Key Indicator:	3.3 Research Publication and Awards
3.3.2	Number of papers published per teacher in the Journals notified on UGC website during the year
3.3.2.1	Number of research papers in the Journals notified on UGC website during the year
File Description	Any additional information

3.3.2	Number of papers published per teacher in the Journals notified on UGC website during the last year	
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Research Publications of 2023-2024

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ASIAN JOURNAL OF CHEMISTRY

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Design, Synthesis and Biological Evaluation of Pyridyltriazole Derivatives as Potent Antitubercular Agents

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In current investigation, a new series of pyridyltriazole derivatives were synthesized by conventional methods and characterized through spectroscopic techniques such as IR, NMR (^{1}H) and mass spectroscopy. Based on colour observation and percentage of inhibition, all 24 pyridyltriazole derivatives were subjected to *in vitro* anti-mycobacterial testing using MABA techniques against the *Mycobacterium tuberculosis* (H37Rv) strain. It was found that all of the synthesized compounds were efficient in suppressing the *M. tuberculosis* H37Rv strain at concentrations of 1, 5 and 10 µg/mL. Among all the synthesized compounds, only **2**, **3**, **6**, **7**, **8**, **11**, **14**, **15**, **18**, **20**, **21**, **22**, **23**, **24** has good anti-TB efficacy in contrast to the standard medication. According to the *in silico* ADME prediction, every synthesized molecule has drug-like qualities and is appropriate for oral bioavailability. Furthermore, research utilizing molecular docking have been conducted to get mechanistic understanding and molecular interactions in opposition to the mycobacterial InhA enzyme. Utilizing a molecular docking analysis, hits against specific molecular targets were found. This *in silico* study delved into the molecular interactions between potential compounds and the Mtbenoyl-reductaseInhA (PDB 5JFO).

Keywords: *In silico*, Molecular docking, Pyridyltriazole, *Mycobacterium tuberculosis*, Tuberculosis, Mtbenoyl-reductaseInhA.

INTRODUCTION

Tuberculosis (TB), caused by *Mycobacterium tuberculosis* (Mtb), is one of the most deadly and ancient infectious illnesses [1]. Tuberculosis, a persistent global human health problem, with considerable morbidity and mortality rates globally [2]. According to the World Health Organization's 2022 global tuberculosis report, 10.6 million new tuberculosis cases are predicted to result in about 1.3 million fatalities worldwide by 2022 [3]. The burden of tuberculosis in India remains a substantial public health problem, highlighting its global prevalence and the worrisome incidence of drug-resistant infections inside the country [4]. India is one of the top eight countries, accounting for more than two-thirds of all tuberculosis cases [5]. Furthermore, one in every four cases of multidrug-resistant tuberculosis (MDR-TB) in the world is reported in India. In 2022, India registered an expected 119,000 MDR-TB cases [6,7]. However, these figures may be significantly underestimated due to testing limitations and the fact that only 76% of newly diagnosed TB cases and 73% of patients who have previously received treatment have been tested for rifampicin resistance [6]. In India, the number of patients who received further therapy for MDR-TB and extensively drug-resistant (XDR)-TB was very low, at 4 per 100,000 and 1 per 100,000 in 2021, respectively [8-10]. Alarmingly, the total success rates of tuberculosis treatment in India were only 57% in 2019. These worrying numbers from India highlight the critical need for improved diagnostics, proper treatment and expanded measures to prevent drug-resistant tuberculosis [11].

Enoyl-reductase InhA is a crucial enzyme required for Mtb survival [12]. InhA regulates the formation of mycolic acid, which is an important component of the mycobacterial cell wall [13]. InhA catalyzes the final step of fatty acid elongation and eliminates double bonds in fatty acids to produce mycolic acid and maintain bacterial cell wall integrity [14]. Isoniazid, a first-line anti-TB medicine, inhibits its activity and prevents the generation of mycolic acid [15]. The emergence of drug-resistant strains has highlighted the need of

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Review article

Phyto constituents with Anti-Asthmatic Potential

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ABSTRACT

Since antiquity, medicinal plants and their phytoconstituents have played an important role in managing various chronic diseases. Asthma is one of the heterogeneous, chronic inflammatory disorders of the respiratory system which is characterized by narrowing and inflammation of the lung's airway, difficulty in breathing, coughing, chest pain, wheezing, etc. Asthma causes around 2, 50,000 annual deaths and it has been predicted that an additional 100 million people will suffer from asthma up to 2025 worldwide. The anti-asthmatic therapy currently available ruins its success because of the high cost of treatment and the undesirable effects of synthetic drugs. The pathophysiology of asthma involves various macromolecular causes such as histamine, bradykinin, IgE antibodies, TNF alpha of leukotriene cells and mast cells, etc. Therefore, for managing asthma "multi-talented compounds" are needed, rather than working alone medications, which can show different activities in a single package. According to the researches, it was concluded that phytoconstituents can play this role effectively because they show the multi-tasking property with good efficacy, potency, and minimal side effects. Hence the current review summarizes various ethnopharmacological components which have been successfully studied for their anti-asthmatic potential along with animal models used for screening of anti-asthmatic activity.

Keywords: Asthma, Pathophysiology, Phytoconstituents, Anti- asthmatic activity, Animal models

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INTRODUCTION

From ancient times, medicinal plants and their phyto-constituents are used in the management of different chronic diseases such as diabetes, cancer, cardiovascular diseases, hypertension, different respiratory, skin disorders, and many more. [1] Over the past few years, the prevalence and severity of asthma increases day by day, especially in children. All over the world 155 million individuals suffer from different types of asthma-like bronchial, occupational, allergic, cough-variant, exercise-induced, nocturnal and childhood asthma, etc.[2, 3] .

Various medicinal plants and their phytoconstituents have shown their efficacy in the management of asthmatic conditions. They have shown their therapeutic effect through various activities such as bronchodilation, stabilization of mast cell degranulation, antiallergic, anti-histaminic, anti-inflammatory activity, inhibition of leukotriene activity, reduction in plasma level of leukotriene C4, nitric oxide, T cell activation, TNF alpha, and IgE, etc. The current review sum up the phytoconstituents which proves their application in the management of asthma by various mechanisms. [4]

Pathophysiology of asthma

Asthma is heterogeneous, chronic inflammatory disorder of the respiratory system. It is characterized by narrowing, inflammation of the lung's airway, difficulty in breathing, coughing, chest pain, wheezing, etc. [4, 5, 6].

Various factors such as environmental pollutions especially air pollution, allergens, and respiratory infections, physical and mental stress etc. are responsible to alleviate cases of various types of asthma. [2, 7]

These factors activate different metabolic ways which results in release of certain bio-mediator molecules such as histamine, bradykinin, IgE antibodies, TNF Alpha from leukotriene cells and mast cells. These molecules individually show different symptoms like edema, excessive mucous secretion, bronchial constriction, inflammation of airways etc. If attack persist frequently it leads to damage of respiratory system.

Currently, symptoms and complications of asthma are managed with the help of β agonists, anticholinergic, and xanthine class drugs such as theophylline, methy lxanthines, and steroidal anti-inflammatory agents (corticosteroids). But apart from high cost, they show following side effects:

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Review article

Phyto constituents with Anti-Asthmatic Potential

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Various medicinal plants and their phytoconstituents have shown their efficacy in the management of asthmatic conditions. They have shown their therapeutic effect through various activities such as bronchodilation, stabilization of mast cell degranulation, antiallergic, anti-histaminic, anti-inflammatory activity, inhibition of leukotriene activity, reduction in plasma level of leukotriene C4, nitric oxide, T cell activation, TNF alpha, and IgE, etc. The current review sum up the phytoconstituents which proves their application in the management of asthma by various mechanisms. [4]

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Currently, symptoms and complications of asthma are managed with the help of β agonists, anticholinergic, and xanthine class drugs such as theophylline, methy lxanthines, and steroidal anti-inflammatory agents (corticosteroids). But apart from high cost, they show following side effects:

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RESEARCH ARTICLE

Natural Polymer-Based Nanogel for pH-Responsive Delivery of Sorafenib Tosylate in Hemangiosarcoma

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Abstract

Smart nanomedicinal treatment for cancer manifests a solubility challenge with inherent nanoscale size and nonspecific release with stimuli-responsive potential. This is the limelight in novel chemotherapy to pursue physiochemical differences between the tumor microenvironment (TME) and normal cells, which introduces active groups of nanocarriers responding to various stimuli, endowing them with concise responses to various tumor-related signals. The nanogels were successfully prepared by a modified solvent evaporation technique. Nine batches were formulated by changing the chitosan concentration (12, 14, 16 mg/ml) and sonication time (5, 10, 15 min). The formulations were optimized for particle size and zeta potential with high percent entrapment efficiency (%EE) through Central Composite Design software. The optimized batch F7 had a 182-nm size and high zeta potential (64.5 mV) with 98% EE. The drug release of F7 was higher at pH 6 (97.556%) than at pH 7.4 (45.113%). The pharmacokinetic study shows that the release follows the Hixon plot model (R^2=0.9334) that shifts to zero order (R^2=0.9149). The nanogel F7 was observed for stability and showed an absence of color change, phase separation, and opacity for 6 months. In the present study, the pH difference between cancer cells and normal cells is the key point of the smart nanogel. This study is promising but challenging depending on the *in vivo* study. The nanogel was successfully prepared and evaluated for pH-responsive release. As hemangiosarcoma commonly occurs in dogs, this formulation helps to limit the difficulties with administration.

Keywords cationic polymer · chitosan · hemangiosarcoma · nanogel · natural polymer

Introduction

Sorafenib tosylate is a synthetic multitargeted small compound that acts as an inhibitor of the mitogen-activated protein kinase (MAPK) cascade. These pathways are involved in various cellular processes, such as cell growth and cell survival, and are hence known as hallmarks of cancer [1–3]. Sorafenib decreases blood flow to the tumor by inhibiting several of these kinases, which are involved in angiogenesis. The mechanism of action of sorafenib tosylate is shown in Fig. 1. The sorafenib tosylate is approved for human beings by the US Food and Drug Administration in hepatic cancer, thyroid cancer, or renal tumor patients [4–6]. Sorafenib demonstrated strong anticancer efficacy *in vitro* against canine osteosarcoma and HSA cells in dogs [7]. The conventional dosage forms of sorafenib tosylate face challenges such as low solubility, low permeability, and drug resistance across cancerous tissues, necessitating a focus on nanotechnologies such as "Smart Nanogel" [8–10]. The site-selective ability that goes along with the controlled stimuli-responsive drug release behavior remains a significant problem for today's drug delivery systems. Killing as many cancer cells as possible without harming healthy cells has been the ultimate goal of cancer healing up to this point. High water content, biocompatibility, and tunable chemical and mechanical characteristics are characteristics of nanogels. They also have a high surface area for multivalent bioconjugation, an internal network for the inclusion of therapies, and a configurable size range from submicrons to tens of nanometers. Because of these special qualities, nanogels have a lot of potential for use in bionanotechnology, tissue engineering,

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RESEARCH ARTICLE

Ethosomes: A Novel Tool for Vesicular Drug Delivery

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ABSTRACT:
Ethosomes are elastic, phospholipid-based nanovesicles with a high concentration of ethanol (20-45%). Ethosomes exhibit desirable features as vesicular systems. As a result of their bilayer composition (aqueous and lipid), they exhibit improved bioavailability for both hydrophilic and lipophilic drugs. Higher ethanol concentrations (30–45%) cause stearic stability, which allows the loaded medication to penetrate deeper into the stratum corneum, and deeper skin layers with a high transdermal flux. Due to the ease of preparation. non-irritancy, efficiency to encapsulate wide range of drug molecules with varying lipophilicity/hydrophilicity and higher stability than previously formulated other vesicular systems ethosomes are the optimal carriers for topical drug delivery. The use of ethosomal transporter opens up a variety of challenges and opportunities for researchers for future study and the creation of novel, superior treatments. The scope of this small review is to elaborate on the novel concept of ethosomes and to describe their methods of preparation, mechanism of penetration, composition, characterization, marketed products of ethosomes, patents and their applications.

KEYWORDS: Ethosome, Ethanol, Permeation, Lipid, Transdermal.

INTRODUCTION:

Researchers have been working toward effective medicine delivery into and across the skin for many years[1], the body's expanding skin typically has a surface area of $2m^2$ and gets around 33% of the blood flow[2]. As is obvious, the skin is the largest and most accessible organ in the body, making it a viable channel for administering drugs for both topical and systemic effects[3,4]. The stratum corneum (SC), the skin's outermost layer, is subordinated by the epidermis and dermis, making up the skin's multi-layered structure. Fibroblasts, sweat glands and hair follicles that originate in the dermis blood supply are interspersed within various layers of skin[5]. The use of the skin as a drug delivery method has many benefits, including the ability to target the active ingredient for a local effect, avoidance of first-pass metabolism, reduced dose fluctuations, controlled drug delivery, and improved patient compliance because it is a non-invasive delivery method[6,7]. The SC, which is the skin's outermost layer, is the layer that most effectively prevents drugs from penetrating the epidermis, due to the fact that it is made up of insoluble bundled keratins that are stabilised by cross-linked proteins and covalently attached lipids, which restricts the drug's transdermal bioavailability[8].

In order to transfer drug molecules with various physicochemical qualities to the deep layers of skin and systemic circulation, specific carriers are needed to overcome the natural skin barrier[3,4]. Novel lipid vesicles have recently been created to get around the problem of transporting medications to and via the SC. When liposomes were first created, they were used to deliver medications topically. Since then, numerous innovative vesicular systems based on lipids have been created[9]. New lipid vesicles such as transferosome, ethosomes, binary ethosomes, etc. were created to address the limitation of conventional liposomes' drug permeability through various skin layers[10].

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RJPT

RESEARCH ARTICLE

Antioxidant, Antistress, Nootropic activity and its Correlation studies of aqueous extract of *Punica granatum* fruit estimated by Noninvasive biomarkers and Y-maze test in rodents

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ABSTRACT:
The memory loss associated with increased oxidative stress due to increased level of free radicals. Oxidative stress has been involved in several diseases includes cancer, atherosclerosis and neurodegenerative diseases.This study aimed to estimate the correlation of antioxidant and antistress activity with nootropic activity of aqueous extract of pomegranate (*Punica granatum*) *by in-vivo* noninvasive studies using rats. The *in-vitro* antioxidant activity was determined based on the ability of the *Punica granatum* to scavenge free radicals and lipid peroxidation inhibiting activity. The antistress effect of the aqueous extract of *Punica granatum* for 24h treatment (100 and 300mg/kg, p.o.) was evaluated by using the forced swim stress test in rats. The 24h urinary excretion of vanillylmandellic acid (VMA), 5-hydroxyindoleacetic acid (5-HIAA), homovanillic acid (HVA) and ascorbic acid (AA) was determined in all groups under normal and stressed conditions by HPLC and spectrophotometric methods in all groups, were selected as noninvasive biomarkers. Nootropic activity activities of *Punica granatum* fruit extract were estimated as locomotor and working memory in rats in a Y-maze apparatus. Administration of aqueous extract of *Punica granatum* at a dose of 100 and 300mg/kg reduced the urinary metabolite levels. *Punica granatum* treatment showed significant dose dependent variation in non-invasive biomarker levels in urine samples of rats taken after 24h. The treatment with *Punica granatum* extracts improved the percentage entry of rats into safer zone, it means acquisition (learning) retention and retrieval (memory) were improved in rats compared to stress controls. Cognition determined by working memory and locomotor activity results were shown to be dose-dependent. The results of this study strongly suggestedantioxidant, antistress and nootropic activity effect of *Punica granatum*in rodents were correlated. The data obtained were analyzed by one-way ANOVA followed bytukey test. $p<0.05$ was considered to be significant. There is substantial evidence that flavonoids play an active role in providing antioxidant, antistress and nootropic activities of *Punica granatum* extracts. The findings of the present investigations indicate that the *Punica granatum* has significant antistress activity, which may be due to the immunostimulating property and increased resistance, nonspecifically, against all experimental stress conditions. The study provided scientific evidence for their utility as nootropic agents and to advocate their use in foods.

KEYWORDS: Antistress activity, *Punica granatum*, Nootropic activity, Forced swim test, Y-maze test.

INTRODUCTION:

Homeostasis is the term refers to maintenance of our internal medium constant in face of changing environment.

The things which menace the homeostasis is known as stress. Stress represents a reaction of the body to a stimulus that tends to alter its regular physiological equilibrium or homeostasis and has been described as a nonspecific response of the physique to any demand imposed on it.[1] Stress alters the normal physiological conditions and spring in state of endangered homeostasis. This has been result into the etiopathogenesis of disorders such as GI disorders,

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RESEARCH ARTICLE

Preparation, statistical optimization, in-vitro evaluation and characterization of solid lipid nanoparticles of an anti-retroviral drug Nevirapine

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ABSTRACT:
Nevirapine-loaded solid lipid Nanoparticles (SLNs) were manufactured using lipid and emulsifying agent by hot homogenization method. The goal of research was to formulating a SLN system to target the HIV reservoir which is mostly found in the lymphatic system and to conquer the obstacle of drug itself. Also, nearly 50% of antiviral drugs fall within BCS class 2, which have low solubility. 44% antiviral drugs belongs to BCS class 3 have inadequate permeability and 6% belongs to class 4 with inadequate solubility and inadequate permeability. Depending on the NVP solubility and stable formulation, stearic acid as a lipid and poloxamer 188 and tween 80 as an emulsifying agent were chosen and SLNs were manufactured with the help of hot homogenization method. Optimization of independent variables such as lipid concentration, emulsifying agent concentration and no. homogenization cycle was carried. The effect of independent variables on the dependent variables i.e. particle size and entrapment efficiency was studied. Optimized formulation which was lyophilized (L-SLN) and this L-SLN additionally characterized using DSC, SEM and XRD analysis. Also, in-vitro drug release of optimized batch studied in 0.04 M Sodium phosphate buffer pH 6.8 containing 2% SLS, demonstrated 41.83% release at the end of 24th hr. Absence of low intensity in XRD indicated the presence of amorphous SLNs. SEM showed the morphology of SLNs. No prominent changes observed in the accelerated stability studies.

KEYWORDS: Solid lipid nanoparticles, High pressure homogenization, HIV, DOE, Nevirapine.

INTRODUCTION:

Drug delivery technologies significantly change from the last few decades. Oral drug delivery is the conventional drug delivery system as well as most preferred route of drug administration. Also, oral dosage form can be manufactured at large scale with cost effectiveness. It is the rapidly expanding drug delivery system. Almost half of antiviral drugs fall within BCS class 2, which has low solubility. 44% drugs are of BCS class 3 with low permeability and 6% of class 4 with inadequate solubility and inadequate permeability.[1]

Pharmaceuticals with low solubility can be made more soluble through complexation, crystal engineering, salt production, solid dispersion, surfactant usage, and other methods. These methods involve modifications to drugs' physical and chemical composition as well as different strategies.[2] The majority of BCS Class II medicines have substantial first pass metabolism in addition to having poor water solubility, which is another factor contributing to less bioavailability, as per reported by Biopharmaceutical Drug Disposition Classification System (BDDCS), which bases its classification on the drug disposition forecast by the interaction of transport, absorption, and elimination.[3,4]

HIV infection affected over and above 72-75 million people worldwide, and currently infected population nearby 38 million and they are battling the HIV. If the infected person do not treat with anti-HIV therapy, then progressive CD4+ cell reduction take place as well as various types immune system disorder, raising the

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Antimicrobial Activity of Flaxseed Marketed Oil on Different Microbes

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ABSTRACT

Flaxseed has antibacterial, antifungal, anti-inflammatory, and antimicrobial activity. The purpose of this study is to check the activity of two different marketed cold-pressed flaxseed oils. In that study, the two different oils are taken and their activity was checked against different gram-positive and gram-negative bacteria (*Escherichia coli, Staphylococcus aureus)* pathogenic fungus (*candida Albicans, and aspergillus Niger),* and periodontal bacteria (*streptococcus mutans and porphyromonas gingivalis).* The agar well diffusion technique was utilized against these six microbicides. The wells of 6 mm diameter were bored and oil was applied to two different wells. The zone of inhibition of it was measured in millimeters after 48,72 hours of incubation at 38°C.No inhibitory effect was noticed against *S mutans,* low effect against *S aureus* and *E Coli, p gingivalis*and good inhibition against *candida Albicans* and *Aspergillus Niger.* In conclusion, flaxseed oil is a good alternative medication and it can be used for the treatment of wound infections caused by bacteria andas an antifungal agent.

KEYWORDS: marketed flaxseed oil, *E Coli, S aureus, candida Albicans, A Niger, S mutants, P gingivalis.*

I. INTRODUCTION

The scientific name for flaxseeds is *Linumusitatissimum L,* which translates to "most helpful" in Latin. It is a multifaceted crop that can be planted for fiber or oil production (El-Beltagi, Salama, & El-Hariri, 2007; Diederichsen & Richards, 2003; Vaisey-Genser & Morris, 2003; Tour'e & Xueming, 2010)[1]. Flax comes in yellow and brown variants. Depending on how the seeds will be used, end consumers in the food business typically have a preference for one colour kind over the other. If the flax is crushed for oil, the colour kind is less significant. Some types, which may sell for more money, were created with higher quantities of omega-3 fatty acids.[2]

Linseed oil is commonly marketed as a food under the name flaxseed oil. It is obtained from the dried ripe seeds of the flax plant, *Linum usitatissimum,* and consists of the glycerides of linolenic, linoleic, oleic, stearic, palmitic, and myristic acids (Merck 2015) [3], flaxseed oil is an edible oil obtained from the flax plant. It is high in α-linoleic acid and has hydrophobic properties that help it to reduce moisture and seal porous surfaces. These properties are believed to be responsible for the effective reduction of microorganisms and fungal infections.[4] In earlier studies, the *L. usitatissimum* fixed oil has been reported to exhibit significant anti-

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Formulation and Evaluation of Herbal Lipstick from Beetroot Powder

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ABSTRACT

The aim of present study to create the herbal lipstick from the natural colorants. In order to prepare herbal lipstick from the beet root powder and evaluate the prepared lipstick. Lipstick are formulations commonly used to improve the gorgeousness of lips and add glamorous touch to the makeup. Herbal lipstick is a cosmetic formulation containing pigments, perfumes, waxes, preservatives, anti-oxidants, oils, colors. The advantage of herbal lipstick is safe, cost effective, non-toxic, and pigments used from easily available plants and vegetables. The aim of the present study which includes the formulation and evaluation of herbal lipstick using color pigments from natural sources such as beetroot.

Due to lot of side effects of available synthetic formulation in the market the prepared herbal lipstick evaluated on parameters such as color, pH parameter, skin irritation test, perfume stability, solubility study, surface anomalies, aging stability. The present study concluded that the use of natural colorants in lipstick formulation having less or no side effects. It has potential to increase consumer acceptance because of use of different natural ingredients and harmless colorant used.

KEYWORDS: Beet root, Natural colorant, Herbal lipstick formulation, *Betavulgaris*,color cosmetic, skin testing.

I. INTRODUCTION

Cosmetics is a word comes from the Greek word **"Kosmtikos"** it means the organization, power and skill in beautifying[1].Cosmetics are the formulations that are used to improve the appearance of the human beauty[2,3]. Cosmetic substances include lipstick, skin care creams, lotions, perfumes, powders, hair colors, nail polish, gels, baby products and other so many products are in huge demand in developing and developed countries[4]. Herbal cosmetic products have increasing demand in the world market and they are precious gift from the nature. There is broad choice of herbal cosmetic products to convince our beauty regime[5]. Herbal lipsticks are produced from natural color from frequently available vegetables and plants. Commonly used colored pigments are beet root, rose, papaya, tomato, carrot, henna, alkanet root, indigo and it is easy to produce blends for our need. The commonly used ingredients for the preparation of lipstick are oil, emollients, waxes and pigments. Such ingredients mainly used for protection of lips, texture and color[6].Herbal lipstick contains many natural nutrients are present which are safer to use and it is free from hazardous chemicals and it is safe

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Original Article

Development and Evaluation of Fenofibrate Surface Solid Dispersion for Improved Solubility and Dissolution Rate

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ABSTRACT

Objectives: The current work aimed to prepare and characterize Surface-Solid Dispersion (SSD) of Fenofibrate (FNB) in order to improve its solubility and dissolution. **Materials and Methods:** SSD of FNB has been prepared using solvent evaporation techniques through the combination of hydrophilic polymers such as Aerosil 200, Avicel PH 101, Sodium Starch Glycolate (SSG), Crospovidone (CP) and Croscarmellose Sodium (CCS). The produced SSDs were tested for saturation solubility, production yield, Fourier-Transform Infrared Spectroscopy (FTIR), Powder X-ray Diffraction (PXRD), Differential Scanning Calorimetry (DSC), Scanning Electron Microscopy (SEM), and *in vitro* dissolution study. **Results:** PXRD results demonstrated a conversion of the crystalline FNB to an amorphous state when formulated with the carrier, which improved FNB solubility. A decrease in the endothermic peak with respect to FNB in the DSC thermogram of SSD, confirms the loss of crystallinity. Hydrophilic carriers such as Aerosil 200 and CCS at 1:2 (drug: polymer) ratios were found to increase solubility by 3 fold. **Conclusion:** As a result, the creation of SSD using hydrophilic polymers (Aerosil 200 and CCS) by solvent evaporation seemed to be a novel method that enhanced FNB solubility and dissolution.

Keywords: FNB, Surface solid dispersion, Solvent evaporation, Solubility, Dissolution rate.

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INTRODUCTION

Drug delivery through oral administration is the most prevalent. Nevertheless, for many medications, especially those that are not well soluble in water, it is a difficult and ineffective method of delivery. Such medications often have a poor dissolving profile, as well as poorer absorption and bioavailability, due to their limited water solubility. Therefore, increasing drug solubility and subsequent oral bioavailability is still among the most challenging steps in the drug development process, especially for systems that administer drugs orally. There are numerous nanotechnology strategies for addressing inadequate water solubility, or poor bioavailability, of pharmaceuticals. However, these strategies require complex technology and expensive apparatus and are ultimately ineffective. Although many techniques exist and are documented in the literature for improving drug solubility, such as salt formation, co-crystal formation, particle size reduction, and solid dispersion, they have not been widely used.[1]

Solid dispersion, among other methods, has shown promise in increasing the drug's solubility, wettability, rate of drug dissolution, and ultimately its bioavailability.[2] However, there aren't many solid dispersion options on the market.[3,4] Recently, SSDs have gained popularity as a method that can improve on some of the drawbacks of traditional solid dispersions.

It is an effective pharmaceutical strategy for improving the therapeutic efficacy, solubility, and absorption of medicines in formulations. A method for performing and precipitating solid dispersion over an inert carrier surface is SSD. The carrier's hydrophilic characteristics, particle dimension, porosity, and circumference all influence how rapidly a drug is released from it.[5] This method reduces drug agglomeration by increasing the exposed surface area. Smaller amounts of carrier can result in a higher dissolution rate for carriers with greater surface areas, such as silicon dioxide.[6] Aerosil 200, Avicel PH 101, SSG, and CCS were used to improve the solubility of hydrophobic drugs.[7] FNB, the precursor to fenofibric acid, has become among the most commonly used fibrate anti-lipidemic drugs. It is primarily used in the treatment of mixed hyperlipidemia, hypercholesterolemia, and hypertriglyceridemia. Additionally, hyperlipidemia linked to diabetes, hypertension, and other cardiovascular disorders is effectively treated with FNB.[1] The Biopharmaceutics Classification

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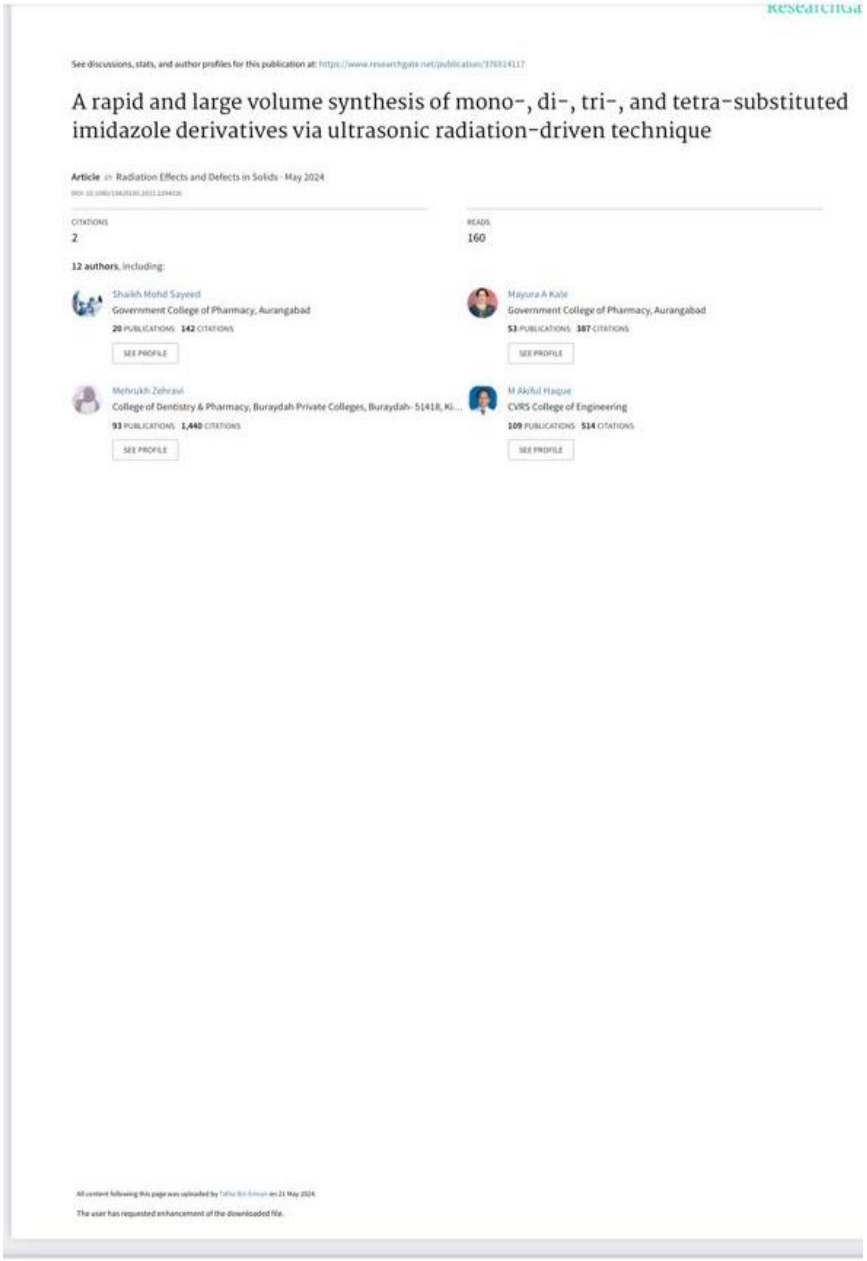

A rapid and large volume synthesis of mono-, di-, tri-, and tetra-substituted imidazole derivatives via ultrasonic radiation-driven technique

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Research Article

In silico Investigations, Design and Synthesis of Some Novel Quinazolinone Derivatives

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ABSTRACT

The present research has been focused on designing and synthesizing new derivatives of quinazolinone heterocycle. The designed derivatives were subjected to in silico investigations by conducting PASS studies in which novel predicted antiviral activity of this heterocycle against picornavirus was explored. These designed derivatives were also subjected to in silico toxicity risk assessment studies using Osiris property explorer in which toxicities viz., mutagenicity, tumorigenicity, carcinogenicity and irritability were predicted and prediction of properties viz., c logP, solubility, mol weight and drug score was also done. All the compounds were found to be devoid of any predicted toxicities with predicted properties in acceptable range. Hence, they were further subjected to docking studies where interaction with protein 4CTG identified as target for the antiviral (Picornavirus) activity was studied. The docking results were found to be comparable to that of the parent quinazolinone molecule. Hence, the designed quinazolinone derivatives were further subjected to wet-lab synthesis. The compounds were recrystallized and subjected to structure elucidation studies by IR spectroscopy. As these derivatives of quinazolinone have shown promising results in docking, with compounds 2a, 2b and 2c showing optimum binding affinity of -8.0 kcal/mol, -8.1 kcal/mol and -8.2 kcal/mol; respectively which is better than that shown by parent compound showing binding affinity of -7.1 kcal/mol to the target protein 4CTG. Conclusively, it can be surmised that these synthesized compounds can be further subjected to in vitro and in vivo biological screening against Picornavirus.

Keywords: *In silico*, quinazolinones, Docking, PASS studies, Toxicity studies, Synthesis.

INTRODUCTION

Quinazoline heterocycle is considered to be an important class of six-membered fused heterocycles in which quinazolin-4(3H)-one and its derivatives have gained structural importance because of their biological significance viz., quinazolinone alkaloids form a basic core of febrifugine and isofebrifugine, which has been found to possess significant antimalarial activity and have been extracted from the traditional Chinese medicine [1]. The chemistry of quinazolinone has been well-explored during the conduct of its synthetic studies, although still many novel and multifaceted variants of quinazolinone structures are needed to be discovered.

After extensive research on quinazolinones, an exact understanding of the complex behavior of quinazolinone ring with different targets in the body has been understood with definite conclusions. The majority of substitutions found at 2nd and 3rd positions of the quinazolinone system have been found to be influencing their biological activities viz., antimalarial, antitubercular, anticancer activities[2], antiparkinsonian properties[3]. For antimalarial and antitubercular activities, the groups substituted at 2nd and 3rd positions of the ring can be phenyl, ketone, ether, amide or carboxamide and in case of anticancer activity, thioether and aryl ketone have been observed as beneficial substitutions on the same positions. Likewise for anticonvulsant activity, substitutions of phenyl or benzyl groups as well as short and long simple alkyl group thio-ethers and carboxamides have been found to be good for the said biological activity [4].

Quinazolinone derivatives have been found to be elevated melting crystalline products, which are generally insoluble in water and organic solvents but found to be soluble in aqueous alkali and sometimes in concentrated acids viz., 6N hydrochloric acid. They have been found to form stable salts of mono-hydrochlorides, chloro-platinate, chloro-aurates and picrates including their metal salts such as silver and mercury [5,6]. Overall, the quinazoline and quinazolinone skeleton has been frequently encountered in medicinal chemistry. Besides the above mentioned biological activities, this skeleton has also been explored for antitumor[7], antihypertensive[8], analgesic [9], antibacterial and antimicrobial [10], anti-inflammatory [11], antineoplastic, antidepressant, antipsychotic, antiarrhythmic, sedative-hypnotics, antifungal, anticoccidial and many other activities [12-16].

MATERIALS AND METHODS

PASS studies

PASS studies were performed on the designed compounds. It is a web tool that has the ability to predict nearly 3678 pharmacological effects; mechanisms and special toxicities of the molecule including mutagenicity, carcinogenicity, teratogenicity, and embryotoxicity. The predicted activity spectrum includes 65 of 374 pharmacological effects, 176 of 2755 molecular mechanisms, 7 of 50 toxic effects, 11 of 121 metabolism terms at default Pa > Pi cutting points. The

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Research Article

Dissolution thermodynamics and solubility prediction of satranidazole in mono-solvent systems at various temperatures using a single determination

Abolghasem Jouyban, Pavan B. Rathi, Mayura A. Kale & Fleming Martinez

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Concurrent oral delivery of non-oncology drugs through solid self-emulsifying system for repurposing in hepatocellular carcinoma

Rameshwar M. Ardad, Arehalli S. Manjappa, Shashikant C. Dhawale, Popat S. Kumbhar & Yogesh V. Pore

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RESEARCH ARTICLE

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Concurrent oral delivery of non-oncology drugs through solid self-emulsifying system for repurposing in hepatocellular carcinoma

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ABSTRACT

Objective: The present study aimed to identify a safe and effective non-oncology drug cocktail as an alternative to toxic chemotherapeutics for hepatocellular carcinoma (HCC) treatment. The assessment of cytotoxicity of cocktail (as co-adjuvant) in combination with chemotherapeutic docetaxel (DTX) is also aimed. Further, we aimed to develop an oral solid self-emulsifying drug delivery system (S-SEDDS) for the simultaneous delivery of identified drugs.

Significance: The identified non-oncology drug cocktail could overcome the shortage of anticancer therapeutics and help to reduce cancer-related mortality. Moreover, the developed S-SEDDS could be an ideal system for concurrent oral delivery of non-oncology drug combinations.

Methods: The non-oncology drugs (alone and in combinations) were screened *in vitro* for anticancer effect (against HepG2 cells) using (3-(4,5-dimethylthiazolyl-2)-2,5-diphenyltetrazolium bromide; MTT) dye assay, and cell cycle arresting and apoptotic behaviors using the fluorescence-activated cell sorting (FACS) technique. The S-SEDDS is composed of drugs such as ketoconazole (KCZ), disulfiram (DSR), tadalafil (TLF), and excipients like span-80, tween-80, soybean oil, Leciva S-95, Poloxamer F108 (PF-108), and Neusilin® US2 (adsorbent carrier), which was developed and characterized.

Results: The cocktail composed of KCZ, DSR, and TLF has showed substantial cytotoxicity (at the lowest concentration of 3.3 pmol), HepG2 cell arrest at G0/G1 and S phases, and substantial cell death via apoptosis. The DTX inclusion into this cocktail has further resulted in increased cytotoxicity, cell arrest at the G2/M phase, and cell necrosis. The optimized blank liquid SEDDS that remains transparent without phase separation for more than 6 months is used for the preparation of drug-loaded liquid SEDDS (DL-SEDDS). The optimized DL-SEDDS with low viscosity, good dispersibility, considerable drug retention upon dilution, and smaller particle size is further converted into drug-loaded solid SEDDS (DS-SEDDS). The final DS-SEDDS demonstrated acceptable flowability and compression characteristics, significant drug retention (more than 93%), particle size in nano range (less than 500 nm), and nearly spherical morphology following dilutions. The DS-SEDDS showed substantially increased cytotoxicity and Caco-2 cell permeability than plain drugs. Furthermore, DS-SEDDS containing only non-oncology drugs caused lower *in vivo* toxicity (only 6% body weight loss) than DS-SEDDS containing non-oncology drugs with DTX (about 10% weight loss).

Conclusion: The current study revealed a non-oncology drug combination effective against HCC. Further, it is concluded that the developed S-SEDDS containing non-oncology drug combination alone and in combination with DTX could be a promising alternative to toxic chemotherapeutics for the effective oral treatment of hepatic cancer.

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KEYWORDS
Drug repurposing; hepatocarcinoma; oral delivery; self-emulsifying drug delivery; anti-cancer activity; *in vivo* toxicity

Introduction

Cancer is one of the most common causes of death worldwide [1]. With a projected incidence of >1 million cases by 2025, liver cancer remains a global health challenge. The most common type of liver cancer is hepatocellular carcinoma (HCC). Chronic liver inflammation and damage play a key role in the onset and progression of HCC [2,3]. A range of treatment strategies has been documented for the treatment of cancer including liver cancer. Chemotherapy is one of the extensively used strategies; however, lethal side effects, multi-drug resistance (MDR), etc. necessitated the development of new drug molecules. Additionally, conventional chemotherapy is largely ineffective against HCC [4]. Furthermore, due to underlying hepatic dysfunction, patients with HCC are typically intolerant to treatment [5–7].

The discovery and development of new drug molecules are a protracted, complicated, and pricey process [8]. Drug repurposing is a strategy wherein the drugs approved for one clinical use are

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RESEARCH

Fabrication of PF-127 Based Niosomal In Situ Gel for Intranasal Delivery of Lurasidone Hydrochloride and Optimization by Using 3^2 Factorial Design

Rais Shikalgar[1] · Vinay Deshmukh[1] · Sonu Rathod[1] · G. S. Bangale[1] · Yogesh V. Pore[2] · D. P. Pawar[3]

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Abstract
Schizophrenia and bipolar disorder stand as intense and persistent mental illnesses. This research underscores the development of a niosomal thermoreversible gel for intranasal drug delivery with a focus on precise administration to the olfactory lobe. Utilizing a 3^2 factorial design, lurasidone hydrochloride niosomes were fabricated through the thin film hydration method. The niosomes underwent assessment to determine their encapsulation efficiency, particle size, zeta potential and polydispersity index whereas thermoreversible niosomal in situ gel based on PF-127 in conjunction with HPMC K4M was characterized for pH, gelation time, temperature responsiveness, in vitro release and rheological characteristics. The results indicated that the optimized batch (F4) illustrated a particle size of 171.4 ± 5.12 nm and an encapsulation efficiency $94.67 \pm 0.73\%$. Optimized niosomal gel (poloxamer 17%) characterized with gelation at 37 °C, pseudoplastic flow and virtuous structural integrity. Both in vitro and ex vivo drug release exhibited sustained release through in situ gel. These findings concluded that lurasidone HCL loaded intranasal niosomal in situ gel embraces significant potential to improve inclusive effectiveness of lurasidone.

Keywords Lurasidone hydrochloride · Niosomes · Factorial design · In situ gel · PF-127 · Intranasal delivery

Abbreviations

LH	Lurasidone hydrochloride
CHL	Cholesterol
SPN 80	Span 80
PF-127	Poloxamer 407
SCH	Schizophrenia
IN	Intranasal
BP	Bipolar disorder
BBB	Blood brain barrier
PBS	Phosphate buffer saline

1 Introduction

Schizophrenia and bipolar disorder affect 0.32% of the global population, with onset possible in adolescence (0.5%). These disorders disrupt cognition, emotions and functioning across various life domains. Genetics and environmental factors interact in their development. Effective treatment involves antipsychotic medications and psychosocial support for both short and long-term management. Notably, second-generation atypical antipsychotics are favoured over typical antipsychotics, especially in adolescent cases, to maximize benefits while minimizing risks [1].

Lurasidone hydrochloride (LH) received approval from the US food and Drug Administration (USFDA) in the year 2007. As a potent second-generation atypical antipsychotic drug, it is prescribed for the treatment of schizophrenia [2, 3]. It is utmost efficient in situations where significant concerns include muscle tremors, orthostatic hypotension and hyperlactataemia. It possesses good forbearance and minimal extrapyramidal effects due to low affinity towards α, H_1, M_1 and 5-HT_2C receptors [3, 4]. It belongs to the class of *n*-aryl piperazines chemically, which has an improved negative effect on dopamine (D2) and (5-HT_2A) serotonergic

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RESEARCH ARTICLE

Pharmacokinetic assessment of Natural Anticancer Berberine Chloride in presence and absence of some Herbal Bioenhancers in rabbit model

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ABSTRACT:
The present study investigated the influence of pretreatment of herbal bioenhancers quercetin, curcumin and piperine, separately on pharmacokinetic profile of berberine chloride (BBC) in rabbit model. Initially, ex-vivo permeability studies were conducted to optimize the batches of drug and bioenhancer combinations, wherein, the optimized batches were subjected for in-vivo pharmacokinetic studies in rabbits via single oral dose. All experimental procedures on animals were conducted according to the CPCSEA guidelines. The collection of blood samples were done at predetermined time intervals appropriately processed and analyzed by HPLC method. The data were processed using software and pharmacokinetic parameters (AUC, C_{max}, T_{max}, K_{el}) of BBC were obtained. The results showed that piperine exhibited strongest bioenhancing effect on BBC absorption as compared to quercetin and curcumin. The C_{max} of BBC was increased by 626.53%, 401.86% and 168.60% for piperine, quercetin and curcumin optimized batches, respectively, with notable reduction in T_{max} as compared to BBC (Control). These bioenhancers showed outstanding enhancement in the pharmacokinetic profile of BBC. BBC has been reported to be P-glycoprotein (P-gp) substrate, exhibiting extremely poor bioavailability, which could be successfully overcome by pre-treatment with bioenhancers, attributed to bioenhancer mediated inhibition of the P-gp efflux pump and drug metabolizing enzymes. This improvement in bioavailability and other pharmacokinetic parameters of BBC in presence of bioenhancers would be expected to reduce dose, dosing frequency and toxicity of BBC, thereby contributing improved patient compliance. Thus, it could be concluded that, pre-treatment of herbal bioenhancers could be an effective approach to improve pharmacokinetics of drug like molecules.

KEYWORDS: Berberine Chloride, Quercetine, Curcumin, Piperine, *in-vivo* pharmacokinetic profile.

INTRODUCTION:

Berberine chloride (BBC) is herbal isoquinoline alkaloid with manifold promising therapeutic activities and has been widely utilised in Ayurveda and traditional Chinese medicine for decades. Due to cost effectiveness, minimal toxic impact and innumerable therapeutic actions, recently it has gained remarkable curiosity and tremendous attention.

In spite of its significant activities, its oral use has been severely curtailed as it shows extremely low and variable plasma concentrations in humans with an absolute oral bioavailability of less than 1%. In clinical emergencies, it takes a massive dose (up to 1.5g/day) that could cause adverse gastrointestinal consequences[1].

The key factors for poor membrane permeability and subsequently poor bioavailability of drug are the prevalence of cytochrome P450 enzymes in the gut/ liver which are accountable for presystemic drug metabolism, impaired absorption, predominant tissue distribution, drug excretion into the lumen, bile or urine

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Original Article

FORMULATION AND DEVELOPMENT OF GALLEN GUM LOADED SELF-ASSEMBLED MIXED MICELLES SYSTEM BASED ON FLAVONOID PHOSPHOLIPID COMPLEX

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ABSTRACT

Objective: Research on the development of pharmaceutical self-assembled mixed micells systems is in that they have the advantage of keeping the drug's encapsulating qualities while also enhancing its physicochemical characteristics. The goal of this study was to make the class II biopharmaceutical quercetin more soluble in water and more bioavailable when taken orally (QCT). The enhancement of encapsulation and flavonoids loading within mixed micelles using solvent evapouration technique.

Methods: In the present study, pharmaceutical mixed micells of a BCS class II drug, QCT were prepared using solvent evapouration technique method. Prepared mixed micells were characterized using Critical micelle concentration (CMC), Fourier Transform Infrared (FT-IR), Particle size and zeta potential, Powder X-Ray Diffract meter (PXRD), *In vitro* dissolution, Transmission electron microscopy (TEM). In addition *in vitro* drug release studies were also performed.

Results: The results of the characterization studies indicated the designing of gallen gum loaded self-assembled mixed micelles system based on flavonoid phospholipid complex. The CMC of LS-75 and LS-100 binary mixture had shows good results to be 0.0013%. The FTIR spectra of complex showed characteristic peak of QCT shows abundant effect on O-H (aromatic), C-O (aromatic), C-C, and aromatic C-O is observed at 3282.2, 1620.1, 1058.7, and 1162.2 respectively. The average particle size of design-optimized quercetin mixed micells (QCT-MMs) was demonstrated to be ~116.1 nm, as evaluated by Malvern. From the obtained particle size, it indicated that the particle size of QCT in QCT-MMs was widely distributed. The polydispersity index (PDI) for QCT-MMs was found in the range of ~ 1.000, zeta potential value for QCT-MMs as evaluated by Malvern was observed to be ~-99.2 mV. The P-XRD, SEM, showed good powder diffraction results with having good flow property. Also formulation were evaluated for the *In vitro* drug dissolution study for rate of extent of drug release and dissolution rate release of QCT from QCT-MMs was sustained up to 72 h. TEM images of QCT-MMs, where the micelles exhibited relatively regular dark stained shapes appearing more or less spherical or spheroid.

Conclusion: It can be concluded that the QCT-MMs enhance the aqueous solubility of the QCT and increased the bioavailability and retention time.

Keywords: QCT, Phospholipids S-75, Phospholipid S-100, Solvent evapouration method, Mixed micells

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INTRODUCTION

Micellar amphiphile compositions for drug delivery are successful. Due to the hydrophobic core of micelles, water-insoluble drugs can be easily solubilized and delivered [1]. Targeted drug delivery systems reduce drug degradation and loss, limit side effects, promote medication bioavailability, and increase the number of medicines at the zone of interest [2]. Drug carriers include soluble and insoluble polymers, microparticles, cells, cell ghosts, lipoproteins, liposomes, and amphiphilic polymer-based micellar systems. Globally, people get cancer. Uncontrolled, uncoordinated, unfavorable cell division characterizes it. Cancer cells continue to divide and move through the blood and lymph systems, unlike normal cells [3]. When faulty cells don't die and new cells form when the body doesn't need them, they can create a malignant tumor or neoplasm. Mutations can affect normal cell development and division if cells' DNA is damaged or altered. The major cause of cancer death is metastasis [4].

National Cancer Institute (NCI) and WHO anticipates that 1.9 million men and women will be diagnosed with all cancers at some time in their life. Comparatively, there were enough cancer-related deaths [5]. Lung, liver, stomach, colorectal, and breast cancers are the most deadly. High BMI, inadequate fruit and vegetable intake, lack of exercise, and cigarette and alcohol use cause 81% of cancer fatalities [6]. Cancer treatments include surgery, chemotherapy, radiation, immunotherapy, and monoclonal antibody therapy. The sort of therapy chosen depends on the tumor's location, grade, stage, and the patient's condition [7]. In cancer patients, physiological changes resulted in negative energy balance, growth standstill, and weight loss. In other cases, such as gastrointestinal difficulties, the cause of decreased intake may be clear [8]. Higher energy consumption in cancer patients involves both tumor and host energy demands [9]. The tumor's glucose and protein metabolism will be detailed below. Tumor blood flow may increase heart energy use. Energy expenditure increases oxygen intake and carbon dioxide production, which may increase breathing work [10].

Conventional chemotherapy has medication delivery problems. Particle size, content, and surface charge affect drug transport. Pathophysiological tumor heterogeneity inhibits uniform drug delivery throughout the tumor [11]. The acidic tumor microenvironment destroys acid-sensitive medications [12]. Most medicines are given orally. The bioavailability pharmacokinetics profile of an orally administered drug depends on solubility in water [13]. Oral administration is the most common route due to patient compliance and reduced manufacturing costs. Limited bioavailability is a hurdle to oral dose formulations. Poor bioavailability is due to low aqueous solubility and plasma membrane permeability [13-15].

In the present study developed QCT-MMs using was selected as the Phospolipid S-100 and phospholipid S-75 carrier and employed in the micells formulations at various drug/phospholipid ratios. The QCT-MMs was characterized for CMC, FTIR, particle size and zeta potential, PXRD, *in vitro* drug dissolution study.

MATERIALS AND METHODS

Quercetin was gifted by Yucca Enterprises, Mumbai India. Lipoid S-75, Lipoid S-100, by Ludwigshafen, Germany. Ethanol (Absolute), Tween 80, Di chloro methene, and Acetonitrile Iodine was purchased from Ozone* International, Ahmedabad, India.

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Is nanoformulation a key player or spectator to enhance the solubility of Manidipine: Promising approaches

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Abstract

The solubility of drugs is a vital factor in dosage form development. When a poorly water-soluble drug has to be incorporated into a hydrophilic vehicle, the formulation tends to decrease the bioavailability. Various nanoformulations like nanoparticles (NP), nanosuspensions, nanocapsules, nanospheres, nanogels, nanotubes, etc, are used for improvement in dosage form regarding solubility, absorption, targeted drug delivery, and increase in half-life. Nanoparticles are being used for various drug delivery systems for the betterment of dosage forms as discussed in the current study. The current study has reviewed the problem of solubility of the poorly water-soluble drug manidipine, an antihypertensive drug with the application of nanotechnology nanocrystals. The drug manidipine is a proven antihypertensive drug and acts by blocking the calcium channels. The daily dose of manidipine is 10-40 mg. The manidipine drug is not prescribed as a drug of choice for the treatment of hypertension, the reason behind this is that manidipine is a BCS class two molecule which means poor solubility and high permeability, it is unable to reach in maximum amount to the systemic circulation because of its poor water solubility. The nanoformulation is used for improving the solubility of the drug by increasing its surface area. Nanocrystal (NC) one of the nanoformulation is having the

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A REVIEW ON VARIOUS ASPECTS OF MOUTH DISSOLVING TABLETS

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ABSTRACT

The oral route administration is regarded the most favorable over other routes due to its simplicity, convenience of usage, patient compliance, cost – effectiveness, and painlessness. It is also the safest way of administration. Recent years have seen difficulties with standard dosage forms including patients who are unable to take oral medicament due to dysphasia, unconsciousness, behavioral disorders or CNS abnormalities. So, the first modern alternative to conventional dosage form is to initiate a rapid and swift breakdown in the oral cavity to solve these issues. Mouth dissolving tablets seems to be demanding, promising & one of the most extensively used dosage form over the conventional ones. The development of MDTs aims to provide products with adequate hardness, integrity, taste masking property, pleasant mouth feel, quick disintegration without needs of water within short time period. i.e., ≤60secs. The formulation of mouth dissolving tablets has been potential benefits, especially for pediatric, geriatric, bed – ridden, uncollaborative, and traveling patients who may not have access of water for tablet swallowing. The appropriate weight of tablets, specific disintegration time as well as selection of API's that meet the criteria of MDT are important requirements during formulation of MDT's. This review focused on the formulation challenges with mouth dissolving tablets where flavour masking is the key factor in enhancing the patient acceptability of these formulations. This study emphasizes obstacles and the method of preparation, significance and demerits, mechanisms, selection criteria of pharmaceuticals which should be incorporated in MDT's, challenges as well as recently developed sophisticated formulation approaches of MDT's, quality control tests of medicament. And also give a brief overview of formulation techniques of MDT's as well as usage of various

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Review Article

Pharmaceutical Cocrystals: An Emerging Approach to Modulate Physicochemical Properties of Active Pharmaceutical Ingredients

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Abstract

Most of the Active Pharmaceutical Ingredients (APIs) are typically formulated and administered to patients in oral solid dosage forms due to ease of administration, patient compliance and cost effectiveness. Poor water solubility, low permeability and low bioavailability of APIs are major hurdles in development of oral solid dosage forms. In recent years, cocrystal development has evolved as a feasible approach for enhancing the solubility and bioavailability of poorly soluble drugs. Crystal engineering strategies have been asserted to enhance the likelihood of discovering new solid forms of an API. A pharmaceutical cocrystal is made up of two basic components, an API and a harmless material known as a coformer in stoichiometric ratio. Cocrystallization of an API with a pharmaceutically acceptable coformer can improve the physical characteristics of the API, such as solubility, hygroscopicity, and compaction behavior, without affecting the API's pharmacological efficacy. This review article offers a comprehensive overview of pharmaceutical cocrystals, their physiochemical characteristics, and methods of preparation, with an emphasis on cocrystal screening and cocrystal characterization. The review also included recent FDA and EMA guidance on pharmaceutical cocrystals as well as an outline of multidrug cocrystals.

Keywords: Pharmaceutical co-crystals, crystal engineering, coformers, supramolecular synthons, Solubility

INTRODUCTION

In recent times, there has been an awful great deal of interest towards the design and manufacturing of pharmaceutical cocrystals. The production of new drug products with superior physical and pharmacological properties, such as solubility, stability, hygroscopicity, dissolving rates, and bioavailability, is greatly facilitated by cocrystallization of active pharmaceutical ingredients.[1] The idea of creating cocrystals, or pharmaceutical cocrystals, was developed from the fundamentals of crystal engineering and inspired both industries and academics to expand their horizons in search of more effective solid forms of APIs.[2] Cocrystals are homogenous solid phases that are solid at room temperature and are kept together by weak interactions, mostly hydrogen bonding, between two or more neutral molecular components in a crystal lattice with prescribed stoichiometry.[3] The design and creation of crystalline molecular solids with the goal of influencing material properties is often referred to as crystal engineering.[4] In 1955, Pepinsky first coined the term Crystal engineering and Schmidt implemented it in 1971.[5,6] It is well known that many new chemical entities have poor permeability and/or solubility; up to 90% of new medications are classified as BCS II.[7] Cocrystals are a type of pharmaceutical substance that can improve solubility and dissolution by producing a crystal of an API and another harmless molecule or coformer with specified stoichiometric compositions. The variety of coformer characteristics and interactions in the solid and solution phases allows for a variety of ways for controlling cocrystal solubility.[8]

PHARMACEUTICAL COCRYSTALS

In the year 1844, Friedrich Wohler created the first known cocrystal known as "quinhydrone" using benzoquinone and hydroquinone.[9] In the Cambridge Structural Database, it was the first cocrystal structure that was described.[10] Etter published the first reports on the term "co-crystal" and the design guidelines for hydrogen bonding in an organic co-crystal.[11,12] Supramolecular synthons were first conceptualized by Desiraju in 1995, marking an important turning point for the development of crystal engineering and cocrystal design.[13] Cocrystals are described as solids that are neither solvates nor simple salts and are composed of two or more different molecular and/or ionic compounds, usually in a stoichiometric ratio in the crystal lattice.[14] The FDA defines pharmaceutical co-crystals as "crystalline materials composed of two or more different molecules, typically active pharmaceutical ingredient (API) and co-crystal formers, in the same crystal lattice."[15]

A pharmaceutical cocrystal is made up of two basic components: an active pharmaceutical ingredient (API) and a harmless material known as a coformer should be a safe component from the Generally Recognized As Safe (GRAS) list by US-FDA.[16] The distinct crystal structure of a cocrystal from either of its source materials results in unique

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Method Development for Identification of Manidipine HCl using High Performance Liquid Chromatography

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ABSTRACT: Manidipine HCl (MND) is a third-generation dihydropyridine calcium (Ca) channel antagonist that is lipophilic and highly selective for the vasculature, leading to significant peripheral vasodilation and minimal cardio depression. MND appears to increase insulin sensitivity without altering metabolic function and helpful in hypertensive individuals with comorbidities such as type 2 diabetes mellitus and/or renal impairment. MND is a first-line medication for people with essential mild-to-moderate hypertension as a result.

The discovery, development, and production of pharmaceuticals depend heavily on the development and validation method, among all HPLC is one of them due to its very effective separations and often high detection sensitivity, HPLC is the most widely used separation method in contemporary pharmaceutical and biomedical analysis. Its numerous benefits, includes its speed, specificity, accuracy, precision, and ease of automation, the majority of medications in multi-component dosage forms can be examined using this technique. The development and validation of HPLC procedures are crucial to novel discoveries, the creation of pharmaceutical medications, and numerous other human and animal investigations.

This study provides details on the various steps that go into developing and validating a HPLC technique for MND. According to ICH Guidelines, its include testing for system appropriateness as well as accuracy, precision, specificity, linearity, range and limit of detection, limit of quantification, robustness, and other performance characteristics. The developed HPLC method effectively identified and quantified Manidipine HCl, including impurities, with reliable results.

Keywords: Manidipine HCL (MND), Identification, Validation, High Performance Liquid Chromatography (HPLC), Method development.

INTRODUCTION

A well-known antihypertensive medication, Manidipine HCL (MND) is chemically 2-[4-(diphenyl methyl) piperazin-1-yl] ethyl methyl 2, 6-dimethyl-4-(3-nitrophenyl)-1, 4 dihydropyridine-3, 5-dicarboxylate. (Cheer and McClellan 2001) Manidipine is the third-generation antihypertensive drug effective in depressing BP (Blood Pressure) among those who have mild to moderate essential hypertension (HTN). It is useful since long duration without signs of tolerance (Bellinghieri *et al.*, 2003). It has a moderate start & a lengthy duration of action, successfully sustaining lower BP levels over the one-day dosing period (Casiglia *et al.*, 2004). Its ability to reduce blood pressure is comparable with other well-known DHPs (Dihydropyridines) and angiotensin-converting enzyme inhibitors (Cavalieri and Cremonesi 2009). The therapy is beneficial for patients with mild to severe HTN who are diabetic and very old (Fogari *et al.*, 2011). It is often well tolerated and has no effects on glucose and lipids metabolism. Thus, a first choice in decreasing BP in those with mild-to-moderate.

MND prevents the passage of calcium into the arteriolar muscle cells, it dilates the blood vessels. Additionally, MND appears to have some renal protective properties. (McKeage and Scott 2004; Richy and Laurent 2011; Martínez Martín 2009). MND determination is officially recognized by the Japanese Pharmacopoeia (JP). In JP liquid chromatography was used to estimate MND. It is strongly advised for the quality control (QC) of pharmaceutical formulations to develop stability indicating assays utilising the method of stress testing as outlined by the International Conference on Harmonization (ICH) recommendation. Although MND is commercially accessible, it is not yet included in any other pharmacopoeia. The current study's goal was to create and test a straightforward HPLC approach for the

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RESEARCH ARTICLE

Ethosomes: A Novel Tool for Vesicular Drug Delivery

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ABSTRACT:
Ethosomes are elastic, phospholipid-based nanovesicles with a high concentration of ethanol (20-45%). Ethosomes exhibit desirable features as vesicular systems. As a result of their bilayer composition (aqueous and lipid), they exhibit improved bioavailability for both hydrophilic and lipophilic drugs. Higher ethanol concentrations (30–45%) cause stearic stability, which allows the loaded medication to penetrate deeper into the stratum corneum, and deeper skin layers with a high transdermal flux. Due to the ease of preparation. non-irritancy, efficiency to encapsulate wide range of drug molecules with varying lipophilicity/hydrophilicity and higher stability than previously formulated other vesicular systems ethosomes are the optimal carriers for topical drug delivery. The use of ethosomal transporter opens up a variety of challenges and opportunities for researchers for future study and the creation of novel, superior treatments. The scope of this small review is to elaborate on the novel concept of ethosomes and to describe their methods of preparation, mechanism of penetration, composition, characterization, marketed products of ethosomes, patents and their applications.

KEYWORDS: Ethosome, Ethanol, Permeation, Lipid, Transdermal.

INTRODUCTION:

Researchers have been working toward effective medicine delivery into and across the skin for many years[1], the body's expanding skin typically has a surface area of $2m^2$ and gets around 33% of the blood flow[2]. As is obvious, the skin is the largest and most accessible organ in the body, making it a viable channel for administering drugs for both topical and systemic effects[3,4]. The stratum corneum (SC), the skin's outermost layer, is subordinated by the epidermis and dermis, making up the skin's multi-layered structure. Fibroblasts, sweat glands and hair follicles that originate in the dermis blood supply are interspersed within various layers of skin[5]. The use of the skin as a drug delivery method has many benefits, including the ability to target the active ingredient for a local effect, avoidance of first-pass metabolism, reduced dose fluctuations, controlled drug delivery, and improved patient compliance because it is a non-invasive delivery method[6,7]. The SC, which is the skin's outermost layer, is the layer that most effectively prevents drugs from penetrating the epidermis, due to the fact that it is made up of insoluble bundled keratins that are stabilised by cross-linked proteins and covalently attached lipids, which restricts the drug's transdermal bioavailability[8].

In order to transfer drug molecules with various physicochemical qualities to the deep layers of skin and systemic circulation, specific carriers are needed to overcome the natural skin barrier[3,4]. Novel lipid vesicles have recently been created to get around the problem of transporting medications to and via the SC. When liposomes were first created, they were used to deliver medications topically. Since then, numerous innovative vesicular systems based on lipids have been created[9]. New lipid vesicles such as transferosome, ethosomes, binary ethosomes, etc. were created to address the limitation of conventional liposomes' drug permeability through various skin layers[10].

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RESEARCH ARTICLE

Antioxidant, Antistress, Nootropic activity and its Correlation studies of aqueous extract of *Punica granatum* fruit estimated by Noninvasive biomarkers and Y-maze test in rodents

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ABSTRACT:

The memory loss associated with increased oxidative stress due to increased level of free radicals. Oxidative stress has been involved in several diseases includes cancer, atherosclerosis and neurodegenerative diseases.This study aimed to estimate the correlation of antioxidant and antistress activity with nootropic activity of aqueous extract of pomegranate (*Punica granatum*) *by in-vivo* noninvasive studies using rats. The *in-vitro* antioxidant activity was determined based on the ability of the *Punica granatum* to scavenge free radicals and lipid peroxidation inhibiting activity. The antistress effect of the aqueous extract of *Punica granatum* for 24h treatment (100 and 300mg/kg, p.o.) was evaluated by using the forced swim stress test in rats. The 24h urinary excretion of vanillylmandellic acid (VMA), 5-hydroxyindoleacetic acid (5-HIAA), homovanillic acid (HVA) and ascorbic acid (AA) was determined in all groups under normal and stressed conditions by HPLC and spectrophotometric methods in all groups, were selected as noninvasive biomarkers. Nootropic activity activities of *Punica granatum* fruit extract were estimated as locomotor and working memory in rats in a Y-maze apparatus. Administration of aqueous extract of *Punica granatum* at a dose of 100 and 300mg/kg reduced the urinary metabolite levels. *Punica granatum* treatment showed significant dose dependent variation in non-invasive biomarker levels in urine samples of rats taken after 24h. The treatment with *Punica granatum* extracts improved the percentage entry of rats into safer zone, it means acquisition (learning) retention and retrieval (memory) were improved in rats compared to stress controls. Cognition determined by working memory and locomotor activity results were shown to be dose-dependent. The results of this study strongly suggestedantioxidant, antistress and nootropic activity effect of *Punica granatum*in rodents were correlated. The data obtained were analyzed by one-way ANOVA followed bytukey test. $p<0.05$ was considered to be significant. There is substantial evidence that flavonoids play an active role in providing antioxidant, antistress and nootropic activities of *Punica granatum* extracts. The findings of the present investigations indicate that the *Punica granatum* has significant antistress activity, which may be due to the immunostimulating property and increased resistance, nonspecifically, against all experimental stress conditions. The study provided scientific evidence for their utility as nootropic agents and to advocate their use in foods.

KEYWORDS: Antistress activity, *Punica granatum*, Nootropic activity, Forced swim test, Y-maze test.

INTRODUCTION:

Homeostasis is the term refers to maintenance of our internal medium constant in face of changing environment.

The things which menace the homeostasis is known as stress. Stress represents a reaction of the body to a stimulus that tends to alter its regular physiological equilibrium or homeostasis and has been described as a nonspecific response of the physique to any demand imposed on it.[1] Stress alters the normal physiological conditions and spring in state of endangered homeostasis. This has been result into the etiopathogenesis of disorders such as GI disorders,

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RESEARCH ARTICLE

Preparation, statistical optimization, in-vitro evaluation and characterization of solid lipid nanoparticles of an anti-retroviral drug Nevirapine

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ABSTRACT:
Nevirapine-loaded solid lipid Nanoparticles (SLNs) were manufactured using lipid and emulsifying agent by hot homogenization method. The goal of research was to formulating a SLN system to target the HIV reservoir which is mostly found in the lymphatic system and to conquer the obstacle of drug itself. Also, nearly 50% of antiviral drugs fall within BCS class 2, which have low solubility. 44% antiviral drugs belongs to BCS class 3 have inadequate permeability and 6% belongs to class 4 with inadequate solubility and inadequate permeability. Depending on the NVP solubility and stable formulation, stearic acid as a lipid and poloxamer 188 and tween 80 as an emulsifying agent were chosen and SLNs were manufactured with the help of hot homogenization method. Optimization of independent variables such as lipid concentration, emulsifying agent concentration and no. homogenization cycle was carried. The effect of independent variables on the dependent variables i.e. particle size and entrapment efficiency was studied. Optimized formulation which was lyophilized (L-SLN) and this L-SLN additionally characterized using DSC, SEM and XRD analysis. Also, in-vitro drug release of optimized batch studied in 0.04 M Sodium phosphate buffer pH 6.8 containing 2% SLS, demonstrated 41.83% release at the end of 24th hr. Absence of low intensity in XRD indicated the presence of amorphous SLNs. SEM showed the morphology of SLNs. No prominent changes observed in the accelerated stability studies.

KEYWORDS: Solid lipid nanoparticles, High pressure homogenization, HIV, DOE, Nevirapine.

INTRODUCTION:

Drug delivery technologies significantly change from the last few decades. Oral drug delivery is the convential drug delivery system as well as most preferred route of drug administration. Also, oral dosage form can be manufactured at large scale with cost effectiveness. It is the rapidly expanding drug delivery system. Almost half of antiviral drugs fall within BCS class 2, which has low solubility. 44% drugs are of BCS class 3 with low permeability and 6% of class 4 with inadequate solubility and inadequate permeability.[1]

Pharmaceuticals with low solubility can be made more soluble through complexation, crystal engineering, salt production, solid dispersion, surfactant usage, and other methods. These methods involve modifications to drugs' physical and chemical composition as well as different strategies.[2] The majority of BCS Class II medicines have substantial first pass metabolism in addition to having poor water solubility, which is another factor contributing to less bioavailability, as per reported by Biopharmaceutical Drug Disposition Classification System (BDDCS), which bases its classification on the drug disposition forecast by the interaction of transport, absorption, and elimination.[3,4]

HIV infection affected over and above 72-75 million people worldwide, and currently infected population nearby 38 million and they are battling the HIV. If the infected person do not treat with anti-HIV therapy, then progressive CD4+ cell reduction take place as well as various types immune system disorder, raising the

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