DM). Both type 1 and type 2 diabetes expressed to insulin resistance. It observed that a prolonged state of hyperglycemia causes insulin resistance. Insulin resistance is the leading cause of diabetes in the world. The long-term health effects of hyperglycemia include damage and eventual failure of several organs, most notably the nerves, blood vessels, kidneys, eyes, and heart.[1,2]

Diabetes is currently becoming a serious concern on a global scale and a main cause of morbidity and death in the majority of countries. It is estimated that there are 382 million individuals who are affected by the disease, and 5.1 million people lost their lives to diabetes in 2013. According to statistics compiled by the World Health Organization (WHO), there was a huge increase in the number of diabetes patients from 1980 to 2014; WHO estimated the possible increase of 592 million diabetes patients by 2035 in underdeveloped and developing countries.[3,4]

Since the beginning of time, people have been trying to find cures for a wide variety of illnesses, including hyperglycemia, with the help of various medicinal herbs. WHO stated approx 80% of diabetes patient in underdeveloped nations takes herbal medicines for the management of diabetes. The use of herbal medicines is enhanced due to their minimum toxicity, easy availability and cost-effectiveness. About one-quarter of all medications in today's pharmacopeia are derived from natural substances once utilized in conventional medicine. Presently metformin is most widely used for the management of diabetes and it is first extracted from the *Galega officinalis*.[5,6]

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INTRODUCTION

International Journal of Drug Delivery Technology (IJDDT) provides the forum for reporting innovations, production methods, technologies, initiatives and the application of scientific knowledge to the aspects of pharmaceutics, including controlled drug release systems, drug targeting etc. in the form of expert forums, reviews, full research papers and short communications.

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ROBUST SIMPLE ANALYTICAL TECHNIQUE FOR DEVELOPMENT AND VALIDATION OF STABILITY INDICATING ASSAY METHOD FOR ESTIMATION OF TENELIGLIPTIN IN PHARMACEUTICAL DOSAGE FORM

Bhagyashri A. Borade *[1], Sachin J. Dighade [1] and Suhas P. Padmane [2]

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Department of Quality Assurance [2], Gurunanak College of Pharmacy, Nagpur - 440026, Maharashtra, India.

Keywords:

Teneliglitpin hydrobromide, HPLC, Degradation Study, Method Validation, Methanol, Acetonitrile

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ABSTRACT: As per the ICH guidelines and regulatory authorities' worldwide, it has become mandatory to establish a stability-indicating assay method (SIAM) for the drug substance (DS) and drug product (DP) to generate the stability data. It was undertaken to develop a precise, accurate, reliable, rapid, simple and specific method for estimating Teneligliptin free of interference from its probable degradation products. The present investigation has exploited the high-performance liquid chromatography (HPLC) technique. The retention time of Teneligliptin under optimized chromatographic conditions was found to be 5.71 ±0.02 min with a sharp, symmetrical peak (asymmetry of 0.66 ± 0.02). In the system suitability, the drug was found to adequately retain at 5.71 ±0.02 min with a sharp, symmetrical peak and high theoretical plate value of 4808, indicating high column efficiency. The solutions were observed to undergo hydrolysis in 0.1 N HCl and 0.1 N NaOH at room temperature and reflux. Teneligliptin was also found to be susceptible to rapid oxidation. Photolytic stress study indicates that drug in solid-state upon exposure to sunlight for 12 days up to 48%. Thermal stress conditions do not degrade the drug upon exposure to 100 °C for 15 days. This indicates that Teneligliptin is quite stable in thermal stress conditions. The standard and sample solutions of the drug have reasonably good stability over a period of about 24 h. The results of the assay of the Tenglyn tablet obtained by the proposed HPLC method are quite concurrent and reproducible. The recovery rate of the drug was 100% which indicates accuracy and reproducibility.

INTRODUCTION: The active pharmaceutical ingredients (API) in the formulation, processing and storage may expose to a variety of environmental conditions like heat, humidity, light, *etc*. and may undergo degradation.

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This would contaminate the product with its degradation products, thus adversely affecting the therapeutic efficacy and safety of drug products (DP).

Therefore, the stability studies of API and its formulation are an utmost important aspect of formulation development to minimize its degradation and establish appropriate storage conditions [1]. The ICH guidelines explicitly require forced decomposition studies under various conditions like extreme pH, light, oxidation, dry

Asian Journal of Pediatric Research

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ISSN: 2582-2950

Pediatric Drug Development Process: A Review

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Review Article

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ABSTRACT

This review includes New Formulation approaches to improve Pediatric compliance such as Mini tablets, 3D printing, Orodispersible films, Chewable tablets. Various strategies to improve patient adherence such as 'nipple shield' delivery system, dry solid formulations to be converted to liquid at the point of administration, pill swallowing cups, Medicated dosing straw. It is important to formulate pediatric medicines that are tailored to a child's age, size, physiological condition, and treatment requirements. Legislations for pediatric formulation to ensure that products to treat pediatric patients are appropriately authorized for use in the pediatric population, minimize the worst effect of Off-label medication and to improve the information available on the use of these products in the various pediatric populations. Also, the review consists of Information on legislative obligation and requirement, current State, challenges and effect of regulations. Recent progress has been made in the development of pediatric formulations due to new regulations, additional funding opportunities, and collaborative research initiatives.

Keywords: Patient compliance strategies; innovative solutions; pediatric legislation.

[#] *Dr.*
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Applications of Microparticles: A Review

Adiba Khan [1] , Mitali Bodhankar [2] , Nikita Pal [3]

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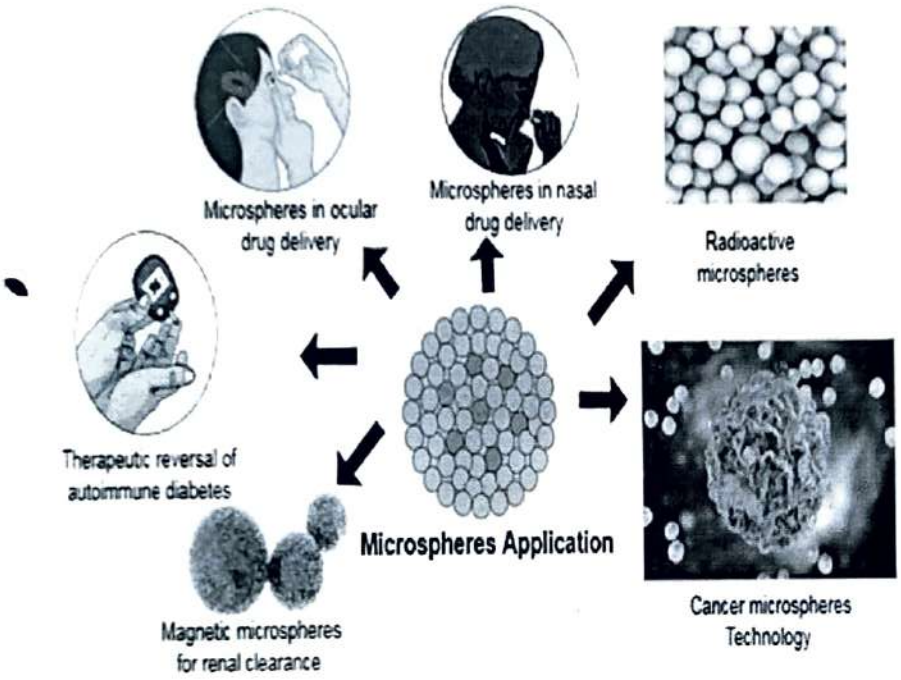

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Review Article

Natural Excipients used for Formulation of Pharmaceutical Beads

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ABSTRACT

The Herbal or natural excipients have a great advantage over their synthetic analogues as these are non-toxic, less expensive and freely available. The increasing awareness about these herbal excipients, which are manly polymers of natural origin, the pharmaceutical industries is getting more inclined towards their use in formulation development. The plant derived gums, polymers from natural sources like carrageenan, thaumatin, lard, storax, agar, gum acacia, tragacanth and many more to name comply with many requirements of pharmaceutical excipients. These can be preferred for formulation development as being stable and involving less regulatory issues as compared to their synthetic counter parts. They can also be easily modified to meet the specific needs, thereby being a potent and economic vehicle for delivering active pharmaceutical ingredient in formulation. Due to advances in drug delivery technology, excipients are included in novel dosage forms to fulfill specific functions and also in some cases to increase the bioavailability of the drug. Recent trends towards the use of natural products demand the replacement of synthetic additives. Natural excipients have been studied for their application in different pharmaceutical dosage form such as tablets, beads etc. Natural excipients that are mainly used are natural polymers, gums and waxes.

Keywords: Natural excipients, Beads, polymers, waxes, Gums.

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INTRODUCTION

Excipients are the substances or compound other than the active pharmaceutical ingredient and packaging materials that affect finished product quality. Excipients are the pillar of pharmaceutical formulations that determine dosage form as well as pharmacokinetics and pharmacodynamics of drug.[1] Nowadays majority of excipients used are synthetic excipients that causes various side effects in pharmaceutics , so industries are impending natural resources as they are safe, non-toxic, biocompatible, less expensive and widely available. Excipients partly decide the status of the medicines.[2] The long- established conception of the excipients as any component other than the active substance has gone through a considerable development from an inert and affordable vehicle to an necessary set up of the formulation. Natural excipients are studied for their uses in different formulations such as tablets, nanoparticles, microspheres, beads etc. This review mainly focuses on natural excipients that are used in formulation of solid dosage form i.e., Beads. Natural excipients mainly used in formulation of beads are natural polymers, gums, waxes etc.[3]

1. NATURAL POLYMERS:

These polymers are naturally discovered in plants and animals e.g., cellulose, starch, resins, proteins etc. Natural polymers play important role in pharmaceutical formulations, they are used in preparation of microspheres, beads, films, nanoparticles, implants, injectables as well as liquid formulations. In this dosage form polymeric materials have many roles such as binders, viscosity enhancers, thickeners, disintegrants, emulsifiers, suspending agent, bio adhesive, gelling agent.[2]

Importance of herbal polymers over synthetic polymers:

1) Easily available: Natural polymers are low-priced than synthetic ones and grow in the form of herbs in many countries and have no side effects. They are produced in large amount hence their availability can be guaranteed than synthetic polymers.

2) Economic: Natural polymers are low-priced than synthetic polymers, hence its production cost is also less.

3) Biodegradable: Natural polymers are obtained from living organisms hence there is no side effects on human being and environment on the other hand, synthetic polymers have adverse effects as they are prepared with the help of chemicals.

4) Bio-compatible and non-toxic: As all the plant materials are carbohydrates in nature, they are non-toxic as compared to synthetic polymers.

5) No side effects: Natural polymers are found in plants and animals hence they have no side effects.[4]

Review Article

Current and Future Trend of Polyherbal Cough Suppressant (Anti-Tussive) Syrup: A Review

Gule Samreen kazi*, Dimple S. Sahare, Bhairavi V. Gawande, Dr. Suhas P. Padmane, Dr. Sheelpriya Walde
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ABSTRACT

Cough is the most common problem is faced by all the people. There are two types of cough 'Dry cough and Wet cough.' The dry cough is without mucous and wet cough is with mucous or secretion. The syrup is most commonly used and popular dosage form, it is used for curing cough and cold because it having ease of patients compliance. The Polyherbal cough syrup are formulated using various crude drugs. Antitussive, Antimicrobial, Antioxidant are some of the activities produced by the Polyherbal formulation. The antioxidant and anti-inflammatory syrup is used to treat the acute as well as chronic cough mainly chronic cough in patients of all the ages. In addition, the growing interest in alternative and complementary medicine is also contributing to the increasing popularity of herbal syrups. Many people are turning to traditional healing systems like Ayurveda, Chinese medicine, and herbalism for their health needs, and herbal syrups are a natural part of these systems. Overall, the current scope of herbal syrups is quite broad, and there is a growing demand for natural and herbal remedies. As more research is conducted, we may see the development of more effective and targeted formulations that can provide relief for a range of health conditions.

Keywords: Polyherbal Formulation, cough syrup, Crude drug, Antimicrobial, Antitussive.

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INTRODUCTION

Cough is a typical, enduring sign of numerous acute and chronic illnesses. Due to its disruptive effects, many people seek medical advice, and an enormous over-the-counter remedy market is supported. Upper respiratory tract infections (URTIs) and colds, as well as environmental exposure to smoke and/or allergens, are the most common causes of acute cough symptoms. Although most people cough at least once in their lives, the frequency of coughs is correlated with things like gender and allergy sensitivity.[1]

Herbal medicines are part of a wide range of treatments such as phytotherapy, hydrotherapies, and Traditional Chinese Medicine (TCM), a few of which are applied in conventional medicine.[2] Whilst herbal treatments have a long history of use in varied cultures, randomized controlled trial (RCT) data on their effects is generally lacking. Herbal cough treatments with proven clinical efficacy include ivy/primrose/thyme-based preparations which are recommended as expectorants in current European guidelines.[3]

Polyherbal anti-tussive agents are available in various forms, such as syrups, tablets, and capsules. However, it is important to note that the efficacy and safety of these agents have not been extensively studied, and their use should be done under the guidance of a qualified healthcare provider.[4]

Why switch to polyherbal syrups?[5]

Polyherbal syrup is a type of herbal medicine that contains a combination of different herbs. It has gained popularity in recent years as people seek natural alternatives to conventional medicines.

There are several reasons why one may consider switching to polyherbal syrup:

1. **Synergistic effects:** Polyherbal syrup contains a combination of herbs that work together to produce a stronger therapeutic effect than each herb would have on its own.
2. **Holistic approach:** Polyherbal syrup takes a holistic approach to healing by addressing multiple aspects of a health condition instead of just one.
3. **Fewer side effects:** Polyherbal syrup is often considered safer than conventional medicines because it is made from natural ingredients and has fewer side effects.
4. **Long-term benefits:** Unlike conventional medicines that often only treat the symptoms of a health condition, polyherbal syrup can provide long-term benefits by addressing the root cause of the condition.[5]

However, it is important to note that not all herbal remedies are safe or effective. It is essential to consult with a healthcare professional before making any changes to

Review Article

Skin Hyperpigmentation and its Herbal Treatment: A Review

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ABSTRACT

A frequent dermatological disorder known as hyperpigmentation is marked by the darkening of specific skin regions. Despite the availability of several conventional treatments, the demand for natural and herbal remedies has been rising as a result of worries about the potential adverse effects of goods made of chemicals. Patients with several skin-related ailments, often known as patients with skin pigmentation, are becoming more and more prevalent. Hyperpigmentation is one of the most prevalent problems in people with skin of colour. As a result, herbal formulations are required for the treatment of hyperpigmentation. This review article discusses the many forms of hyperpigmentation, their causes, and herbal remedies for managing skin hyperpigmentation. As hyperpigmentation, or uneven skin pigmentation, is a frequent skin issue caused by an increase in melanin production, it is important to understand this condition. As a result, blotches or patches of skin may seem darker than the surrounding skin. Due to sun exposure and damage, certain types of hyperpigmentation including post-inflammatory, melasma, and sun spots are more prone to afflict parts of the face, arms, and legs. Although there are several therapies for the problem, which can have some negative side effects, dermatologists still face difficulties in managing hyperpigmentation.

Keywords: Hyperpigmentation, Melasma, Tyrosinase, Age spot, Melanin.

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INTRODUCTION

Skin hyperpigmentation, a common dermatological disorder, causes the skin's colour to typically darken. Several internal and external causes, such as hormonal shifts, inflammation, injury, acne, eczema, certain medications, UV exposure, etc[1] can cause these changes in skin colouration. The biological mechanisms that result in the generation of the skin pigment melanin by melanocytes in different layers of skin determine the colour and pigmentation of the skin. Skin hyperpigmentation diseases are consequently caused by changes in melanocyte production or melanin distribution[2].

Under the general term "hyperpigmentation," a number of illnesses connected to skin darkening, pigmentation, and discolouration are included. Melasma, post-inflammatory hyperpigmentation, ephelides, lentigines, and many more are examples of prevalent hyperpigmentation conditions. Melasma is a term for an acquired hyper melanosis skin disorder in which sporadic grey-brown lesions or patches of light to dark-brown skin form on exposed areas of the skin[3]. It typically affects the face and neck regions and is more frequently seen in women.), post-inflammatory hyperpigmentation (PIH) is another hyper melanosis skin disease in which dark areas appear after skin damage or inflammation. Solar lentigines, also known as "Age spots" or "Sunspots," are a disorder where areas of darkened retinal lesions result in hyperpigmentation. Ephelides, often known as freckles, is a common condition characterised by darker, reddish to light brown spots that typically appear on the face, neck, and arms. They emerge in the formative years and are more common in people with lighter or fairer skin tones[4].

Although hyperpigmentation is not a dangerous or fatal condition, it can harm patients' quality of life by harming their emotional and psychological well-being. For hyperpigmentation, there are numerous treatment options. These medications are typically used topically as creams, gels, or ointments. However, these topical treatments come with several side effects, including hypopigmentation, peeling, skin drying, and irritation. Long-term treatments that last for months or even years may result in low patient satisfaction and compliance. The need for new treatment alternatives is highlighted by the fact that there is still no effective medication for hyperpigmentation[5].

Why skin hyperpigmentation?

A common cause of hyperpigmentation is an excess production of melanin. Melanin is a pigment that gives skin its colour. It's produced by skin cells called melanocytes. Several different conditions or factors can alter the production of melanin in your body. Certain medications can cause hyperpigmentation. Also, some chemotherapy drugs can cause hyperpigmentation as a side effect.

Review Article

Anticancer Activity, Phytochemical Screening, Isolation and Structure Elucidation of Scopoletin in *Ipomoea reniformis* Choise: A Review

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ABSTRACT

The quality of herbal medicines used to treat various cancers has significantly increased because to extensive pharmaceutical research. We are now much better equipped to detect many anticancer plants thanks to the development of molecular science and the improvement of isolation and structural elucidation tools. *Ipomoea reniformis* was exposed to the MTT test using various solvent fractions of the total plant. Human cervical cancer Hela and human breast carcinoma MCF cell lines were discovered to be cytotoxic by the ethylacetate fraction of the whole plant. The ethylacetate fraction's IC_{50} value was 51.57 g/ml for Hela cell lines and 39.6 g/ml for MCF-7 cell lines. Significant outcomes were seen, consequently supporting the use of plants in the conventional medical system. Along with a well-known Coumarin derivative called Scopoletin, the irodoids gardenoside were also isolated for the first time from an *Ipomoea* species, specifically *Ipomoea reniformis* (Convolvulaceae). Its spectroscopic measurements were used to establish its structure.

Keywords: Anticancer activity, MTT assay. Scopoletin, UV spectroscopy, IR Spectroscopy, NMR spectroscopy, Mass Spectroscopy.

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INTRODUCTION

The perennial herb (creeper) *Ipomoea reniformis* belongs to the family Convolvulaceae. It is widely spread over all of India, notably in wet areas of the upper Ganges plain, Gujarat, Chhattisgarh, Bihar, West Bengal, Western Ghats, ascents to 900m in the highlands, Goa, Karnataka, Ceylon, and Tropical Africa[1-7,9]. The synonym of *Ipomoea reniformis* is *Merremia emarginata* Hallier. in India, it is known by many names in different regions, including Mooshakarni in Sanskrit, Underkani in Marathi, Indurkani in Bengal, Underakani in Gujarat, Toinnuatali in Telugu, Chukakani in Urdu, Goromusha in Persian, Mushkani in Hindi, Paerattaekirae in Tamil, and Yellikkadukirai in Madras [2,5,7-10]. There are numerous significant claimed therapeutic benefits of it. In the Native *Ipomoea reniformis*, according to the Traditional Chinese Medicine (TCM) system of medicine, is beneficial for renal disease, fever caused by liver enlargement, cough, headache, neuralgia, rheumatism, diuretic, inflammation, and nose problems. The root contains a diuretic and a laxative and is used to treat eye illness and gums, while the powder from the leaves is used as a snuff during epileptic episodes. For its therapeutic uses, the entire plant decoction is primarily to blame [7-11]. The plant reportedly includes resin and glycosides, according to investigations in the literature. Amino acids, tannins (condensed tannins, pseudo tannins), and caffeic, pcoumaric, ferulic, and sinapic acid esters[12].

More than one-third of the world's population suffers from cancer, which accounts for more than 20% of all fatalities and is a leading cause of mortality. Tobacco, viruses, chemicals, radiation, environmental variables, and nutritional factors are a few of the factors that might cause cancer[13]. The primary conventional cancer treatments in China include chemotherapy and radiation, which are frequently complemented by other complementary and alternative therapies[14]. In the past, people have treated cancer with plants as a natural cure. Etoposide and Teniposide, clinically effective medications used to treat lymphomas, bronchial cancer, and testicular cancer, were developed as a result of extensive research conducted at Sandoz facilities in Switzerland in the 1960s and 1970s[15]. By restoring physiological homeostasis and training the body tissues, these plants may support the host's resistance to infection. According to numerous research, medicinal plants' ability to fight cancer is a result of the antioxidants that are naturally present in them. Compared to contemporary (allopathic) medications, therapeutic plants are more readily available, less expensive, and toxic-free[16]. The creation of new plant-derived natural compounds and their analogues for anticancer activity describes attempts to synthesis novel derivatives based on bioactivity- and mechanism of action-directed isolation and characterization coupled with rational drug design-based modification[17]. Cellular communication with the outer world is regulated by oncogenes. Proto-oncogenes are mutated to produce them. Exposure to chemical, environmental, or viral carcinogens stimulates mutated oncogenes, which causes cell changes and causes them to

Review Article

Gastro Retentive Drug Delivery System: A Novel Approach for Prolong Therapeutic Activity

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ABSTRACT

Gastro-retentive drug delivery systems have a particular emphasis on oral controlled release and site-specific drug delivery systems, which have generated a significant amount of interest in the pharmaceutical industry in an effort to improve therapeutic action. The idea for a sophisticated drug delivery system emerged as a means of resolving issues with formulations and drug molecules' physicochemical qualities. Gastro-retentive drug delivery system aims to target site-specific drug release for oral or systemic effects. It increases drug bioavailability by extending the duration of gastric residence time, a therapeutic improvement of drug. This method is particularly helpful for drugs with a narrow window of absorption in the upper Gastro intestinal Tract. Several gastro-retentive drug delivery methods, including floating and non-floating systems, have been covered in this review.

Keywords: Floating system, non-floating system, gastric residence time, evaluation parameter, Gastric retention, Cra controlled release.

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INTRODUCTION

The ability to design, develop, and control the emptying time is a crucial asset for dosage forms that remain in the stomach longer than conventional dosage forms since gastric emptying is a highly variable process. Designing a controlled release system involves many challenges in order to improve bioavailability for improved absorption. One of these challenges is the inability to keep the dosage form at a certain region of the digestive system. Drug absorption from the gastrointestinal system is a complex process that depends on a number of factors. It is commonly accepted that the period of the drug remaining in contact with the small intestine influences how much of a drug is absorbed.[1]

The most feasible and preferable method of distribution to systemic circulation is oral administration. The pharmaceutical industry has recently shown a rising interest in oral controlled release drug delivery to achieve better therapeutic benefits such convenience of dosage administration, patient compliance, and formulation flexibility. Drugs with short biological half-lives and fast absorption from the Gastro Intestinal Tract (GIT) are removed from the bloodstream rapidly. These drugs must be dosed frequently to have a therapeutic effect. To get around these restrictions, oral sustained controlled release formulations have been developed in order to release the drug gradually into the gastrointestinal tract and sustain a stable drug concentration in the systemic circulation for an extended period of time. Such a drug delivery would remain in the stomach after oral administration and release the drug under controlled environments so that the drug could be constantly given to its absorption site in the GIT.[2]

By employing the mechanisms of mucoadhesion,[3] flotation, sedimentation, expansion, magnetic dosage systems, or concurrently implementing pharmacological agents[4] that prolong stomach emptying, solid dosage forms can be regulated gastric retention. These methods have led to a detailed description of the classification of floating drug delivery systems (FDDS). Scientists have talked about evaluating FDDS in vivo and in vitro to determine how effective the system is. There have been a number of recent comments published demonstrating the effectiveness of such approaches for drugs with bioavailability issues. Due to the demand for gastro-retentive dosage forms (GRDFs), there have been significant efforts made in both academia and industry to create such a drug delivery mechanism. The gastric emptying rate is unaffected by the buoyancy of floating drug delivery systems since their bulk density is lower than that of gastric fluids. The drug is released from the stomach gradually and at the desired pace while the system is floating on the gastric contents. As a result, the GRT rises and the variation in plasma drug concentration drops is effectively controlled. Several FDDS utilizing development and sustainability, with their own benefits and drawbacks, has been designed. Examples are hollow microspheres, raft-forming systems, single- and multiple-unit hydrodynamically balanced systems (HBS). The development of GRDFs using natural polymers, which has lately emerged as the industry's preferred methodology, is the subject of the current review. Natural

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Review Article

A Review on Floating Drug Delivery Systems

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ABSTRACT

The purpose of writing review on Floating Drug Delivery System (FDDS) was to compile the recent literature with specific focus on the principal mechanism of floatation to achieve gastric retention. The recent developments of FDDS including the physiological and formulation variables affecting gastric retention, approaches to design single-unit and multiple-unit floating systems, and their classification and formulation aspects are covered in detail. FDDS improves the drug bioavailability and patient compliance by increasing the gastric residence time and controlling the drug release. Gastro-retentive systems can remain in the gastric region for several hours for significantly prolong residence time of drugs by which improves bioavailability, reduces drug waste, and improves solubility for drugs that are less soluble in a high PH environment. These systems are useful to overcome several problems encountered during the development of a pharmaceutical dosage form.

Keywords: Floating drug delivery systems, multiple unit, bioavailability, gastric residence time.

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INTRODUCTION

Drug delivery system that floats Low-density systems having enough buoyancy to float over the contents of the stomach and remain buoyant there without slowing down the rate at which the stomach empties its contents are known as floating drug delivery systems (FDDS) or hydrodynamically controlled systems. The medicine is slowly withdrawn from the system at the desired rate while the body is floating on the contents of the stomach. The stomach's residual system is emptied after the medication has been released. As a result, the oscillations in plasma drug concentration are better managed and GRT is raised. However, in addition to the minimal gastric content necessary for the proper application of the buoyancy retention principle, the buoyancy retention principle also calls for a minimal level of floating force (F).[1]

For dose forms that stay in the stomach longer than standard dosage forms, the ability to extend and control the emptying time is a crucial asset. Gastric emptying of dosage forms is an incredibly varied process. Designing controlled release systems for greater absorption and increased bioavailability presents a number of challenges. The difficulty to limit the dose form in the desired region of the gastrointestinal tract is one of these challenges. The process of drug absorption from the digestive system is intricate and influenced by a variety of factors. It is commonly accepted that the length of time a medicine spends in contact with the small intestinal mucosa influences how much of the gastrointestinal tract it absorbs. Small intestinal transit time is therefore a crucial factor for drugs that incompletely absorbed.[2]

Drugs stomach residency times can be greatly extended by floating delivery systems since they can stay in the gastric region for several hours. For medications that are less soluble in a high pH environment, prolonged stomach retention increases bioavailability, lowers drug waste, and enhances Solubility. It can be used to administer medications locally to the stomach and nearby small intestines. Gastro retention aids in improving the accessibility of novel drugs with fresh therapeutic opportunities and significant patient advantages. Mucoadhesion, flotation, sedimentation, expansion adjusted shape systems, or the concurrent administration of pharmacological agents that delay stomach emptying can all be used to manage the gastric retention of solid dosage forms.[3]

Without having any control over the drug delivery system, solid oral dosage forms like capsules and tablets supply a certain drug concentration in the systemic blood circulation and also generate significant changes in plasma drug concentrations. The oral administration of any medicine is the most practical and preferable method of delivering it to the systemic circulation. The oral controlled release drug delivery method has recently attracted more attention in the pharmaceutical industry in order to gain greater therapeutic advantages. Such as case of dosage administration, patient adherence to the product, and adaptability in drug formulation. Drugs with short half-lives and easy absorption from the gastrointestinal tract[4,5]

Review Article

Natural Excipients As Teeth Whitening Agents: A Review

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ABSTRACT

Patients are increasingly expecting more from dental aesthetics and spend a lot of money on oral hygiene products such as toothbrushes, toothpaste, mouth rinses and so on. People who have their teeth whitened feel more socially accepted and satisfied with their appearance. Natural teeth whitening excipients improve oral health and reduce enamel erosion while bleaching. Popular bleaching products were ineffective at whitening teeth. Furthermore, brushing with dental formulations containing agents such as hydrogen peroxide increased the surface roughness of the enamel and decreased the microhardness of the enamel over time. As a result, people are attempting to replace these products with natural, cost-effective and safe alternatives that produce significant results. This article was focusing on efficacy of natural excipients as teeth whitening agents.

Keywords: Dental aesthetics, Teeth whitening, Natural excipients, Enamel erosion, Dental formulation.

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INTRODUCTION

Patients are increasingly expecting more from dental aesthetics and spend a lot of money on oral hygiene products such as toothbrushes, toothpaste, mouth rinses, and so on. People who have their teeth whitened feel more socially accepted and satisfied with their appearance.[1] The main cause of tooth discoloration is the consumption of certain foods or beverages such as coffee, tea, wines, and alcohols, as well as the continuous consumption of some fruits such as apples, pineapple, pomegranate, and vegetables such as potatoes and beetroot. Other factors like continuous smoking and tobacco chewing cause nicotine deposition in the enamel, use of antibiotics such as Tetracycline or Doxycycline. Environmental factors also play a significant role in tooth discoloration, with some areas' ground water containing higher concentrations of fluoride result in tooth discoloration. Poor oral hygiene, such as improper brushing and tooth paste, is another cause of yellow teeth. Tooth discoloration is also linked to age.[2] These factors, alone or in combination, are linked to changes in tooth colour and surface texture. Bleaching is the term used to describe the process of removing stains from teeth and the substances that are used for this process are referred to as bleaching agents. Different bleaching agents, both natural and artificial, are easily accessible on the market.[3]

Tooth whitening or bleaching is divided into two categories: professional and natural methods. The professional techniques are further divided into three categories: professionally prescribed, professionally performed (in-office), and over-the-counter bleaching. In professional teeth whitening procedure, the bleaching agent is applied directly to the teeth by the dentist, who performs the procedure. This involves use of peroxides based agents like hydrogen peroxide and carbamide peroxide. However, as chemical whitening agents have a detrimental effect on tooth enamel, individuals are now promoting and using natural teeth whitening products since natural herbal teeth whitening products perform as well to chemical bleach, they have more advantages in terms of improving oral health, reduction of enamel erosion while bleaching, cost and safety.

The purpose of this article was to discuss the effectiveness of natural excipients as teeth whitening agents.

Enamel Structure and Teeth Whitening Metabolism

Enamel structure: On top of the dentin, enamel covers the tooth's crown and a portion of the neck. Physically, tooth enamel is extremely tough because it is mostly made of inorganic minerals; 95% comprises calcium and phosphate ions that compose a strong substance - hydroxyapatite crystals.[4]

Teeth whitening metabolism: It's crucial to comprehend the physiology and metabolism of teeth in order to comprehend the causes of teeth discolouration. The structure that makes up the majority of a tooth's crown and root is called dentin. Dental pulp that is fed by blood vessels nourishes the interior of the crown and tooth. The cementum covers the root dentin, which aids in the root's attachment to the bone. The thickness of the enamel, which shields the crown dentin, varies with age and dietary

Review Article

Protein Energy Malnutrition: An Overview for Child Health

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ABSTRACT

In this current scenario, modernization of world in all aspects is one of the tremendous pressure for influencing lifestyle of people which has led to an explosive increase on working for whole body protein. Various new diseases, disorders and syndromes are under research for the measures to overcome such medical conditions. Protein Energy Malnutrition is one of the medical condition affecting the growth and development of people's health at the most crucial period of life. WHO reports that every age group of human beings suffers from this health condition and even death ratios are also reported from the same. PEM is most commonly seen in infants, paediatrics and children under the age of 5 approximate 24.8% of population suffer from stunting, 2.21% by overweight and 6.41% by wasting and severe wasting by the survey reports of UNICEF, WHO, and World Bank. From the study it is reported that, besides of developing medical facilities there is still a need to promote the child health programs for the recovery from malnutrition in children.

Keywords: Protein Energy Malnutrition, WHO (World Health Organization), paediatric, health programs, under nutrition, stunted, wasted, obesity, UNICEF.

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INTRODUCTION

In recent years, Public health issues and improvements in people's health have received more attention. Children are an important segment of the present and future of the country. Therefore, one of the biggest deals in the global aspect is reducing child disease and death. It is a significant public health issue in India that primarily affects infants and young children (under the age of 6), with devastating effects on everything from physical development to cognitive growth to infection susceptibility. [1]

What is protein energy malnutrition?

Protein-Energy Malnutrition, indicates a mismatch between the amount of protein and energy available and what the body needs to grow and function at its best. This imbalance encompasses both insufficient and excessive energy intake, the latter of which causes overweight and obesity while the former causes malnutrition in the form of wasting, stunting, and underweight.[2]

Intake, requirements, and expenditure of energy and/or specific nutrients are very rarely directly assessed. Instead, practise and research rely on anthropometric measurements compared to a control population. Wasting (thinness) is defined by (WHZ) weight for height/length among children under 5 years old, and Body Mass Index (BMI) for age among 5 to 19 year olds. Stunting (linear growth impairment) is measured in terms of (HAZ) height (or length) for age.[3]

Need to study protein energy malnutrition:

Despite the fact that this population has not significantly improved, a sizable portion of children still suffer from nutritional inadequacies. Yet, due to worries about other infectious diseases, simple issues like PEM have gone unnoticed.[4] Undernutrition is linked to decreased immunological responses, which increases susceptibility to infections, which worsen undernutrition. If this vicious cycle persists, the child may die. Complex relationships exist in pre-schoolers between dietary intake, nutritional status, and morbidity.[5]

Poor nutrition (poor diet quantity and/or quality resulting in over- or undernutrition) and lack of early learning opportunities contribute to the loss of growth and academic potential and result in lifelong health and economic disparities for learning. Learning has been linked to positive early child development (ECD) outcomes when it is supported by responsive caregiving behaviours that are prompt, contingent on children's actions, and developmentally appropriate and stimulating.[2]

One important measure of a community's nutritional quality and health is considered to be a child's growth. The World Health Organization estimates that approximately half of all child fatalities under the age of five are caused by undernutrition. According to the Joint Child Malnutrition Estimates, stunting and wasting affected 151 and 51 million under-5 children worldwide, respectively. One of the rare nations with a high frequency of both

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Review Article

Natural Disintegrating Agents in Pharmaceutical Formulation and Development: Review

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ABSTRACT

The development of new excipients for potential use as disintegrant agent in tablet formulations continues to be of interest. This is due to the fact that various disintegrating agents can be helpful in boosting moisture penetration & dispersion of tablet matrix, and disintegration of tablets has recently drawn significant attention as a necessary step in achieving rapid drug release. Natural disintegrants are substances added to tablets and also some encapsulated formulations to help break up tablet and capsule "slugs" into smaller pieces in an aqueous environment. This increases the surface area that is available and speeds up the release of the therapeutic component. Natural polymers including starches, gums, mucilage, & dried fruits are used as a binder, diluent, & disintegrants to speed up the disintegration of drugs that aren't very water-soluble, boost nutritional supplementation, and raise the solubility of the medicine. Natural disintegrants are more cost-effective and secure than synthetic ones. The advantages of natural excipients over semi-synthetic and synthetic excipients include their soothing effect, biocompatibility, availability, cheap cost, and non-irritating nature. They are also more readily available and less expensive. Therefore, in the present review, an attempt has been made to explore the various natural disintegrants which have been used in pharmaceutical formulation and development.

Keywords: Natural Excipients, Plant products, Natural Disintegrants, Natural superdisintegrants, Tablet formulation, Disintegrating tablets, Research articles.

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1. INTRODUCTION

The function of an API and the support for safety and efficacy are greatly influenced by the excipient. Excipients are generally used in historical indeterminate dosage forms like tablets, capsules, etc. as diluents, binders, disintegrants, adhesives, glidants, and sweeteners. Excipients work in conjunction with API to enhance the functionality and potency of a medicinally active molecules[1]. Excipients are used to improve the bulk, durability, stability, and absorption of active substances. Excipients play a crucial role in the variability of the final product. Excipients often make up three times as much of a pharmaceutical formulation as the therapeutically active ingredient[2].

The globe is now becoming more and more interested in natural medications and excipients. Natural excipients have attracted a lot of attention recently because of their numerous pharmacological uses as diluents, binders, lubricants, & disintegrants in tablets. Because of their absence of toxic effects, low cost, availability, calming effect, and non-irritating nature, these are preferred to semi-synthetic & synthetic excipients because they are biocompatible, affordable, and easily accessible[3].

This research review shows the use of various natural, plant based disintegrants in various pharmaceutical dosage formulation and development.

2. NATURAL EXCIPIENTS

Nature is rich in a variety of priceless elements that either directly or indirectly contribute to the wellbeing of living things. Natural excipients, including their derivatives, are widely distributed in plants, animals, and minerals. These excipients include binders, diluents, sweeteners, colorants, preservative, film formers, etc. Pharmaceutical firms are showing interest in using natural excipients to create novel medicine formulations, cosmetics, and food products since they are inert, biocompatible, and biodegradable with little harmful, as well as cost-effective[4]

Natural excipients have attracted a lot of attention lately because of their numerous medicinal uses. For instance, when creating and manufacturing medicinal dosage forms, natural polysaccharides polymers are used. They safeguard, support, or improve bioavailability, stability, or patient acceptance. Moreover, improve any aspect of the drug's overall safety, effectiveness, or delivery during storage and usage, or help identify the product[5].

2.1 Sources of natural excipients:

a) **Animal source**: -, Stearic acid Lactose, Bees wax, Honey Gelatin, Musk, Lanolin etc.

b) **Vegetable source**: - Starch, Peppermint,

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QUALITY BY DESIGN (QBD): APPLICATION OF QBD IN PELLETIZATION

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ABSTRACT

The primary idea of QBD is "The Quality cannot be examined into the product; however it must be constructed into it." Quality through design is the cutting-edge technique for the true standard of pharmaceuticals. It describes use of Quality through design to make certain grade quality of Pharmaceuticals. In this review paper, the Quality through design and a number of its parameters are described. This review article involves the benefits of QBD, steps involved in the QBD process and the applications of QBD. The compiled data from various research articles explains the importance as well as future need of QBD parameters. QBD plays a major role in screening of various formulated product, it is not only saving the time but it is proven beneficial for the economy of various manufacturing companies. Now a days emerging pharmaceutical companies are developing their interest towards QBD studies to depict factors interfering in the results. QBD makes it easier to achieve the best suitable batch in pharmaceuticals. QBD has its own contribution to the drug layout, improvement, and manufacture of extraordinary drug merchandise. It is better to know the quality target product profile (QTPP) for identification of critical quality attributes (CQA). This article will be beneficial in predicting CQAs, CMA etc. QBD involves the application of different design tools such as Plackette Burman, Boxe-Behnken, Central Composite, RSM etc. Hence Quality through design is totally a novel technique for making advancement in the field of medicine, which may be stated as a remedy with pharmaceutical advances.

KEYWORDS: Pellets, FMEA, Ishikawa Plot, CQA, ANOVA.

INTRODUCTION

The aim of pharmaceutical development is to style a prime quality product and its manufacturing process to consistently deliver the intended performance of the merchandise. The data and knowledge gained from pharmaceutical development studies and manufacturing experience provide scientific understanding to support the establishment of the look space, specifications, and manufacturing controls. Information from pharmaceutical development studies are often a basis for quality risk management. It is important to accept the fact that the quality can never be tested into products, such as quality should be built-in by designing the different Changes in formulation and development processes during manufacturing and lifecycle management should be considered as opportunities to realize additional knowledge and further support establishment of the design space. Also, addition of relevant knowledge gained from experiments giving unexpected results also can be useful. Design space is suggested by the applicant and is subjected to regulatory assessment and approval. Working within the design space isn't considered as a change. Movement out of the design space is taken into account to be a change and would normally initiate a regulatory post approval change process.[1,2]

Definition [ICH Q 8(R1)]

A systematic development approach that starts with predefined goals and emphasizes product and process understanding as well as process control supports sound science and quality risk management.

Benefits of QBD

- QBD is good Business
- Eliminate batch failures
- Minimize deviations and costly investigations
- Avoid regulatory compliance problems
- Organizational learning is an investment in the future
- QBD is good Science Better development decisions
- Empowerment of technical staff

Opportunities

- Efficient, agile and flexible system

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Research Article

Formulation Development of Flaxseed Oil Beads Containing ω-Fatty Acid

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Abstract

Background: Nutraceuticals are in high demand as dietary supplements on the international market since decades. Nutritional and therapeutic supplements called nutraceuticals are widely accessible. Alpha linolenic acid (ALA), fibre, proteins, and vital omega-3 fatty acids are all present in high concentrations in flaxseed, one of the oldest and most widely utilised food supplements. The present work was aimed to formulate and develop flaxseed oil beads containing omega fatty acids as a replacement supplement for marine source. Flaxseed oil beads were formulated by ionic gelation method. Minitab 21.1.0 was used to screen and optimise the process and formulation parameters. Plackett Burman design was used for the initial screening. Twelve batches were made ready for screening, and each batch was evaluated for optimization based on the percentage of drug release and the percentage of drug encapsulation efficiency. RSM was used to carry out the optimization. After optimization and validation, the batches showed the satisfactory results complying with IP specifications.

Results: Twelve batches were formulated and evaluated for percentage encapsulation efficiency and percentage drug release. The formulated batches F4, F6 and F10 shown the optimal results.

Conclusion: Polyunsaturated fatty acids found in the flaxseed oil were confirmed with hexabromide test. Several nutritional advantages of the extracted flaxseed oil's omega fatty acid were incorporated in beads utilising the ionic gelation process.

Keywords: Nutraceutical, Flaxseed, Beads, QbD, Omega fatty acid, Alpha linolenic acid.

1. INTRODUCTION

Nowadays "Nutraceutical" movement has created a huge need for the creation of novel dietary supplement formulations. These are the supplements which are used as medication in addition to nutrition to benefit health, prevent chronic diseases, modulate the immune system, lengthen life expectancy, and many other things. The idea of essential fatty acids derives from the fact that they are necessary lipids for the human body because of their cellular roles linked to inflammatory and immune responses. They are also endogenously incapable of synthesis, necessitating their consumption[1].

Omega-3 essential fatty acids are a class of nutraceuticals under the study for food enrichment due to their functional properties. The main classes of essential fatty acids are omega-3 and omega-6, represented by the major compounds in foods: Alpha-Linolenic Acid (ALA, C18:3) and Linoleic Acid (LA, C17:2), respectively[2,3].

Long-chain polyunsaturated fatty acids in the omega-3 family, such as docosahexaenoic acids (DHA, C20:5) and eicosapentaenoic acids (EPA, C22:6, n- 3)., have drawn interest because of their potential to protect cardiovascular illnesses and to regulate body homeostasis Omega-3 fatty acids, which have important cardioprotective qualities, also have anti-inflammatory, antiarrhythmic, vasodilatory, and active effects on dyslipidaemia, diabetes mellitus, and obesity [4,5]. LA and ALA are essential fatty acids since neither humans nor other higher animals are able to manufacture them. Eicosanoids, which are produced from these Fatty Acids, are also referred to as locally acting bioactive signalling lipids. EPA and DHA create anti-inflammatory eicosanoids, whereas arachidonic acid (ARA) produces pro-inflammatory eicosanoids[6,7].

α-Linolenic acid makes a notable contribution to the fatty acids within green leafy tissues of plants, typically comprising over 50 % of the fatty acids present. This is because α-linolenic acid is an essential component of the membranes of thylakoids within chloroplasts. α-Linolenic acid is found in significant amounts in several seeds, seed oils and nuts. Linseeds (popularly known as flaxseeds) and their oil typically consists of 45–55 % of fatty acids as α- linolenic acid. In contrast, soyabean oil, rapeseed oil and walnuts contain 5–10 % of fatty acids as α- linolenic acid[8].

The oils are more prone to oxidation on exposure to different environmental conditions. The oil containing omega fatty acid to encapsulate in beads was one of the difficult approaches to encapsulate in bead formulation. The aim of current research work was aimed to design and develop ω -fatty acid containing pectin beads using QBD.

2. MATERIALS AND METHOD

2.1. Materials

Flaxseeds were obtained from Wagh Brothers Pvt. Ltd. (Nagpur, India). Pectin, Chitosan and Calcium Chloride were purchased from Himedia Laboratories Pvt. Ltd. Acetic acid and