Criteria: 3	Curricular Aspects
Key Indicator: 3.3	**Research Publication and Awards**
Metric No : 3.3.1	***Number of papers published per teacher in the Journals notified on UGC website during the last five year***

- Number of research papers in the Journals notified on UGC website during the last five years

Year	2017-18	2018-19	2019-20	2020-21	2021-22
No. of Publication	10	07	12	12	09

Formula-

$$\frac{\text{Number of publication in UGC notified journals during the last five years}}{\text{Average number of full time teachers during the last five years}}$$

Data Verified by:

Principal

PRINCIPAL

Annasaheb Dange College of B. Pharmacy, Ashta.

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Key Indicator	**3.3 Research Publication and Awards**
3.3.1	**Number of papers published per teacher in the Journals notified on UGC website during the last five year**
File Description	**Any Additional Information**

3.3.1	**Number of papers published per teacher in the Journals notified on UGC website during the last five year**
Sr. No	**Details of documents**
1.	Research publication of 2021-22
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5.	Research publication of 2017-18

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Review article

Polydopamine surface-modified nanocarriers for improved anticancer activity: Current progress and future prospects

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ABSTRACT

From its inception, plenty of anticancer agents and gene therapies have been developed to account for cancer treatment. Despite this, the effectiveness of these therapies is flawed by toxic effects and failure to efficiently reach the target site. In this shade, novel drug delivery systems with advanced theranostic approaches have become a prerequisite in the domain of nanomedicines and nanotherapeutics. Despite this, the challenges associated with drug delivery have been urged to be discovered in the area of "drug delivery" intended for the delivery of drug to a targeted site for enhancement in clinical results. To deal with these issues, attachment of ligands that offer the selective targeting of active moiety in cancer therapy. In this present review, we have discussed the polydopamine (PDA) surface-modified nanocarriers for improved anticancer activity. In brief, methods for cancer treatment, challenges in cancer drug delivery, and approaches for targeted delivery of anticancer drugs have been described. Afterward, PDA in drug targeting and surface modification has been disclosed that including the significance and mechanism of PDA coating along with functionalization, toxicity, and cellular uptake of polymeric nanoparticles-polymerized dopamine (NPs-pD). Finally, the conclusion and prospects of PDA surface-modified nanocarriers have been discussed in detail. Importantly, the adaptability and flexibility of dopamine polymerization is playing a central role in functionalized nanoparticulate drug carriers in cancer treatment. Predominantly, multifunctionality present on the PDA surface and possible secondary modification approaches offer the potential for delivery of nanocarriers to target cancer cells very selectively and efficiently.

Abbreviations: CT, Chemotherapy; PDA, Polydopamine; NPs, Nanoparticles; NPs-pD, Nanoparticles-polymerized dopamine; CSCs, Cancer stem cells; 5-FU, 5-fluorouracil; PTX, Paclitaxel; DOX, Doxorubicin; DNR, Daunorubicin; EPR, Enhanced permeation and retention; MTT, 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide; PEG, Polyethylene glycol; RES, Reticuloendothelial system; MPS, Mononuclear phagocytic systems; PTT, Photothermal therapy; FR, Folate receptor; FA, Folic acid; PC, Prostate cancer; HA, Haluronic acid; Tf, Transferrin; AML, Acute myeloid leukemia; MSNs, Mesoporous silica nanoparticles.

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In Silico Molecular Modeling Study on Isatin Derivatives as Anti-Covid Agents Based on Qsar and Docking Analysis

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ABSTRACT

COVID 19 disease caused by novel SARS-CoV-2.It rapidly infects mammals and causes serious illness and death. The drug development against COVID 19 is a challenging task as COVID 19 disease spreads rapidly throughout the world. Drug development is a time-consuming process, but pandemics create an emergency to Design drugs as earlier as possible. In silico drug design is the key to fast-developing drug candidates. Corona virus's main protease plays a vital function in the viral reproduction cycle and is a potential target for COVID 19 inhibitor development. Most of the Isatin derivatives show potential activity against COVID 19. All possible COVID-19 inhibitors were designed by using reference molecule and QSAR study. V life MDS software has the facility drug development techniques like 2D-QSAR MLR analysis and 3D-QSAR kNN analysis. We designed 50 new Chemical entities molecules from 2 D QSAR and 3D QSAR and screened through the Lipinski rule of 5. All designed molecules satisfied the Lipinski screening criteria for the compatibility of drug to the body. Target enzyme i. e Main Protease (PDB: 6lu7) were downloaded from PDB site and studied docking interaction of new molecules with target enzyme by using Auto dock software. Docking of these new molecules also were checked with target enzyme by using V-life MDS software and docking score calculated. Study shown that one of the Isatin derivative methyl 2-(2, 3-dioxo-5-(1-(pyridin-3-yl) ethyl) indolin-1-yl) acetate (Dock score: -76.040 kcal/mol) new molecule entity shown potent activity than reference standard that is Ritonavir (Dock Score:-14.694 kcal/mol). This study indicates that Isatin derivatives potentially act as Anti-SARS-CoV-2 drugs.

Keywords: COVID 19; docking studies; Isatin derivative; Main Protease inhibitor; NCE; QSAR studies

INTRODUCTION

At the end of the year 2019, Coronavirus was identified in Wuhan, China. This is a highly pathogenic and transmissible viral infection spread throughout the world. It predominantly attacks human respiratory system causing the severe acute respiratory syndrome. Based on genetic, the viruses have four genera: Alpha-coronavirus and Beta-coronavirus infect the mammals, and Gamma-coronavirus and Delta-coronavirus infect birds [1].

The virus causing COVID-19 disease is a spherical enveloped having positive-sense single-stranded RNA associated with a nucleoprotein within a capsid comprised of matrix protein. The envelope bears crown-shaped glycoprotein projections. Some coronaviruses also contain a hemagglutinin-esterase protein 4. The genome contains a unique N- terminal fragment within the spike protein [2]. Also, coronavirus invades the epithelial cells by using angiotensine-converting enzyme 2 (ACE2), or other cell components like integrins, as targets of the SARS-CoV-2 S protein after inhaling droplets containing the virus. Viral reproduction starts in Type II alveolar epithelial cells causes a severe change of innate immunity. Lungs are rapidly compromised following direct damage of the pulmonary tissue, mainly through uncontrolled immune mediators that enhance the entry of monocytes and neutrophils into the infected tissue. Additionally, a pro-inflammatory cytokine storm affects virus replication and increases its diffusion to nearby cells [3].

The main protease enzyme in corona virus participates in assemble and multiplication of the virus. Disrupting this virus's self-replicating machinery can be one of the best targets without causing harm to the host. It has an active site for inhibition. The new chemical entity can interact at this site

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ORIGINAL ARTICLE

Pharmacognostical evaluation of *Arisaema murrayi* (J. Graham) Hook. leaves and tubers for quality control assessment

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Abstract

Introduction: *Arisaema murrayi* (J. Graham) Hook. is one of the plants belonging to the family *Araceae*, commonly called Murray's Cobra Lily or Snake Lily which is known for its medicinal benefits. However, no published work is available to date on pharmacognostical evaluation. **Materials and Methods:** Pharmacognostic evaluation of leaf sand tubers was carried as per the standard guidelines which are based on morphological, microscopical, and physicochemical analysis. **Results:** The morphological evaluation of tubers revealed that tubers were hemispheric in shape, up to 5 cm radius, leaves were found to be coming up shortly after the peduncle, with peltate shape. The layers of the epidermis in the leaf are closely packed. Below the epidermis, there is 2–3 layer of collenchyma cells present. Microscopy study of powder showed the presence of a few layers of fibrous tissue. Cluster crystals of calcium oxalate and starch grains were also present in the powder. Preliminary phytochemical analysis showed the presence of carbohydrates, proteins and amino acids as primary metabolites, and alkaloids as secondary metabolites. **Conclusion:** Pharmacognostic characters studied will be helpful in morphological and microscopical standardization of *A. murrayi*.

Key words: Pharmacognostical evaluation, *Arisaema murrayi*, quality control, evaluation

INTRODUCTION

Since ancient times humans have been dependent on nature for multiple supplies and this dependency persists to date. Due to the utilization of herbs for survival, the human race comes to know about various health beneficial properties of herbs. Soon after initial discoveries, medicine becomes an indispensable part of human life. However, the quality and therapeutic properties are the two key points that were most discussed during the evolution of almost all systems of medicine. In the modern era, although the utilization of herbs and herbal products as medicine is gaining importance, at the same time, the urge for quality control methods for herbal drugs arises. Pharmacognostical evaluation is considered the first step of quality control and utilization of any herb to be used as medicine.[1]

The newly discovered herbs are been identified and evaluated as per certain recommended methods under pharmacognostical evaluation. Once the herbal material is evaluated for specific parameters, then the results obtained are considered as standards for that drug. These set standards are further used for purpose of standardization of the same drug in future. Whenever the herb is collected from the wild or cultivated source, the task of standardization is rudimentary practice.[2] Once the standards are set for any crude drug, then it is easy to carry out an evaluation of the same drug sample in the future.

Arisaema is a genus of flowering plants belonging to the family *Araceae*. Genus Arisaema covers more than 160 plants.[3] These plants are widely distributed throughout the globe and found native to eastern Africa, central Africa, Asia, and eastern North America. Asiatic species of Arisaema are often called Cobra lilies. *Arisaema murrayi* (J. Graham) Hook. is also one of the plants belonging to the family *Araceae*, commonly called Murray's Cobra Lily or Snake Lily. The plant gets its name due to its beautiful flower which often resembles with cobra snake's hood. The plant is believed to be

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RESEARCH ARTICLE

Simultaneous Estimation of Atorvastatin and Aspirin by Dual-Wavelength Spectrophotometric Method from Tablet Dosage Form

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ABSTRACT

Atorvastatin calcium (ATR) and Aspirin (ASP) are beneficial in combination for elderly people in various health management conditions. Aim of present study is to develop simple, accurate, and precise method for simultaneous quantitative estimation of ATR and Aspirin from combined tablet dosage form. Method involves simultaneous equation, using methanol as common solvent. Calibration curves determination for both drugs has been carried out in 0.1 N HCl, phosphate buffer pH 6.8, and methanol as solvent. Linearity range was observed in the concentration range of 20-120µg/ml for ASP when scanned in 224 to 264 nm ranges (R^2 = 0.999) and 10-60µg/ml for ATR when scanned at ranges of 247 to 284 nm (R^2 = 0.998) respectively. Percent concentration estimated for ASP and ATR were 100.13±1.8218 and 99.98 ± 0.98, respectively. The method was found to be simple, economical, accurate and precise and can be used for quantitative estimation of ATR and ASP.

Keywords: ATR, ASP, accuracy, HPLC, methanol, Linearity.

INTRODUCTION

The number of drugs and drug formulations introduced into the market has been increasing due to increase in rate of diseases. The pharmaceutical formulations with combinations of drugs have shown an increasing trend to counteract other symptoms specific to one drug and formulation, and hence analytical chemist will have to accept the challenge of developing reliable methods for analysis of drugs in such formulation. Drug development involves estimation of drugs from pharmaceutical formulation and biological samples which has got immense role in drug discovery. Pharmaceutical industries are typically depending upon quantitative chemical analysis to ensure that the

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RESEARCH ARTICLE

Formulation and assessment of quick dissolving tablet of Candesartan cilexetil arranged from their circular agglomerates

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ABSTRACT:
Candesartan cilexetil is water insoluble drug which comes under BCS class second category. Drug was used in the treatment of acute and chronic hypertension. The research workgenerally focuses on the solubility enhancement, increasing dissolution behavior, flowability and compressibility of the drug. Tablets and capsule are the solid dosage form mostly used. Spherical agglomerates of Candesartan cilexetil were prepared. Candesartan cilexetil water insoluble drug was used. With the incorporation of polymer, Agglomerates of such drug was prepared. Fast dissolving tablet was prepared and evaluated. Evaluation parameter like FTIR, DSC was carried out. Precompression parameters like bulk density, tap density, angle of repose, compressibility index was carried out. Post compression parameters like friability, hardness, thickness, disintegration time, wetting time was carried out and evaluated. Effect of different disintegrant like Crospovidone, cross carmellose sodium was studied. From in vitro study it was found that cross carmellose sodium containing batch F3 shows better drug release so it shows enhanced dissolution rate while if cross carmellose sodium level increases thus decreasing their dissolution rate.

KEYWORDS: FTIR, DSC, Disintegrates, Dissolution rate etc.

INTRODUCTION:

Solid dosage forms are the most common and convenient dosage form. It's having versatile advantages over liquid dosage from. The oral route of drug administration is the most common and preferred method of delivery due to convenience and ease of administration.[1]The orally administered drug gets completely absorbs only when they show fair solubility in gastric medium and such drugs show good bioavailability. As about 70% of the human body is made up of water, a drug must be soluble and thus possess an acceptable bioavailability level.[2] The drug in the dosage forms is released and dissolves in the surrounding gastrointestinal fluid to form a solution for easy absorption. Therapeutic effectiveness of a drug depends upon the bioavailability and ultimately upon the solubility of drug molecules.[3] Solubility is one of the important parameter to achieve desired concentration of drug in systemic circulation for pharmacological response to be shown. Currently only 8% of new drug candidates have both high solubility and permeability.[4]

Kawashima et.al developed spherical agglomeration as a method of novel particulate design. It is the particle engineering technique by which the crystallization and agglomeration can be carried out simultaneously in one step.[4,5] Spherical Crystallization process transforms the fine crystals obtained during crystallization into spherical agglomerates. Agglomerates formed further improves the flowability and compressibility of pharmaceutical ingredient which enables direct tabletting of drug instead of further processing like mixing, granulation, sieving, drying etc.[6] There are certain parameters which have to be optimized in order to obtain the maximum amount of spherical crystals. The principle steps involved in the process of spherical crystallization are flocculation zone, zero growth zone, fast growth zone and constant size zone.[7,8]The solvent change method was used in the preparation of spherical agglomerates. Solution of drug in a good solvent is poured into the poor solvent under controlled conditions of temperature and speed to obtain fine crystals. These crystals are agglomerated in the presence of bridging liquid.[9] The poor solvent has miscibility with good

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Formulation, characterization and evaluation of *in vitro* antioxidant potential of melatonin and quercetin loaded liposomes

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Abstract

The aim of the work was to use the thin film hydration process under vacuum condition to synthesize liposome loaded with melatonin and quercetin, as well as to improve the bioavailability of melatonin and quercetin from liposome. Phosphatidyl choline, cholesterol ratio, pH of hydration medium, rotating speed, and volume of solvent system were investigated as parameters impacting the entrapment of melatonin and quercetin liposome for formulation optimization. The result revealed that the λ_{max} of the melatonin and quercetin was at 276 and 372 nm, respectively. The size of optimized liposome formulation was 43.25 nm by FESEM having a zeta potential of –26.4 mV. Average particle sizes were found to be 1109 nm and PDI of 0.624. The drug entrapment efficiency was found to be 58.56% and 95.03% for melatonin and quercet, in respectively. The percentage drug release respectively for melatonin and quercetin was 68.1% and 79.5% in 24 h, respectively. The IC_{50} value of melatonin and quercetin for DPPH inhibition was found to be 9.315µg/ml and 6.261 µg/ml, respectively and for synthesized liposome 5.64 µg/ml. Finally, the results concluded that the prepared liposome could be used as controlled drug delivery system that provided the better bioavailability and antioxidant activity as compared with the standard ascorbic acid, quercetin and melatonin.

1. Introduction

Novel drug delivery is considered as a best well-known technique for targeted drug delivery system by which drugs' bioavailability can be improved and also controlling the rate of drug delivery for the better therapeutic efficacy. Preparation and use of liposome is such an advanced methodology in drug delivery system which improves therapeutic efficacy. Liposome is spherical natural phospholipids vesicles consisting of one or several lipid bilayers which delineate an aqueous cavity (Lorin *et al*., 2004). The main structural components of liposome are lipids such as egg or soybean phosphatidyl choline, di-palmitoylphosphatidylcholine (DPPC), similar to those found in biological membranes (Mufamadi *et al*., 2011; Suntres, 2011). Cholesterol, a sterol, most commonly used in thereafter, in liposome formulations the empty spaces between the phospholipids molecules are filled with cholesterol which strengthens the liposomal membrane and provides structural stability (Sinsha *et al*., 2012). In the last decades, liposome's have received considerable attention due to their particular characteristics such as high biocompatibility, low toxicity, ability to encapsulate both hydrophilic and hydrophobic compounds (Malam, *et al*., 2009; Chen *et al*., 2010). As drug delivery systems, liposomes have been proposed for transporting different therapeutic agents for cancer treatment, vaccine immunization, gene therapy, radiopharmaceuticals and cosmetic formulations (Torchilin, 2005; Iranche *et al*., 2011).

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Melatonin (N-acetyl-5-methoxytryptamine, MT) is a synchronizer of biological rhythms that is found in animals and humans. Melatonin is a neurohormone, secreted primarily by the pineal gland in the hours of darkness. The organs like retina, lens, ovary, testis and bone marrow in a circadian rhythm also produce MT. Melatonin plays an important role as a regulator of sleep and can also mediate several cellular, neuroendocrine and physiological processes. Moreover, the free radical scavenging activity of MT established it as an endogenous antioxidant (Tan *et al*., 2000). For such relevant biological properties associated with extremely low toxicities, MT can be utilized for its therapeutic potential, especially in patients suffering from delayed sleep phase syndrome, sleep disturbances in blind people. It also facilitates adaptation to jet lag in travelers, cosmonauts and shift workers (Srinivasan *et al*., 2008; Roach and Sargent, 2019). Further, several clinical and preclinical studies are in progress in order to justify the therapeutic efficacy of this neurohormone especially in the fields of cancer treatment and topical protectant (Najafi *et al*., 2017). When just a modest proportion of the free drug reaches the cancer, systemic administration of the drug is the most typical clinical failure of chemotherapy in anticancer therapy as active pharmaceutical ingredients in chemotherapy are particularly cytotoxic to both malignant and non-cancerous cells. As a result, tumors treatment must concentrate on the tumor's blood vessels. Anticancer drugs incorporated in the liposomal system provide safe platforms for drug delivery system. Targeted administration of liposomal anticancer drugs may be advantageous in reducing the harmful effects of free anticancer drugs on normal tissues.

Quercetin (3,3',4',5,7-pentahydroxyflavone, a natural flavonoid, ubiquitously present in the plant kingdom, is considered to be one

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AN OVERVIEW ON LIPOSOMES AS A NOVEL DRUG DELIVERY SYSTEM

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ABSTRACT
The Liposomes are the sphere-shaped vesicles consisting of single or more bilayers of phospholipids. These can deliver both hydrophobic & hydrophilic drugs for the antibacterial, cancer, immunomodulation, antifungal, ophthalmic, diagnostics, enzymes, vaccines & genetic elements. The liposomes are characterized with respect to the physical, chemical & biological parameters. The multilamellar vesicle, the small unilamellar vesicle, and the large unilamellar vesicle are the major types of liposomes. Liposomes are biocompatible & biodegradable in nature. In this review article the mechanism, structural components, different methods of preparation, evaluation and applications of liposomes are explained.

Keywords: Liposomes, Structural components, Methods of preparation.

INTRODUCTION

The liposomes are concentric vesicles which are spherical in shape and it is derived from 2 Greek words lipos means fat & soma means body. In 1961 the Liposome were first made by Bangham et al, it was an accidental discovery in which he scattered in water the phosphatidyl choline molecule, during this he found that a molecule was forming the closed bilayer structure having an aqueous phase which were enrapped by the bilayer of lipid. The Liposome are very useful because they act as the carrier for the variety of drugs having the potential therapeutic action or other properties. The liposomes are the colloidal carriers having the size range of 0.01-5.0µm in diameter. The drug encapsulated by the liposome achieve the therapeutic level for longer duration as the drug must first be released from the liposome before the metabolism & excretion. These are small artificial vesicles which are spherical in shape which will be created from the cholesterol & natural phospholipids which are non-toxic, due to their size & hydrophilic & hydrophobic character [besides biocompatibility] the liposomes are the promising systems for the delivery of drug. To entrap drugs of both the aqueous & the lipid phase, is the unique ability of the liposomes & it makes them attractive drug delivery systems for the hydrophilic & hydrophobic drugs. The Liposomes are the novel drug delivery system that aims to deliver the drug directly to the site of action. To accommodate both hydrophilic and lipophilic compounds to protect the drug from degradation and release the active ingredients in a controlled manner, they have potential. It is found that glycerol is the backbone of the molecule that's why the phospholipid containing glycerol were found to be the essential component of the liposomal formulation & it represents 505 weights of lipid. [1-7]

THE STRUCTURAL COMPONENTS ARE

1] The Phospholipids:
The major structural components of liposome are the Phospholipids. The most common phospholipids used in liposomal preparation are the Phosphatidylcholine (PC). The Phosphatidyl-choline is the amphiphatic molecule which consist of:
a) The bridge of glycerol
b) The hydrophobic acyl hydrocarbon chains pair.
c) The polar head group which is hydrophilic, phosphocholine
The chemical structure of the naturally occurring Phosphatidylcholine has the glycerol moiety which is attached to 2 acyl chains which may be unsaturated or saturated. The stability of the liposome membrane depends on the packing of the hydrocarbon chains of a lipid molecules. The nature of the fatty acid in the lipid molecule, such as the number of double bonds in the chain is responsible for the bilayer properties such as the phase behavior & elasticity. The phospholipids are very abundant in nature & which contains the choline is used for the liposome's preparation. [8-10]
The examples of phospholipids are:
a) The Phosphatidyl ethanolamine[Cephalin]PE
b) The Phosphatidyl Glycerol [PG]
c) The Phosphatidyl serine [PS]

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Evaluation of potential *in vitro* anticancer and antimicrobial activities of synthesized 5-mercapto-4-substituted 1, 2, 4 triazole derivatives

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Abstract

A series of 1, 2, 4-triazole derivatives ($5a_1$-$5a_{10}$) were synthesized and evaluated for its *in vitro* anticancer activity. In the present investigation, nicotinic acid refluxed with ethanol to form an ester which further refluxed with hydrazide in alcohol to form an intermediate product carbohydrazide. Finally, this intermediate was condensed and different types of azole derivatives were formed. The synthesized compounds were confirmed through spectral characterization using IR, NMR and MASS. Thereafter, *in vitro* anticancer activity was performed for synthesized compounds against MCF-7 (Human breast cancer cell line) by MTT assay method using standard 5-Fluorouracil. The labeled compound $5a_1$ was found to be the most active than others. Thereafter, compounds $5a_2$ and $5a_4$ showed appreciable anticancer activity against MCF-7 breast cancer cell line. Furthermore, antimicrobial activity with respect to antibacterial and antifungal activities were performed and showed significant antimicrobial properties with $5a_1$ and $5a_2$ when compared with standard ciprofloxacin and fluconazole, respectively. Finally, result concluded that azole derivatives showed potential anticancer and antimicrobial activity synthesized from carbohydrazide.

1. Introduction

Worldwide, cancer has been a constant battle with a lot of development in cures and preventative therapies. The disease is continually multiplying in human body cells which are uncontrolled and amorphous mass (Ochwang *et al*., 2014). Its current treatments include chemotherapy, radiotherapy and chemically derived drugs. Not only that, many herbals are also used for the same with their potent antioxidant nature but the onsets of action are very slow (Malik *et al*., 2020; Thakur *et al*., 2020). Chemotherapy, for example, can put patients under a lot of stress and wreak havoc on their health. The chemistry of 1,2,4-triazoles and their fused heterocyclic derivatives has received considerable attention from past few years, owing to their synthetic and effective biological importance. A large number of 1,2,4-triazole-containing ring systems, for example, have been incorporated into a variety of therapeutically promising pharmacological candidates, such as anticonvulsant and anticancer agents (Jawad *et al*., 2016), antibacterial (Buhut *et al*., 2010), antifungal (Khalil, 2010), anti-inflammatory, antitubercular (Neslihan, 2009; Devi *et al*., 2018) and analgesic activity (Neslihan, 2010; Hamid *et al*., 2020) such as fluconazole, intraconazole, voriconazole. Also, there are known drugs containing the 1,2,4- triazole group, *e.g*., triazolam, alprazolam, etizolam, and furacylin. Furthermore, sulphur-containing heterocycles are an important class of sulphur compounds that have the potential to be used in real-world applications. Triazoles act by inhibiting ergosterol biosynthesis through inhibition of the 14 alpha-demethylase. The azole antifungal's basic N3 atom forms a bond with the heme iron of the $CYP4_{50}$ prosthetic group in the position normally occupied by activated oxygen, and the remaining azole antifungal molecules form bonding connections with the apoprotein, which influences the drug's relative selectivity for the fungal demethylase and other CYP450 enzymes (Ono *et al*., 2021). Furthermore, potential antibacterial and antifungal activities are also important to evaluate in current days for the significant protection of the foods, beverages and food supplements due to microbial spoilage. Hence, it is also necessary to evaluate the same with the novel derivates of 1, 2, 4-triazole.

Therefore, it was worthwhile to evaluate the synthesized 1,2,4-triazole derivatives ($5a_1$-$5a_{10}$) for its *in vitro* anticancer, antimicrobial and antifungal activities and revealed the better triazole derivative among the others.

2. Materials and Methods

Open capillary methods on a 'Veego' VMP-D apparatus was used for determination of melting point and are corrected. TLC was performed using silica gel G plates of size 3x8 cm (Sigma-Aldrich). The IR spectra (KBr) were determined on JASCO FTIR 4100. Mass spectra were recorded on Thermo Fisher Scientific mass spectrometry instruments and 1 H NMR spectra were recorded at CDCl3 solution. Tetramethylsilane (TMS) was used as an internal standard.

2.1 Reaction scheme

The reaction scheme for the synthesis of derivatives from 1,2,4-triazole was described below in Figure 1:

Step 1: Synthesis of ethyl pyridine-3-carboxylate (compound 1)

A mixture of nicotinic acid (36 gm, 0.3 mol), absolute ethanol (115 ml, 2 mol) and conc. sulphuric acid (50 ml) was refluxed on a steam bath for 3-4 h the solution was cooled to room temperature and poured slowly with stirring onto crushed ice. Sufficient ammonia solution was added to render the resulting solution strongly alkaline

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Evaluation of CNS stimulating activity of hydroalcoholic extract of *Brassica oleracea* L.var. *italica* in laboratory animals

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Abstract

Brassica oleracea L. var. *italica* Plenck (BOVLI) belongs to the family Brassicaceae, is a very famous vegetable with high content of antioxidant bioactive compounds and having versatile therapeutic applications. In the present study, the CNS stimulating activity of hydroalcoholic extract of BOVLI florets was investigated. Preliminary phytochemical screening of BOVLI was carried out. Thereafter, hydroalcoholic extract of BOVLI was evaluated for CNS stimulant activity, *i.e.*, by locomotor activity using actophotometer apparatus and spontaneous motor activity by using Y maze apparatus test was used as parameter for evaluation of CNS stimulating activity. The phytochemical screening through chemical test revealed the presence of alkaloids, saponins, glycosides, anthraquinones, sterods, terpenoids and flavonoids. Dopamine and serotonin level from rat brain were estimated to evaluate CNS stimulant activity and resulted significant ($p<0.001$) CNS stimulation activity when compared with negative control group. Finally, the result concluded that, due to presence of high content of flavonoids in BOVLI, the hydroalcoholic extract resulted as potent CNS stimulant.

1. Introduction

Depression is a chronic mental disorder that causes changes in mood, thoughts, behavior and physical health. It is a common but serious disease that can take away a person's ability to enjoy life and cause decline in capacity to undertake even the simplest daily tasks (Fekadu *et al*., 2017). As per WHO (2017) estimation, around clinical depression affects 121 million people globally. Suicide will be the second largest cause of death by 2020, owing to the high prevalence of suicide in depressed patients (up to 15%), as well as complications originating from stress and its impact on the cardiovascular system (Agarwal *et al*., 2015). Patients who are having major depression may have effect on level of dopamine, norepinephrine and serotonin (Jayanthi *et al*., 2012; Patil *et al*., 2021; Nargatti *et al*., 2021). Therefore, CNS stimulants are essential drugs whose primary action is to stimulate the CNS activity or to improve the specific physical and mental brain functions (Sonpetkar *et al*., 2012; Tripathi, 2013). CNS stimulants are useful for reducing drowsiness and fatigue and increasing mental alertness (Saha and Banerjee, 2013). From the past, few decades herbal medicines have been used not only for treatment but also for cure of diseases and its disorders (Bishwo *et al*., 2016). Ethnomedicinally, herbs are used in the treatment of pain relief, wound healing and abolishing fever that bring useful information to identify a wide range of compounds to develop new therapies for cancer, hypertension, diabetes and antiinfective medicines (Zaman *et al*., 2015). There are numerous synthetic antidepressant and CNS stimulant medicines available in the market today; however, their efficacy does not extend to the full population suffering from this illness. Further more, side effects and drug interactions are significant limitations in their clinical use. Therefore, herbal medicines are utilized all over the world to prevent the negative effects of synthetic pharmaceuticals because of its wide application and therapeutic efficacy with little side effects. Mahuang (*Ephedra vulgaris* Rich.) in China, Khat (*Catha edulis* Forsk) in Africa, and Coca (*Erythroxylum coca* Lam.) in South America are examples of the drugs which have been used as CNS stimulant from ancient times (Mestry *et al*., 2016).

Of late, *Brassica oleracea* L.var. *italica* Plenck (BOVLI) provides many health-promoting properties with its high antioxidant nature. Not only that, it also claims essential therapeutic benefits with its bioactive compounds. Phytochemical analysis of Broccoli has been showed presence of phenolic compounds, particularly flavonoids, vitamin C and E, amino acids, flavonols like quercetin and kaempferol, the carotenoids b-carotene, lutein, and the glucosinolates (Leja *et al*., 2001). Various parts of the plant have been scientifically proved for many activities, viz., antianemic activity (Vamsee *et al*., 2015), antibacterial activity (Sibi *et al*., 2013), anticancer activity (Talreja and Moon, 2014), antidementic activity (Ashwlayan, 2017), antidiabetic activity (Shah *et al*., 2016), antigenotoxic effects (Kumari *et al*., 2012), and antioxidant (Bhagat *et al*., 2012), but scanty information or no such scientific evidences were established on CNS stimulant activity on BOVLI florets hydroalcoholic extract. Therefore, it was worthwhile to investigate BOVLI florets or Broccoli heads for CNS stimulant activity in laboratory animals.

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DESIGN AND SYNTHESIS OF 1, 3, 4-THIADIAZOLES AS ANTI-INFLAMMATORY CANDIDATE

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ABSTRACT

The N-substituted chloroacetamides (**A**), 2-chloropropionamides (**B**) and 3-chloropropionamides (**C**) were synthesized by acetylating respective amine using chloroacetylchloride, 2-chloropropanoyl chloride and 3-chloropropanoyl chloride respectively. These compounds were characterized by TLC, melting point and IR spectra.

The N –substituted 2-{ [5 - (pyridine-4-yl) - 1, 3, 4 – thiadiazol – 2 -yl]sulfanyl } acetamide (**4a-c**), N-substituted-2-{[5-(pyridin-4-yl)-1,3,4-thiadiazol-2-yl]sulfanyl} propanamide (**5a-c**) and N-substituted-3-{[5-(pyridin-4-yl)-1,3,4-thiadiazol-2-yl]sulfanyl} propanamide (**6a-c**) derivatives were prepared by condensing sodium salt of 5-(4-pyridyl)-2-mercapto-1,3,4-thiadiazole (**3**) and N-substituted chloroacetamides (**A**), N-substituted α-chloropropionamides (**B**) and N-substituted β-chloropropionamides (**C**) respectively. Structure of all synthesized compound was confirmed by IR, and ^{1}H NMR. All synthesized compounds were screened for their anti-inflammatory activity by carrageenan induced rat paw edema model compared to the standard drug diclofenac. The synthesized compounds showed anti-inflammatory activity ranging from 26.97% to 59.99%; whereas standard drug Diclofenac sodium showed 63.70% inhibition after 4 hr.

Keywords: NSAID's, Anti-inflammatory, Acetamide, Propanamide, 1, 3, 4-Thiadiazoles

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Research paper

Effect of polymers and process parameters in augmenting the compactability and dissolution behaviour of oxcarbazepine spherical agglomerates

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Abstract

The hypothesis for the present work is proposed to explore the spherical crystallization technique for improving the micromeritics, compactability, and solubility characteristics of oxcarbazepine (OXZ), an anticonvulsant drug. Agglomerates containing different polymers (PEG 6000 and PVP K30) and process parameters were investigated for the enhancement of overall physicochemical performance and dissolution. Water, dichloromethane, and chloroform were used as a poor solvent, good solvent, and bridging liquid, respectively. Pure OXZ and spherical agglomerates were characterized for several properties including Fourier transformation-infrared spectroscopy, Differential scanning calorimetry, Scanning electronic microscopy, X-ray powder diffraction analysis, micromeritics, solubility studies, and *in-vitro* drug release kinetics. From the results, a considerable improvement in drug solubility and micromeritics of agglomerates than pure OXZ was observed. Compressibility parameters assessed from the Heckel plot showed agglomerates with a polymer having a higher value of slope (k) and less MyP is accountable for plastic deformation in agglomerates. Prepared spherical agglomerates showed an enhancement in solubility and rate of dissolution, which might improve their bioavailability.

Graphical abstract

ORIGINAL ARTICLE

Piperine-hydroxy acid-cyclodextrin inclusion complexes; antioxidant, anti-inflammatory, and stability studies: PART II

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Abstract

Introduction: Piperine (PIP) is a natural ingredient possessing important biological activities. However, its practical usefulness is limited due to its low water solubility. In our previous research article (PART A), we demonstrated inclusion complexation of PIP with cyclodextrins (CDs) in the influence of certain hydroxy acids resulted in tremendous improvement in physicochemical characteristics of PIP. The aim of current research work was to study biological properties and stability analysis of PIP and its lyophilized inclusion complexes. **Materials and Methods:** Initially, Job's plot experiment was carried out to assess the type of solubility and stoichiometry of complexes. The solid inclusion complexes were obtained by lyophilization and characterized by differential scanning calorimetry (DSC), X-ray powder diffractometry (XRPD), saturation solubility, *in-vitro* dissolution, *in-vitro* antioxidant activity, and *in-vivo* anti-inflammatory activity in carrageenan-induced rat paw edema model. The short-term stability studies were carried out as per the ICH guidelines. **Results:** During assessment, the complexes performed better in terms of *in-vitro* antioxidant and *in-vivo* anti-inflammatory activities than the native PIP. However, PIP: Hydroxypropyl β-CD (HPβCD): Ascorbic acid (AA) ternary complexes elicited immediate and maximum onset of anti-inflammatory action, as compared to other test samples. In the stability studies, no noteworthy changes were recorded concerning DSC, XRPD, and *in-vitro* dissolution studies over a period of 6 months except complexes with HPβCD. **Conclusion:** Taking everything into account, complexation of PIP with CDs, in the influence of AA, would be a successful way to improve its biological properties.

Key words: biological properties, complexation, cyclodextrin, hydroxy acids, piperine, stability studies

INTRODUCTION

Cyclodextrin (CD) complexation is the foremost interesting solubility enhancement method. CDs are oligosaccharides and are natural by-products of enzymatic starch degradation.[1-3] CDs have super molecular lattice structure with hydrophilic exterior and hydrophobic interior that reserve it to accommodate hydrophobic drug molecule in to its cavity.[4] Encapsulation with CDs promotes betterment in water solubility, dissolution rate, bioavailability, and stability of low aqueous soluble drugs without any change in their molecular structure and permeability properties.[5,6] Hydroxypropyl β-CD (HPβCD): the hydroxy derivative of βCD exhibits better water solubility with least toxicity, therefore, making it more preferable than fundamental one.[7] It has been published that efficiency of CD complexation could be improved by incorporation of certain ternary components such as low molecular weight hydroxy acids, hydrophilic polymers, and amino acids, to the complexation system.[8-10]

Piperine (PIP) [(2E,4E)-1-[5-(1,3-Benzodioxol-5-yl)-1-oxo-2,4-pentadienyl]piperidine [Figure 1] is a pungent alkaloid observed in black pepper possessing antioxidant, anti-inflammatory, antihypertensive, antithyroid, and antitumor activities. The inadequate solubility of PIP results in poor dissolution rate in gastrointestinal tract after oral administration.[11-13] A few researchers reported inclusion

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ORIGINAL ARTICLE

Piperine-Hydroxy acid-Cyclodextrin Inclusion Complexes; Physicochemical, Computational, and Proton Nuclear Magnetic Resonance Spectroscopy Studies: PART I

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Abstract

Introduction: In an attempt to improve the physicochemical properties of piperine (PIP), its inclusion complexes were prepared with β-cyclodextrin (βCD) and hydroxypropyl-β-cyclodextrin (HPβCD) in presence and/or absence of hydroxy acids by lyophilization technique. **Materials and Methods:** Primarily, the stoichiometry of the complex formation and thermodynamic parameters was accessed by phase solubility study described by Higuchi and Conners method. The molecular modeling studies were performed to elucidate the stability, possible interactions, and geometry of PIP inside the βCD cavity. The prepared lyophilized inclusion complexes were characterized by proton nuclear magnetic resonance spectroscopy (^{1}H NMR) and Two-dimensional Nuclear Overhauser Effect spectroscopy (2D ^{1}H NMR), Fourier transformation-infrared spectroscopic (FTIR), scanning electron microscopic (SEM), Log *P*, and dissolution studies. **Results:** The phase solubility data revealed the formation of 1:1 stoichiometry with A_L type of solubility curve at 25°C. Thermodynamic studies indicated that the inclusion process was spontaneous. The molecular modeling studies were depicted the insertion of piperidine ring inside βCD cavity. As complementary evidence, ^{1}H NMR and 2D ^{1}H NMR studies predicted that whether in presence or absence of hydroxy acids, CD is able to accommodate the piperidine ring. FTIR analysis revealed scattering peaks assigned for PIP were smoothened in all lyophilized inclusion complexes. SEM images indicated modifications in morphology of PIP particles in its lyophilized complexes. Dissolution studies revealed significant improvement in dissolution efficiencies of PIP in all prepared inclusion complexes. **Conclusion:** The effectiveness of ternary hydroxy acids was found to be appreciating toward improvement in aqueous solubility and dissolution properties of PIP.

Key words: Complexation, computational chemistry, cyclodextrin, hydroxy acids, piperine

INTRODUCTION

Piperine (PIP) [(2E,4E)-1-[5-(1,3-Benzodioxol-5-yl)-1-oxo-2,4-pentadienyl]piperidine, is a natural ingredient, possessing seasoning property which makes black pepper as a significant segment in serving of mixed greens dressing.[1] PIP acts as a bioenhancer by repressing the cytochrome P450 enzyme.[2] It likewise shows a few activities such as hypolipidemic, anticonvulsant, antimutagenic, protective effect against gastric ulcer-like activity, slight insecticidal,[3] and antibacterial property.[4] In spite of such properties, its application in food and pharmaceutical industries remains limited due to its low aqueous solubility and bioavailability.[2,5,6] Some researchers earlier reported that the inclusion complexation of PIP with β-cyclodextrins (βCD) improved its aqueous solubility and bioavailability. Few experiments such as oil in water emulsion system, formulation of nanospheres, self-emulsifying drug delivery system, and inclusion complexation

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Ameliorated solubility and dissolution of flurbiprofen using solubilizer Sepitrap 80 and Sepitrap 4000

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Abstract

The capability of novel solubilizer sepitrap 80 and sepitrap 4000 to enhance the solubility, dissolution was assessed in current investigation through the formation of simple physical mixture with a poorly aqueous soluble drug Flurbiprofen, phenylalkanoic acid derivative from non-steroidal anti-inflammatory drugs (NSAIDs).The physical mixtures were prepared in 1: 1, 1: 2 and 1: 3 proportions with sepitrap 80 and sepitrap 4000 and characterized for saturation solubility, dissolution, and stability studies. The physicochemical properties of physical mixtures with solubilizer were confirmed by DSC, PXRD, and SEM. Saturation solubility was carried in order to determine solubility of drug in distilled water. The physical mixtures exhibited solubility of 261% and 369.67%with sepitrap 80 and sepitrap 4000. The dissolution rate and solubility were undoubtedly improved by physical mixtures as compared to model drug alone. Physical mixtures incorporated with sepitrap 4000 at 1: 2 ratio proved better thansepitrap 80. Hence, the sepitrap could be exploited as a solubilizer to improve the solubility of Flurbiprofen.

Top

Keywords

Poor water soluble, Flurbiprofen, Solubilizer, Sepitrap80, Sepitrap 4000.

Top

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ORIGINAL ARTICLE

Evaluation of Nootropic Activity of *Limonia acidissima* Against Scopolamine-induced Amnesia in Rats

Limonia acidissima'nın Sıçanlarda Skopolamin ile İndüklenen Amneziye Karşı Nootropik Aktivitesinin Değerlendirilmesi

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ABSTRACT

Objectives: The present study aimed to evaluate the nootropic activity of *Limonia acidissima* in rats.

Materials and Methods: Methanolic extract of *Limonia acidissima* was used to evaluate nootropic activity, piracetam (200 mg/kg, i.p.) was used as a standard, and scopolamine (1 mg/kg, i.p.) was used to induce amnesia. The effect of drugs on learning and memory in rats was evaluated by using the Y-maze task and elevated plus maze on scopolamine-induced amnesia models. Locomotor activity was performed using an actophotometer. Also, levels of acetylcholinestrease, including histopathological examination of rat brains, were assessed.

Results: Methanolic extract of *Limonia acidissima* showed increased alteration of the behavior response and percentage spontaneous alteration with the Y-maze task. In the elevated plus maze scopolamine-induced amnesia model, methanolic extract of *Limonia acidissima* showed a decrease in transfer latency, which is indicative of cognition improvement. Methanolic extract increased locomotor activity in rats and decreased the levels of acetylcholinestrease enzyme significantly. A histopathological study with both low and high doses of extract showed effective regenerative scores as compared to normal control, negative control and standard treatment.

Conclusion: The results suggested that the administration of methanolic extract of *Limonia acidissima* enhances learning and memory in different experimental models. The histopathological study revealed the neuroprotective property of the extract. The study indicates that the extract may be used in the treatment of Alzheimer's disease.

Key words: Nootropic activity, *Limonia acidissima*, Alzheimer's disease, piracetam, scopolamine

ÖZ

Amaç: Bu çalışmada, sıçanlarda *Limonia acidissima*'nın nootropik aktivitesinin değerlendirilmesi amaçlanmıştır.

Gereç ve Yöntemler: Nootropik aktiviteyi değerlendirmek için *Limonia acidissima*'nın metanol ekstresi, standart olarak pirasetam (200 mg/kg, i.p.) ve amneziyi indüklemek için skopolamin (1 mg/kg, i.p.) kullanıldı. İlaçların sıçanlarda öğrenme ve hafıza üzerindeki etkisi, skopolamin ile indüklenen amnezi modelinde Y-labirent testi ve yükseltilmiş artı labirent testi kullanılarak değerlendirildi. Lokomotor aktivite, bir aktofotometre kullanılarak gerçekleştirildi. Ayrıca, sıçan beyinlerinin asetilkolinestreaz aktivitesinin değerlendirilmesi de dahil olmak üzere histopatolojik incelemesi yapıldı.

Bulgular: Y-labirent testi ile *Limonia acidissima*'nın metanol ekstresinin davranış tepkisinde ve yüzde spontan değişikliklerde artışa neden olduğu gösterildi. Skopolamin ile indüklenen amnezi modelinin kullanıldığı yükseltilmiş artı labirent testinde, *Limonia acidissima*'nın metanol ekstresinin, biliş gelişiminin göstergesi olan transfer gecikmesinde bir azalmaya yol açtığı gösterildi. Metanol ekstresi, sıçanlarda lokomotor aktiviteyi artırdı ve asetilkolinestreaz enzim aktivitesini önemli ölçüde düşürdü. Hem düşük hem de yüksek dozda ekstreyle yapılan histopatolojik çalışmada, normal kontrol, negatif kontrol ve standart tedaviye kıyasla efektif rejeneratif skorlar elde edildi.

Sonuç: Sonuçlar, *Limonia acidissima*'nın metanol ekstresinin uygulanmasının farklı deneysel modellerde öğrenmeyi ve hafızayı geliştirdiğini göstermiştir. Histopatolojik çalışma, ekstrenin nöroprotektif özellikte olduğunu ve ekstrenin Alzheimer hastalığının tedavisinde kullanılabileceğini göstermiştir.

Anahtar kelimeler: Nootropik aktivite, *Limonia acidissima*, Alzheimer hastalığı, pirasetam, skopolamin

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FORCED DEGRADATION STUDY – A NEW APPROACH FOR STRESS TESTING OF DRUG SUBSTANCES AND DRUG PRODUCTS

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FORCED DEGRADATION STUDY - A NEW APPROACH FOR STRESS TESTING OF DRUG SUBSTANCES AND DRUG PRODUCTS

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ABSTRACT: Forced degradation studies are a vital tool in pharmaceutical research and development to predict long term stability. Stress studies should be performed in method development to know drug behavior but can also be performed with method validation for regulatory filing predict stability and measure impurities. It is especially valuable when little data is free about potential degradation products. Forced degradation studies may help encourage drug advancement in regions like formulation development, manufacturing, and packaging, in which information on substance conduct can be utilized to improve a medication item. Hence it is important to realize the purity profile and conduct of a medication substance under various natural conditions. For stable formulation development, comprehension of synthetic conduct forced degradation pathways and degradants of drug substance and drug product is very important. Therefore, by using different regulatory guidelines in the present review paper, we described the broad overview of forced degradation studies by determining the system to perform stress studies & its methods for isolation and identification of degradation.

Keywords:
Forced degradation, Stability, Impurity, Degradant, Purity profile, Drug

INTRODUCTION Forced degradation may be a degeneracy of the latest drug substance and drug product at conditions more severe than surrounding conditions. Forced degradation studies show the chemical performance of the molecule which successively helps with the development of formulation and package. An analysis of dosage forms under stability study is crucial. Forced degradation studies appearance the chemical performance of the molecule, which in turn use within the development of formation and collection.

Additionally, the regulative guidance was very broad and doesn't explain the work of forced degradation studies.[1] Force Degradation study to found the force degradation profile and to develop whether the analytical method for evaluation in stability demonstrate, the Taxes composition of ATN and CTN applied to separate stress conditions to handling forced degradation studies. Stress studies were drifting out under the condition of acid/alkali hydrolysis, oxidation, neutral and thermal degradation in conformation with ICH Q1A (R2) guideline. The collection of stress conditions essentially depends on the literature review and drug profile[2].

The most important considerations in the drug discovery are safety related, not only of the drug but also impurities and degraded products present in them. Impurities present in the drug may lead to cytotoxicity, carcinogenic or teratogenic effects. For diseases like hypertension or diabetes, which are related to changes in body physiology, the patient, for the rest of his life, is going to be on medication. Though the amount of impurities is very min still prolong exposure to them may be hazardous. Hence identification and the check on the presence of a specific amount is a must. Drug produce degradation profiles essential to establish to monitor the stable formulation and provide appropriate drug shelf life valuation. Structural description of impurities and degradation products in bulk API has become an integral part of pharmaceutical product development.[3]

The analysis of these low-level unidentified impurities and degradant is very challenging. Various regulatory bodies like ICH, USFDA, Canadian Drug and Health Agencies have started erecting on characterization and development of complete impurity profile of Active Pharmaceutical Ingredient's (API's) as well as pharmaceutical formulations. Structural elucidation of impurity and degradants is a collaborative effort involving spectral analysis as well as analytical method development identification of the degradation in samples may give a clue about the mechanism of degradation.

In the present state, development within the traditional instrumental methods that aid in fast description of impurities and related substances /degradation products spectral analysis and isolation, using new analytical techniques, like UPLC, LC-MS, LC-NMR, GC-MS, SFC-MS, CE-MS etc. has become easy. The conventional method included the separation and identification of impurities or related substances by an appropriate method. Eventually, they are isolated and characterized using various spectroscopic techniques.

Impurity is something whose presence is unwanted and makes the pure compound impure. An impure substance may be defined as a substance mixed with a substance of interest. The desired compound may be impregnated with extraneous or usually inferior substance[4]. The number of positions has been normally used to define organic impurities. The number of positions has been normally used to define organic impurities that are intermediates, starting material, penultimate

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FORMULATION AND EVALUATION OF IMMUNE-SUPPLEMENTARY NUTRITIONAL GRANULES

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Keywords:

Amla, Ashwagandha, Shatavari, Nutraceutical, Dietary Supplements

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ABSTRACT

In the day today's life people are not caring for proper nutrition and hence relying on the dietary supplements, and are considered as better choice for healthy lifestyle. Seven herbs namely. Amla, Ashwagandha, Shatavari, Ginger, Flax seeds, Moringa, Turmeric Churna were selected for preparation of immune-supplementary nutritional granules.The selected herbs were found to be of best quality in their preliminary observation. This proves that the formulation can be used as herbal medicines, and the significant nutritive values prove that they can be used as dietary supplements. The combination of herbs will definitely give synergistic action considering their nutrition value and medicinal value.

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Bimetallic Ni–Pd Synergism—Mixed Metal Catalysis of the Mizoroki-Heck Reaction and the Suzuki–Miyaura Coupling of Aryl Bromides

Abhijit A. Kashid, Dharmaraj J. Patil, Ramling D. Mali, Vijay P. Patil, T. V. Neethu, Heena K. Meroliya, Shobha A. Waghmode & Suresh Iyer

Catalysis Letters **151**, 353–358 (2021)

Abstract

A combination of Pd and Ni complexes activated aryl bromides for the thermal Mizoroki-Heck reaction and Suzuki coupling giving high yields in short reaction times. A thermal redox mechanism probably occurs whereby Ni complex transfers electron and reduces the Pd (II) to Pd (0) which then takes the reactants through the standard protocol of oxidative-addition, migratory insertion and reductive elimination, typical for the Mizoroki-Heck reaction and the Suzuki coupling.

Graphic Abstract

Sant Dnyaneshwar Sikshan Sanstha's
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ISOLATION AND CHARACTERIZATION OF *SALACIA CHINENSIS* AND ITS EVALUATION OF ANTIOXIDANT ACTIVITY

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Keywords:

Salacia chinensis, Isolation, 25, 26-oxido friedelane 1, 3-dione, Chromatography spectroscopy, Antioxidant activity

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ABSTRACT: *Salacia chinensisis*, commonly known as Saptarangi in the Hindi family of Hippocrateaceae, it is a woody climbing shrub found in Africa, Vietnam, and Thailand. A large number of biologically active compounds like salacinol, kotalanol, neokotalanol, neosalacinol, salasol, and mangiferin are isolated from *S. chinensis*. Traditionally, the plant is used in the treatment of diabetes, but there are few studies that demonstrate its use as anti-inflammatory, nephroprotective, anticancer, and treatment of cardiac disorders. The present study involves extraction, isolation, structural elucidation, and prediction of antioxidant activity from the roots of *S. chinensis*. The roots were extracted with water and methanol by using a hot extraction method. The methanol extract was fractionated with ethyl acetate. The antioxidant activity of different extracts was determined by 1, 1-diphenyl-2- picryl- hydrazyl (DPPH) method. The highest antioxidant activity was found in ethyl acetate extract, followed by methanol extract and water extract. Ethyl acetate extract showed maximum antioxidant activity, so the extract was used for the isolation of antioxidant compounds by column chromatography. The compound was isolated from the *Salacia chinensis* with higher yield and new technique. The compound isolated was characterized as 25, 26-oxido friedelane 1, 3-dione, and was elucidated using 1H NMR, 13C NMR, and MS. The study shows that the obtained pure compound could be a good source of natural antioxidants.

INTRODUCTION: Large numbers of bioactive compounds are produced by plants that are used as an herbal medicine for the treatment of diseases since ancient times. Various phytochemicals, namely polyphenols, flavonoids, terpenes, phenolic acids, tannins, and coumarins, are present in plant and high concentrations of these phytochemicals may protect against free radical damage [1, 2].

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The plants consist of beneficial phytochemicals, which is a need of the human body, and these phytochemicals act as natural antioxidants and source of supplementation for human diseases [3, 4]. Antioxidants are considered a crucial chemical component, which may be responsible for preventing and delaying various types of cell damage.

The presence of antioxidants enhances the action of the immune system by producing a free radicle that is considered as one of the essential roles [5]. It was observed that flavonoids and phenols are considered as strong antioxidants, and these are found to be distributed amongst various parts of plants.

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RESEARCH ARTICLE

Sporopollenin: The Ground Discussion

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ABSTRACT:
Sporopollenin is an ubiquitous and extremely chemically inert biopolymer .The surface of sporopollenin is richly sculptured, ornamented and porous and is species specific. It is stable in organic and aqueous solvents. It is insoluble in common acids and in most organic solvents. Sporopollenins have very similar chemical structures and to be identical in structure to the synthetic carotenoid polymes. The sporopollenins derived from angiosperms, gymnosperms and ferns and lower plant spores have similar chemical structures and also they are similar to synthetic polymers. Sporopollenins are strongly osmophilic. Sporopollenins react with basic dyes suggesting the presence of weakly annionic groups such as acidic-enolic compounds. Sporopollenin can be isolated from spores or pollen grain by treating with solvents or enzymes that remove intine and cytoplasm. Purified sporopollenin retains the similar shape, size, and surface features as in its spore or pollen grain and remains an empty shell i.e sporopollenin microcapsules. The different methods developed to isolate sporopollenin from L. clavatum proved its exceptional stability and chemical inertness. Wiermann et al has proved that, the sporopollein survived a wide range of enzymes. This may explain why it does not easily submit to bacterial decomposition or digestion. Its principle function is to protect against oxidation and desiccation. The study led by Maak proved that sporopollenin by *Chlorella vulgaris* was harmless and could be rubbed on skin with no irritation, swallowed without any danger or even injected in blood stream. The sporopollenin particles were found to cause an antigenic reation and bind to antibodies. The sporopollenin remains unchanged when heated up to 300^{0}C or treated with concentrated acids and bases. Sporopollenin appears to undergo carbonization and coalification with haet. The sporopollenin decomposes by chemolyses and ozonolysis. An unknown enzymatic sequence linked to the clotting cascade has also been discovered that degrades sporopollenin in the blood, both in vitro and *in vivo*.

KEYWORDS: Sporopollenin, Inert, Osmophilic, Antioxidant, Ozonolysis.

INTRODUCTION:

Sporopollenin is a ubiquitous and extremely chemically inert biopolymer that constitutes the outer wall of all land-plant spores and pollen grains. Sporopollenin protects the vulnerable plant gametes against a wide range of environmental assaults, and is considered as a prerequisite for the migration of early plants onto land.[1] It was first observed and named as "sporonin" by Jolm (1814) and latter characterized by Berzelius (1830). Fossil green algae dating back to Devonian period have been shown to contain sporopollenin.

The oldest sporopolleninous acritarchs occur in Pre-Cambrian rocks, 1.2-1.4 billion years old. The green algae are presumably responsible for the development of sporopollenin and its introduction into the armament of higher green plants, where its principal function is protection against oxidation and desiccation. Further Brooks and Shaw from their study have shown the presence of amorphous insoluble organic material which appears similar to present day sporopollenin. It forms the basic structure of the resistant wall of most palynomorphs, like spores, pollen, dinoflagellates, and acritarchs. It has also been recorded from the spores of Aspergillus niger, sexual (±) spores of Mucor mucedo, asexual spores of Pithophora oedogonia and several algae like, in the cell wall of Phycopeltis epiphyton (a subaerial green alga found growing on the leaves of vascular plants and bryophytes), Char a corallina, cyst of Prasinocladus marinus. A trilaminar sporopollenin

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A CASE STUDY ON- ISSUES IN PHARMACEUTICAL MARKETING

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ABSTRACT

The study is based on a survey method using standard inspection form (SIF) filled by various stakeholders from the pharmaceutical marketing field. This primarily descriptive case study focuses on finding out tools used as promotional devices and their significance in marketing. This study also describes the various issues that the pharmaceutical industry is facing during launching its product and increasing the sale of the product. The Market for medicines all over the world is projected to grow 9-12% over the next 5 years, in which India would become one of the top 10 countries in terms of medical spending. By 2020 the current role of the pharmaceutical industry's sales and marketing workforce will be replaced by a new model as the industry shifts from a mass-market to a target-market approach to increase revenue. We have conducted a survey based on pharmaceutical stakeholders where we have found some factors that would be believed to influence the development of a successful pharmaceutical product that are unmet need, Clinical efficacy, Comparators, safety, and price. The aim of this research, therefore, was to explore the understanding of market access among various stakeholders and how their understanding of this concept improves patient access to pharmaceutical products.

Keywords: - Marketing, Strategies, Challenges, Issues, etc.

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Original Article

FORMULATION AND EVALUATION OF GROUNDNUT OIL-CAKE BASED PROTEIN POWDER AS POTENTIAL ALTERNATIVE FOR DIETARY SUPPLEMENT

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ABSTRACT

The present research work is focuses on formulation and its evaluation of groundnut oilcake based protein food supplements which will be better alternative to commercially available high cost protein supplements in market. Groundnut de-oiled cake is produced in a wooden churned oil extraction machine where oil is produced at 35°C without giving any chemical treatment to oilseeds. The groundnut cake contains on an average 52.5% protein, 26% carbohydrate as well as 5.65% crude fibre with 5% minerals. Milled oil cake was chemically analysed for protein analysis which showed 49.63 % protein concentration while final formulation showed 92.81% protein concentration as fixed proportion of synthetic protein was added during final formulation. The casein and sweetener used in it have a couple of medicinal uses, which again enhances the nutritional properties of this powder. The prepared powder was evaluated for various organoleptic properties as well flow properties with various parameters which showed acceptable results Indicates prepared protein powder suitable for use. The simple formulation process makes it cost-effective and also nullifies the by-product management problems associated with oil extraction companies and its natural nature nullifies many of the side effects of marketed of protein powder.

KEY WORDS: Oil-Cake, Protein Powder, Dietary Supplement & Physico-Chemical Evaluation

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RESEARCH ARTICLE

Polymeric Nanosuspension Loaded Oral Thin Films of Flurbiprofen: Design, Development and *In Vitro* Evaluation

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ABSTRACT:
In the present investigation, effort has been made to stabilize optimized nanosuspension of flurbiprofen through oral thin film formulation. To overcome the issue of stability of nanosuspension and poor bioavailability of flurbiprofen, nanosuspension loaded oral thin films were developed by solvent casting method. Oral thin films can be prepared by simple and scalable method easily. Nanosuspension loaded oral thin films were evaluated for thickness, % moisture absorption and loss, surface pH, weight variation, folding endurance, drug content, disintegration time, *in vitro* drug release and stability. The resultant oral thin films depicted that the particles size range was retained even after their stability study for three months. The dissolution rate of all flurbiprofen oral thin films were significantly increased compared with its marketed oral formulation. Thus it can be concluded that, oral thin films have potential for stabilization of nanosuspension with improved drug release.

KEYWORDS: Oral thin film, Flurbiprofen, Solvent casting method, Nanosuspension, Stabilization.

INTRODUCTION:

Oral route is the most suitable, economical, and common route for drug delivery due high patient compliance and flexibility in the development of dosage form[1-2]. Many drugs exhibit poor aqueous solubility, and oral bioavailability[1-2]. Nanosuspension has potential to enhance aqueous solubility, and dissolution rate but with the challenge of stability[3-4]. Oral thin film (OTF) is a novel dosage form similar to postage stamp in size, shape, and thickness[3,5].These undergo quick disintegration when placed in the mouth without water ingestion or mastication; thus OTF are safe from instability due to pH variations, and enzymes in GI tract[3-6]. Oral thin films have potential for stabilization of nanosuspension with improved drug release. High viscosity of the film prevents aggregation of nanoparticles and drying enhances stability[7].

Such modified formulation, without changing the chemical structure of drug; are significant to produce quick onset of action during emergency circumstances[7-8]. Flurbiprofen (FBF) is a BCS class II drug belongs to non-steroidal anti-inflammatory drugs (NSAID)[9-10]. It shows low aqueous solubility, and high log P value which is suitable in the development of nanosuspension[9-10]. The present study was aimed to develop stable polymeric nanosuspension loaded oral thin films of flurbiprofen.

MATERIALS AND METHODS:

Materials:

Flurbiprofen (FBF), poloxamer 188 (Pluronic F68), and hydroxypropyl methylcellulose E15 (HPMC E15) were gently given by Sun Pharma Pvt. Ltd. Ahmednagar. Glycerol was procured from Sigma Aldrich. All other chemicals with analytical grade, and double distilled water were used during the research work.

Methods:

Preparation and optimization of flurbiprofen nanosuspension:

FBF loaded nanosuspensions were prepared by nanoprecipitation technique. Accurately weighed FBF and HPMC E15 were dissolved in methanol (co-solvent) by sonication. Above organic phase of drug was added in

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RESEARCH ARTICLE

Gas Chromatography-Mass Spectrometry Analysis of Chloroform Extract of *Coccinia grandis* Voigt

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ABSTRACT:
Background: Gas chromatography-Mass spectroscopy is comprehensive techniques for identification of bioactive components present in medicinal plants. **Objective:** Objective of present study was analysis of chloroform extract of stem part of *Coccinia grandis* Voigt plant belonging to Cucurbitaceae by Gas chromatography- Mass spectroscopy (GC-MS). **Material and Methods:** After Successive extraction with petroleum ether, chloroform and ethyl acetate for selected plant, further Chloroform stem extract was analyzed for different bioactive compounds by GC-MS method. **Result and Discussion:** The GC –MS data of chloroform extract of stem part of *Coccinia grandis* Voigt plant showed 24 bioactive phytoconstituents such as Spiro [4.5] dec-6-en-8-one, Hexadecanoic acid methyl ester, Cyclononasiloxane octadecamethyl, 9-Heptadecanone, 2, 4-Di-tertbutylphenol, 1, 7-dimethyl-4-(1-methylethyl), 7, 9-Di-tert-butyl-1-oxaspiro (4, 5) deca-6, 9-diene-2, 8 dione. Hexadecanoic acid and 2, 4-Di-tert-butylphenol are an antioxidant agents and Spiro [4.5] dec-6-en-8-one 1, 7-dimethyl-4-(1-methylethyl), 9 heptadecanone, Hexadecanoic acid methyl ester shown antimicrobial property. **Conclusion:** Present study concluded that development of potential bioactive compounds identified from GC MS analysis could serve better approach for treatment of various diseases such as microbial infection, fungal infection, inflammation, diabetes mellitus.

KEYWORDS: Chloroform extract, Bioactive compounds, Successive extraction, Gas chromatography-Mass spectroscopy, and *Coccinia grandis* Voigt.

INTRODUCTION:

Medicinal plants have become beneficial source for the treatment of different ailments. It can be observed from ancient literature about the utilization of natural medicinal plants or herbal products. The plants are rich wellspring of saponins, flavonoids, alkaloids, glycosides, sterol, and tannins. These phytoconstituents contribute different therapeutic properties. The phenolic compounds and flavonoids possesses antioxidant activity, anticancer activity etc.[1] Frequent utilization of synthetic drugs are not moderate and delivers adverse reactions, subsequently herbal remedies may supportive as economical and therapeutic.

Coccinia grandis Voigt is a perennial creeper or climber plant from Cucurbitaceae family. It is usually known as Ivy gourd or scarlet gourd or kowai fruit or kundru. This plant grows up to 13cm covering small trees, shafts, and buildings. It comprises of 5 lobed glabrous, broad leaves which is 5 to 10cm in length. The upper surfaces of leaves are hairless while lower surface is hairy with heart or pentagon shape. It consists of single tendrils. Juvenile fruit of *Coccinia grandis* Voigt contains white streaks and complete ripe fruit is of bright scarlet. Seeds are rounded at apex, yellowish grey in color, ovoid and compressed. Flowers are 2-3cm long, female and male flowers rise at axils on petiole and contain 3 stamens. *Coccinia grandis* Voigt plant has long, thick, tuberous root with fibrous fracture[2]. The stem of these plants are smooth, green shading and slender when immature however as it develops it gets broad, swollen and glabrous in nature. *Coccinia grandis* Voigt has been used to treat diabetes mellitus[3], bronchitis, urinary tract

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Original Article

Development and Optimization of Capecitabine loaded Nanoliposomal System for Cancer Delivery

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ABSTRACT

Objectives: The Main objective of this study was to develop and optimize Capecitabine loaded nanoliposomes for prolonged drug delivery in cancer treatment. **Methods:** Liposomes were prepared by the thin film hydration method followed by sonication. The parameters affecting the vesicle size and percentage drug entrapment of liposome are amount of soyaphosphatidyl choline and cholesterol used in their preparation. The Capecitabine liposomal formulation was optimized using 3^2 factorial design in this amount of soya Phosphatidylcholine and cholesterol were selected as two independent variables to obtain stable liposome with small vesicle size and maximum entrapment efficiency. **Results:** Compatibility studies were carried out by using FT-IR and DSC, the results showed that there was no significant interaction between drug and excipients. The formulated liposomal prepartions were evaluated for various parameters and results were obtained for optimized batch (B3) Showed vesicle size 178.9nm, zeta potential -77.9mV to -82.7mV, entrapment efficiency 79.65% and percentage drug release 92.07% up to 12 h. **Conclusion:** Liposomal drug delivery is targeted as to provide more drug concentration at the site of action and with a sustainable drug release followed Higuchi-matrix model. Ultimately, reducing the dosing frequency with minimizing the side effects related to high drug intake. Liposome has been provided a spectrum of options and opportunities for designing and practicing site specific, targeted drug therapy.

Key words: Capecitabine, Liposome, 3^2 Factorial design, Percent drug entrapment, Release kinetics.

INTRODUCTION

Nowadays cancer is the main cause of death in human beings after cardiovascular disease. The most common forms of cancer are breast, prostate, colon and lung cancers. Presently chemotherapy, hormonal, gene, surgery and radiation therapies are used to treat cancer. But chemotherapeutic agents are commonly preferred to treat cancer. However, due to high doses of these drugs cause toxic effects. Most common side effects like gastrointestinal problems and systemic side effects will appear in anticancer therapy.[1] Successfully translating anticancer nano medicines to demonstration of therapeutic value in the clinic is challenging. Despite liposomes have been proven to be an ideal drug carrier that has a strong impact on the pharmacokinetics and tissue distribution of incorporated drugs, resulting in enhanced efficacy as well as greatly reduced systematic toxicity of drugs. Liposome have gained attention as a carrier system for a therapeutically active agent, owing to their unique characteristics, biocompatible, biodegradable, low toxicity, lack of opsonization and improves the pharmacokinetics and pharmacodynamics profile of therapeutic agent.[2] Structurally, liposomes are concentric bilayer vesicles of natural or synthetic phospholipid.[3,4] Due to their hydrophobic, hydrophilic and small size; liposomes are promising systems for drug

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Future Science

keratitis

Monali Patil, Swati Waydande & Pravin Pawar

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Abstract

Aim: The objective of present investigation was to increases solubility of voriconazole by using solid dispersion techniques and the development of solid dispersion-based voriconazole ophthalmic solutions. **Materials & methods:** The saturation solubility of solid dispersion containing polyvinylpyrrolidone K90 (PVPK-90) was found to increase the solubility of voriconazole compare other carrier like polyethylene glycol and Polyvinylpyrrolidone K 30 (PVPK-30). Solid dispersion of voriconazole was characterized by saturation solubility, Fourier-transform infrared spectroscopy and Differential scanning calorimetry study. **Results & conclusion:** The Fourier-transform infrared spectroscopy and Differential scanning calorimetry studies of voriconazole-based solid dispersion confirmed the complete changes in original polymorphic form of voriconazole. The antifungal assay showed that the maximum zone of inhibition was produced from optimized ophthalmic formulation containing sodium alginate as compared with other formulations and marketed eye drops.

Keywords: ocular keratitis •PVPK-90 •solid dispersion •transcorneal permeation •voriconazole

Drug Delivery Letters

Editor-in-Chief

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Recent Trends in Antifungal Agents: A Reference to Formulation, Characterization and Applications

Author(s): Kajal Pawar, Rutuja Gadhave, Swati Waydande and Pravin Pawar*

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Abstract

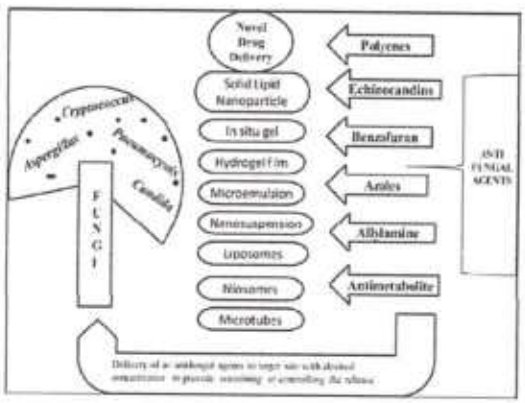
Background & Objectives: Fungi are the heterotrophic eukaryotic organisms which are useful as they causes the biodegradation. There are still some harmful species like yeasts, molds and dermatophytes which cause the infections. As the fungi are eukaryotics, they do not respond to the antibiotic therapy due to the limitations associated with the traditional antibiotic therapies. There are several antifungal agents introduced to treat such infections. These antifungal agents posses severe problems like drug resistance and toxicity due to the higher dose which comprises the need for newer alternatives over conventional dosage forms. Novel drug delivery systems proved to be a better approach to enhance the effectiveness of the antifungals and enhance patient compliance by reducing the adverse effect.

Discussion: This review focused on the general information about fungal infections, types and mechanism of action of antifungal agents and overview of formulation approaches such as vesicular system, colloidal system, nanoparticulate system and in situ gelling which are often studied for antifungal treatments.

Conclusion: We concluded that the novel drug delivery systems are the essential techniques for delivering the antifungal agents to their target site with desired concentration. Moreover, the researchers focused on these novel drug deliveries which mainly concentrate on controlling & sustaining the release of antifungal agents.

Keywords: Antifungal agents, fungi, NDDS, fungal infections, nanoparticulate system, in situ gels.

Graphical Abstract



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RESEARCH PAPER TITLE - FORMULATION AND EVALUATION OF SPHERICAL AGGLOMERATES OF CANDESARTAN CILEXETIL BY SOLVENT CHANGE METHOD

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Abstract

Candesartan cilexetil, exhibits poor water solubility, poor flowability and poor dissolution. Study was directed to improve the dissolution of Candesartan cilexetil. Spherical agglomerates containing Candesartan cilexetil was prepared by solvent change method. By using ternary phase diagram ratio of solvent addition was maintained. Drug was dissolved in methanol (good solvent), water (poor solvent), dichloromethane (bridging liquid) was used in the preparation. The produced drug particles were characterized by scanning electron microscopy (SEM), differential scanning calorimeter (DSC), x-ray diffraction (XRD) and Fourier transform infrared spectroscopy (FT-IR). In vitro dissolution study of prepared particle was carried out. It was found that dissolution profiles of batch B2 were increased. Further micromeritic properties were also increased. It was realized that appropriate amount of polymer addition along with highest speed will give better drug release.

Key words- Spherical agglomerates, DSC, SEM, XRD, FT-IR, in vitro dissolution, etc.

Introduction

In most of the formulations available in market drugs are directly used in the formulation as it is. However there are some other drugs that require modification in their physical, chemical and morphological characters. After changing such modification these drugs will become suitable to be used in the formulation.[1] Many of the drug in the market are come under BCS class 2 having poor solubility in water and less dissolution profile. Due to this problem effective concentration of drug is not achieved. To overcome these problems many solubility enhancement methods are used to increase the dissolution profile of drug.[3,4] Spherical agglomeration is one of the novel technique used to increase the solubility and dissolution rate of poorly soluble drugs. Spherical agglomeration process further helps to improve the flowability and compressibility of drug.[1,2]

Spherical agglomeration is multiple unit process in which crystallization, agglomeration and spheronization can be carried out simultaneously.[8] Formulated crystals can be called as spherical agglomerates. Spherical crystallization technique has been successfully utilized for improving of flowability and compressibility of drug. These technique may enable crystalline forms of a drug to be converted into different polymeric form having better bioavailability.[9]

Spherical agglomeration is a novel particle design method developed by kawashima et.al. It is also come under particle engineering technique in which crystallization and agglomeration carried out simultaneously.[11] Many of the drugs administered by oral route because oral route administration is most convenient route for solid dosage forms. The basic requirement for commercial production of tablet is that material to be tabulated should have a good flowability, mechanical strength and compressibility. Hence is necessary to evaluate and manipulate the above said properties. To impart these properties the drugs are subjected to particle design techniques such as spherical crystallization. Formulated agglomerates will improve the flowability and compressibility of drug which enables the direct tabletting of drug. It also minimizes the process in tabletting like mixing, granulation, drying and sieving etc. There are main four principle steps involved in the process of spherical crystallization like - 1) flocculation zone, 2) zero growth

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INDO AMERICAN JOURNAL OF PHARMACEUTICAL RESEARCH

A REVIEW: REGULATORY REQUIREMENTS OF DRUG MASTER FILE IN CONTEXT TO GHANA

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ABSTRACT

Drug Master Files are required in most African countries as supporting documents for the registration of drug products. Africa is world's second fastest growing pharmaceutical market. The CGAR of African Pharmaceutical market is 11.6%. African people suffer from numerous diseases. The local pharmaceutical market is weak and insufficient to meet the demand of such diseased condition and so Africa relies heavily on externally developed and procured drugs. This combination of economic strength and prevalence of diseases is already driving a demand for medicines across Africa. DMFs generally contain information pertaining to the chemistry, manufacturing and controls (CMC) sections of the drug submission and reflect the drug's identity, strength, purity and quality. Ghana and Australia which are consider as highly regulated markets (HRMs). In GHANA, DMF filing was done through New Drug Submission (NDS) for both drugs and biologic products. They use MF terminology for DMF which contain four types of MASTER FILE- ASMFs, CCS MFs, Excipient MFs, Drug product MFs. In AUSTRALIA different application processes and regulatory requirements apply depending on the type of therapeutic goods that is applied. They consist of eight phase for DMF registration. Where EU guidelines adopted in Australia include references to EU legislation. Now from 2018 onwards most of the regulated countries will use eCTD or their electronic format for their DMF submission.

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Research Article

FORMULATION, OPTIMIZATION, AND *IN VITRO* EVALUATION OF POLYMERIC NANOSUSPENSION OF FLURBIPROFEN

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ABSTRACT

Objective: At present, more than 40% of drugs are poorly water-soluble that leads to reduced bioavailability. The objective of the present investigation was to overcome the issue of poor aqueous solubility of drug; therefore, stable flurbiprofen (FBF) nanosuspensions were developed by nanoprecipitation method.

Materials and Methods: Based on particle size, zeta potential, and entrapment efficiency, the polymeric system of hydroxypropyl methylcellulose E15 and poloxamer 188 was used effectively. The prepared formulations were evaluated for Fourier transform infrared spectroscopy, transmission electron microscopy, differential scanning calorimetry, powder X-ray diffraction, saturation solubility, entrapment efficiency, particle size, zeta potential, dissolution profile, and stability.

Results: The resultant FBF nanosuspensions depicted particles in size range of 200–400 nm and were physically stable. After nanonization, the crystallinity of FBF was slightly reduced in the presence of excipients. The aqueous solubility and dissolution rate of all FBF nanosuspensions were significantly increased as compared with FBF powder.

Conclusion: This investigation demonstrated that nanoprecipitation is a promising method to develop stable polymeric nanosuspension of FBF with significant increase in its aqueous solubility.

Keywords: Nanosuspension, Nanoprecipitation, Flurbiprofen, Hydroxypropyl methylcellulose E15, Lyophilization.

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INTRODUCTION

The large number of active pharmaceutical ingredients emerging from the drug discovery process exhibits poor aqueous solubility resulting in a low dissolution rate and oral bioavailability [1,2]. Solubility, dissolution, and permeability of drugs are rate-limiting parameters for its oral absorption [1,2]. Various physicochemical and physiological parameters of drug affect the oral bioavailability of drugs [1,2]. Size reduction of drugs improves oral bioavailability of drug by increasing its effective surface area and thus increasing solubility and dissolution rate of drugs [1,2]. High log p value and molecular weight of the substance are important factors regarding nanosuspension of less aqueous solubility of drugs [7]. Nanosuspension is the novel approach to overcome the problem of low dissolution rate and compromised oral bioavailability and reduce the delivery issues by maintaining the drug in preferred crystalline state [3-8]. Nanosuspension signifies sufficient safety and efficacy [4-6]. According to Nernst-Brunner diffusion layer model, the peripheral layer of the solid particle gets saturated by small portion of an adjacent solvent. Afterward steady state mass transfer takes place into the bulk solution [8-12]. The formulation can be achieved by top-down (fracturing larger particles to smaller particles) or bottom-up (generation of smaller particles by precipitation at molecular level) approaches [1,9-13]. Nanoprecipitation is one of the promising techniques for the development of nanosuspension of low water-soluble drug molecules [14]. However, particle agglomeration and crystal growth due to Van der Waals forces or Ostwald ripening can be prevented by addition of one or more stabilizer (s) [15]. The selection of polymers and stabilizers is very crucial in the development of nanoformulations. Hydroxypropyl methylcellulose E15 (HPMC E15) and poloxamer 188 (Pluronic F68) are steric stabilizers provide stabilized dispersion by steric hindrance [1,13]. Nanosuspension formulations of several drugs such as Rapamune (sirolimus) and Tricor (fenofibrate) are already successfully marketed [16].

Flurbiprofen (FBF) is a phenylalkanoic acid derivative (Fig. 1), nonsteroidal anti-inflammatory and classified as Biopharmaceutics Classification System Class II drug due to its practical insolubility in water. Its oral bioavailability is affected by low aqueous solubility having pKa value ~ 4.03. The high log p value of FBF is an important feature in the development of its nanosuspension [17,18].

This study was focused to develop stable polymeric nanosuspension for enhancement of dissolution and oral bioavailability of FBF. The solidification of formulations was carried out by freeze-drying.

MATERIALS AND METHODS

Materials

FBF, HPMC E15, and poloxamer 188 (Pluronic F68) were kindly gifted by Sun Pharma Pvt., Ltd., Ahmednagar. Polyvinylpyrrolidone K30 (PVP K30), polyethylene glycol 6000 (PEG 6000), and sodium dodecyl sulfate (SDS) were procured from BASF Ltd. All used supplementary chemicals and reagents were of analytical grade and utilized without additional purification. Double distilled water was used during the experimental work.

Methods

Screening of stabilizer based on settlement volume ratio

To select the optimal stabilizer, the FBF (0.5% w/v) nanosuspensions were prepared using different stabilizers (0.5% w/v) such as PVP K30, PEG 6000, SDS, and poloxamer 188, respectively, by nanoprecipitation technique. The obtained nanoformulations were analyzed by settlement volume ratio (F) for a week, and suitable stabilizer was selected based on the stability of the system [19].

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Open Access Research Article

Design, Development and Characterization of Ketorolac Tromethamine Nanosuspension Loaded *In-Situ* Mucoadhesive Ocular Gel

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ABSTRACT

Currently, a variety of ophthalmic products illustrate low bioavailability after topical administration because of anatomical and physiological barriers of eye. Ketorolac tromethamine (KT) is a BCS class I, potent anti-inflammatory drug. The rationale of present work was to design and develop KT nanosuspension loaded *in situ* gel with sustained effect and greater permeability for ocular drug delivery through increased ocular residence time of drug. KT nanosuspension loaded *in situ* gel was designed by using 3^2factorial design. Polymers and surfactant were optimized through trial batches exhibiting better drug content (%). *In Vitro* trans-corneal permeation (%) and corneal hydration (%).Optimized formulation was evaluated for clarity, pH, gelling capacity, rheological behavior, drug content (%). *Ex-vivo* trans-corneal permeation, corneal hydration, HET CAM assay and physical stability. The resultant formulations revealed optimum viscosity, pH and drug content; as well as higher trans-corneal permeability when compared to the marketed eye drop. Optimized formulation was found as nonirritant to eye with sustained effect and good stability. So, current system can be considered as an efficient ocular drug delivery system for the treatment of postoperative inflammation, which would improve patient compliance and ocular bioavailability.

Keywords: Ketorolac tromethamine, *in situ* gel, corneal hydration, mucoadhesive, trans-corneal permeability

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1. INTRODUCTION

Ketorolac tromethamine (KT) is a BCS class I drug having potent anti-inflammatory activity. Chemically it is a pyrrolizine carboxylic acid; NSAID used for the treatment of post-operative eye inflammation and conjunctivitis[1-2]. Being water soluble agent; to formulate nanosystem is quite difficult by entrapment in polymeric vehicle[3]. Generally the basic problems for topical application in the treatment of ocular infection is drug loss from pre-corneal surface, conjunctival uptake due to poor bioavailability and rapid drainage through naso-lacrimal areas[4-5]. However, short pre-corneal contact time combined with corneal impermeability result in low bioavailability, and frequent dosing is usually needed[6]. Nanosuspension by nanoprecipitation is the novel drug delivery approach for sustaining the drug in its crystalline state[7-9]. Selection of polymers and stabilizers are very essential in the development of nanosuspensions to avoid particle aggregation, and crystal growth[10-11]. Design of experiment has proven effective optimization of formulations[10-11]. In present investigation; formulation was optimized by using 3^2 factorial design. Hence, based on above challenge, KT nanosuspension loaded *in situ* gel increases ocular bioavailability, and residence time on the corneal surface. The rationale of present work was to design and develop KT nanosuspension loaded *in situ* gel with sustained effect and greater permeability for challenging ocular drug delivery.

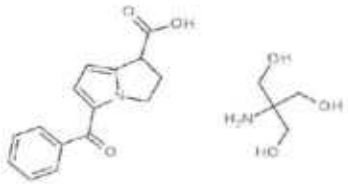

Figure 1: Chemical structure of ketorolac tromethamine

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RJPT

RESEARCH ARTICLE

Influence of Water-soluble polymers on Epalrestat ternary complexation by kneading

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ABSTRACT:
The study reported in this current work objected to demonstrate the formation of binary and ternary inclusion complexes of Epalrestat (EP), a poorly water-soluble acidic type drug, with β-cyclodextrin (CD) and with water-soluble polymers PVP K30 and HPMC E4. The solid systems of EP with β-CD and water-soluble polymers were obtained by kneading and characterized for phase solubility, saturation solubility, dissolution, stability studies. FTIR, DSC, PXRD and SEM data indicated the positive influence of β-CD and hydrophilic polymers on EP solubility and dissolution. Phase solubility studies were carried out to evaluate the solubilizing power of CD, with regards to EP in combination with water-soluble polymers, and to determine the apparent stability constants (*K*s) and complexation efficiency (CE) of the complexes. Phase solubility studies showed A_L (linear) type of solubility curve for the ternary complexes it also showed amelioration in *K*s value for ternary complexes. The CE of β-CD towards EP was promoted by water-soluble polymers signifying its use as a ternary component. The dissolution rate of EP and solubility were undoubtedly improved by complexation with β-CD as compared to model drug EP alone. Ternary complexes incorporated with PVP K 30 and HPMC E4 proved better than binary complex. Hence, the water-soluble carrier could be exploited as a ternary component to improve the solubility of EP via β-CD complexation.

KEYWORDS: Epalrestat, enhanced dissolution, PVP K30, HPMC E4, β-cyclodextrin (β-CD), Binary and ternary complexes.

INTRODUCTION:

Considerable modern active pharmaceutical ingredients belong to the BCS class II category and exhibit low solubility and low dissolution rates. Low solubility turns in an important chemical entity not arriving at a stage of finished pharmaceuticals by reason of not achieving their full potential and therapeutic range. These API needs enhancement in low solubility, dissolution rate and bioavailability which is featured to drug's success. The most common long-term complication in patients suffering from diabetes mellitus is diabetic neuropathy.[1]

EP is a relatively new widely prescribed endocrine and metabolic product, the subcategory is an antidiabetic drug which is a poorly water-soluble known to demonstrate solubility related dissolution constraint.[2-4] Its mechanism of action is largely based on the inhibition of aldose reductase.[5-6] Aldose reductase enzyme of the polyol pathway converts glucose to sorbitol in presence of NADH. Increased aldose reductase expression has been associated with complications of diabetes, as it can create tissues dependent on insulin for glucose uptake. EP reduces oxidative stress in type II diabetes by decreasing lipid hydroperoxide levels in erythrocyte when administered at 150mg/day. Cyclodextrin complexation is a productive approach for enhancing the solubility, dissolution rate and bioavailability of BCS Class II Drugs. Cyclodextrins are a family of three well known, industrially produced, major cyclic oligosaccharides and several minor, rare ones. Cyclodextrins may be

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Future Science

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Design, development and characterization of ketorolac tromethamine polymeric nanosuspension

Pankaj A Jadhav & Adhikrao V Yadav

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Abstract

Aim: At present, various ophthalmic formulations show low bioavailability. The rationale of present work was to design and develop stable ketorolac tromethamine nanosuspension with sustained effect and greater permeability for ocular drug delivery and increased ocular residence. **Materials & methods:** Formulations were designed by using central composite design, developed by combined nanoprecipitation and probe sonication method. **Results & discussion:** Nanosuspensions depicted the size range of the particles in between 199 and 441 nm with slight reduction in crystallinity of drug. *In vitro* drug release revealed that higher % entrapment efficiency of drug in nanosuspension delays the drug release. **Conclusion:** Eudragit RL-100-based nanosuspension increases viscosity and avoids problems like drug loss from precorneal surface and rapid drainage through nasolacrimal areas.

Keywords: ketorolac tromethamine • lyophilization • nanoprecipitation • nanosuspension • probe sonication

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MYANMAR COSMETIC MARKET: CURRENT AND FUTURE PROSPECTS

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ABSTRACT

The cosmetic industry has been expanding rapidly in both developed and developing countries. The cosmetics market in Asia seems to be one of the fastest growing markets. The market value of the Asia Pacific has increased to more than US$70 billion, which is the second highest market after the Western European market. As reported in 2013, Myanmar spent about US$407 million on cosmetics and toiletries products and this demand was mainly met by imports. The skin care products are the main driver of the cosmetics markets, which represent value of US$229 million followed by eye color cosmetics with value of US$20.6 million. In 2013, Malaysia imported about US$295 million worth of cosmetics and toiletries and the top three importing countries are the United States, Japan and Thailand. It is found that Myanmar consumers' interest was influenced by heavy advertising, marketing and growing prosperity that increased their interest in premium brands, and they prefer to use imported cosmetics products. The more recent in the Myanmar market trade is the emerging of halal cosmetics which will be attraction for the country's Muslim customers.

KEYWORDS: Cosmetics; Halal cosmetics; Myanmar; Myanmar consumer; Marketing etc.

INTRODUCTION

The cosmetic industry has been expanding and growing around the world in both developed

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Antidiabetic and Antioxidant Activity of *Coccinea grandis* Voigt Stem Extract in Streptozotocin Induced Diabetic Rats

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ABSTRACT

Objective: In the present study, the antidiabetic and antioxidant study of stem part of Coccinea grandis Voigt plant extracts in Streptozotocin induced diabetic rats were investigated. **Materials and methods:** Fifty four Wistar albino rats were used with nine groups and with six rats in each group. 45 mg/kg body weight streptozotocin was administered to group 2 to 9. Group 2 was diabetic control. Group 3 was given with glimepiride as standard drug. Group 4 and 5 were given petroleum ether extract 250 and 500 mg/kg respectively. Group 6 and 7 were given 250 and 500 mg/kg chloroform extract respectively. Group 8 and 9 were given 250 and 500 mg/kg hydro alcoholic extract respectively. Antidiabetic activity of the extracts was assessed by serum glucose level on glucose kit. Superoxide dismutase (SOD), Catalase (CAT) and lipid peroxidation studies were assessed with histopathology. **Result:** The chronic study data on diabetic rats cleared the administration of all extracts significantly reduced blood glucose level and lipid peroxidation level with better antioxidant activity. **Conclusion:** From the study, the petroleum ether, chloroform and hydro alcoholic extracts of stem part of Coccinea grandis Voigt plant have shown antidiabetic and antioxidant potential.

Keywords: Antidiabetic activity, antioxidant activity, Lipid peroxidation, Superoxide dismutase, Catalase.

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1. INTRODUCTION

Diabetes mellitus is a metabolic disorder characterized by deficient blood insulin level. This may be cause because of lack of sensitivity of receptors to the insulin or autoimmune destruction of pancreatic ß cells of Langerhans which leads to abnormal glucose homeostasis and elevated blood glucose level.[1] Insulin is a hormone secreted in pancreas which allows body to use glucose as a source of energy. Insulin helps to maintain blood glucose level within the normal limit. [2]

According to WHO survey in 2016, 422 million adults are living with diabetes mellitus globally. In India, more than 62 million people suffered by diabetes mellitus. By 2030, it was predicted that 79.4 million people would be diabetic in India. The prevalence of diabetes is more in India due to changes in lifestyle, trend of urbanization, global nutrition transition, genetic factor, environmental influences, rising living standards. Diabetes mellitus is categorized into mainly two types. Type I Diabetes mellitus (Insulin dependent DM) and type II Diabetes mellitus (Non-insulin dependent DM). [3] Amongst these types, 90% people are having type II Diabetes mellitus. (National diabetes Fact Sheet 2005). [4]

Diabetes mellitus is one of the fatal disorders in the world and it is an 6th leading cause of death. [5]The death rate in diabetic people is double to that of normal people. Diabetes mellitus affects many major organs of body. Many complications are associated with diabetes mellitus. It can cause kidney failure, blindness, impotence, cerebrovascular disorder, cardiovascular disorder.

Medicinal plants have become useful remedies for the treatment of diabetes mellitus and its complication because of polyphenol [6], saponins glycosides, flavonoids, sterol constituents present in the plants have ability to reduce the blood glucose level and cholesterol level. It has been described in ancient literature about the use of natural medicinal plants or herbal products in diabetes mellitus. Antidiabetic effect of these plants is may be due to their ability to recover the disturbed function of pancreas or

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Research Article

MELOXICAM-PECTIN-β-CYCLODEXTRIN TERNARY COMPLEX BY KNEADING FOR ENHANCEMENT OF SOLUBILITY AND DISSOLUTION RATE

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ABSTRACT

Objective: The objective of the present investigation was to improve the solubility and dissolution rate of poorly soluble drug meloxicam by its ternary inclusion complexation with natural polymers and beta-cyclodextrin (β-CD) by kneading.

Methods: Equimolar physical mixture (1:1) was prepared by homogeneously kneading drug and β-CD using a solution of agar and pectin in water to get a paste, then paste was dried overnight to get inclusion complex. Inclusion complex was evaluated for drug content, the yield of the adsorption process. Fourier-transform infrared (FTIR), differential scanning calorimeter (DSC), powder X-ray diffractometry (PXRD), scanning electron microscopy (SEM), dissolution, and stability studies.

Results: The phase solubility diagrams exhibit A_L showing a linear increase of drug solubility and indicating the formation of soluble complexes. The FTIR and DSC show compatibility between meloxicam and β-CD, while slight broadening in the peak with a reduction in intensity and early onset indicates the reduction in drug crystallinity which confirms in PXRD pattern. The SEM of binary, as well as ternary, showed no aggregation, and there was a gap between the particles also indicating good redispersibility. The dissolution rate of the drug from the kneaded ternary complex with pectin was significantly rapid compared with the pure drug. The maximum drug release was observed as 85.24±1.84% at the end of 60 min. The ternary complex was found stable after 3 months stability studies.

Conclusion: The results indicated that ternary inclusion complexation with natural polymers and β-CD was most useful for enhancement of solubility and dissolution rate of a poorly soluble drug like meloxicam.

Keywords: Meloxicam, β-cyclodextrin, Natural polymers, Ternary complex, Solubility enhancement.

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INTRODUCTION

Cyclodextrin inclusion complexes play an important role in improving the therapeutic efficacy of drugs with poor solubility and/or stability problems. They are capable of alleviating the undesirable properties of drug molecules through the formation of inclusion complexes [1]. Beta-cyclodextrin (β-CD) is a basic cyclodextrin and hence selected for its higher solubility, and this generally results in more extensive solubilization ability toward lipophilic molecules, with a good safety profile [2]. However, cyclodextrin has problems such as high molecular mass, rather a high cost and potential parenteral toxicity [3]. Strengthening the complexation and solubilization efficacy of cyclodextrins is possible by the use of the ternary agent which may act as a binding agent between cyclodextrin and guest molecule and/or act by solubilizer. Apart from several approaches toward this aim is the addition of suitable auxiliary substances, which can be a useful approach to increase cyclodextrin solubilizing capacity by ternary complex [4-6]. CDs can accommodate a variety of molecules inside the cavity due to its shape to form inclusion compounds. The guest molecules encapsulated by CDs may undergo some changes in their physical, chemical, or biological properties. This feature has been advantageously exploited for increasing the stability and bioavailability of drugs [7-9]. Instead of attempting only binary inclusion complex addition of small amounts of water-soluble polymers to the system, which causes an increase in solubilization efficiency and may result in reducing amounts of CD [10,11]. These results can be attributed to the synergistic effect of polymer and CD solubilization on the formation of drug: CD:water-soluble polymer ternary complexes [12,13]. Water-soluble polymers are able to interact with drugs, CD molecules, and even with the drug: CD complexes [3]. The mechanism involved in increasing CD complexation efficiency in the presence of water-soluble polymers is not yet fully understood; however, it is believed that water-soluble polymers can reduce CD mobility and increase the complex solubility [14]. Cyclodextrin ternary complexes have been tried for overall enhancement of solubility and dissolution rate with carboxylic acid [15,16], amino acids [17,18], sugar alcohol [19], and hydrophilic polymer [20,21]. There are different types of the hydrophilic polymer have been tried including synthetic and semi-synthetic, but there was a rare use of natural polymer for this purpose [22].

Meloxicam (4-hydroxy-2-methyl-*N*-(5-methyl-2-thiazolyl)-*N*-1, 2 benzothiazine-3-carboxamide 1, 1-dioxide) is a potent nonsteroidal anti-inflammatory drug. It is practically insoluble in water (12 mg/mL^{-1}). Its poor solubility and wettability lead to difficulties in oral and parenteral formulations. In the present investigation, attempt was made to improve solubility and dissolution rate of the poorly soluble drug using ternary complexation with β-CD and natural polymers such as agar and pectin as natural polymers have several advantages over synthetic or semi-synthetic polymers.

MATERIALS AND METHODS

Material

Meloxicam was obtained as a gift sample from Cipla Ltd., Mumbai, India. β-CD was gifted by Lupin Ltd Pune. All other chemicals and solvents used were of pharmaceutical and analytical grade. Double distilled water was used throughout the study for all the experimental procedures.

Phase solubility studies

The solubility behavior of meloxicam was examined in distilled water at room temperature (25±2°C) according to the method described by Higuchi

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Research Articles

Lung delivery of nanoliposomal salbutamol sulfate dry powder inhalation for facilitated asthma therapy

Sandip Honmane, Ashok Hajare, Harinath More, Riyaz Ali M. Osmani & Sachin Salunkhe

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Abstract

The motive behind present work was to discover a solution for overcoming the problems allied with a deprived oral bioavailability of salbutamol sulfate (SS) due to its first pass hepatic metabolism, shorter half-life, and systemic toxicity at high doses. Pulmonary delivery provides an alternative route of administration to avoid hepatic metabolism of SS, moreover facilitated diffusion and prolonged retention can be achieved by incorporation into liposomes. Liposomes were prepared by thin film hydration technique using 3^2 full factorial design and formulation was optimized based

Research Article
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Formulation and Evaluation of Fast Dissolving Buccal Film containing Vildagliptin

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ABSTRACT

The present study deals with the formulation of fast dissolving films of vildagliptin that is used for the treatment of Diabetes. The concept of fast dissolving drug delivery emerging from the desire to provide better patient compliance and avoid first pass metabolism. In the present research work, various trials were carried out using film forming agents such as HPMC, Maltodextrine, Polyethylene alcohol, to prepare an ideal film. Solvent casting method was used for the preparation of films. The prepared films were evaluated for weight uniformity, drug content, film thickness, folding endurance. The in vitro dissolution studies were carried out using ph-6.8 phosphate buffer. This approach increase therapeutic efficiency of pharmaceutical actives by avoiding hepatic first pass metabolism, deliver drug molecule in control manner, enhance absorption and improves patient compliance

Keywords: Fast dissolving buccal film, Vildagliptin, HPMC, Maltodextrine, poly-ethylene oxide tween 80, aspartame Glycerin Solvent casting method, In vitro drug release, Ex-vivo drug diffusion studies.

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Research Article

ENHANCEMENT OF SOLUBILITY & DISSOLUTION RATE OF NIFEDIPINE BY USING NOVEL SOLUBILIZER SEPITRAP 80 & SEPITRAP 4000

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ABSTRACT

The enhancement in solubility and dissolution rate of BCS class-II drug Nifedipine was achieved by simple physical mixture with sepitrap 80 & sepitrap 4000 in 1:1 & 1:2 proportion. The saturation solubility studies shows 263 % & 368 % increase in the solubility in physical mixture of Nifedipine with sepitrap 80 & sepitrap 4000 respectively. The physicochemical properties of pure Nifedipine compared to their physical mixtures with sepitrap 80 & sepitrap 4000 were determined using FTIR, DSC & PXRD. The FTIR and DSC studies shows no any interaction in Nifedipine and sepitrap, the marked broadening and distinct reduction in intensity with shifting of drug endotherm was displayed physical mixture with sepitrap demonstrate positive effect. The PXRD diffractograms shows distinctive peaks but reduction in peak intensity in terms of counts indicating conversion of drug in amorphous forms. The surface morphology of the prepared physical mixture was examined by SEM which indicating no significant change in its surface morphology due to no use any solvent during the preparation of physical mixture . Photostability studies shows that rate of photo degradation is very slow in Physical mixture with sepitrap as compared to pure Nifedipine. Dissolution studies in SGF & SIF shows that significant enhancement by use of novel solubilizer sepitrap 80 as well as sepitrap 4000 in 1:2 proportions. The physical mixture containing sepitrap 4000 was found stable as there was no any significant change in appearance and drug dissolution after three month stability studies.

Keywords: Nifedipine, sepitrap 80, sepitrap 4000, physical mixture, solubility enhancement.

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1. INTRODUCTION

Nifedipine is an oral calcium-channel blocking agent, widely used in the treatment of angina pectoris and hypertension. Nifedipine is a poorly water-soluble drug and its oral bioavailability is very low. Diseases like angina, asthma, epilepsy etc. require immediate drug response to manage the disease condition. Improvement of the aqueous solubility of poorly water-soluble drugs is one of the important factors for the enhancement of absorption and obtaining adequate oral bioavailability [1].

The various methods reported till the date for dissolution rate enhancement of Nifedipine (model drug) include compaction with hydroxypropylmethylcellulose [2], co-grinding with HPMC [3] or bile salts [4], formation of solid dispersions as co-precipitates or co-evaporates with mannitol[5], phosphatidylcholine esters [6], HPMC [7], Chitosan derivatives [8], polyethylene glycols [9] and polyoxyethylene-polyoxypropylene copolymers [10], and inclusion complexes with beta-cyclodextrin [11].

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Solubility Enhancement Technique: A Review

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Abstract

Solubility is the phenomenon of dissolution of solid in liquid phase to give a homogenous molecular dispersion which is essential to drug's success. But majority of the active pharmaceutical ingredients are poor aqueous soluble, hydrophobic. The solubility, property of the drugs becomes one of the most challenging aspects in formulation development. Poor aqueous solubility results in important products not reaching the finished pharmaceuticals due to not achieving their full potential and therapeutic range. Hence poor aqueous solubility of drugs is major limiting factor with many new drugs in their successful launch in market inspite of their potential pharmacokinetic activity. Molecules that would have highly beneficial effect on their physiological target would not be further developed if their bioavadability is limited by their solubility in water. Aqueous solubility of drug also affects physical, chemical properties of the drug, dose, stability in gastrointestinal track, severs as standard for test of purity, the rate of dissolution of solid, rate and extent of absorption, achieve desired concentration of drug in systemic circulation for desired (anticipated) pharmacological response. Thus solubility is a most important concept presenting itself as valuable contributor in the formulation of pharmaceuticals. If the molecule has to survive the pharmaceutical development process the formulation scientist has to come up with new API with great demand in market. The usable pharmaceuticals with poor solubility must be answered well by solubilization techniques such as chemical modification which involve use of solubilizer such as soluplus, povacoat, dendrimers, and physical modification, complexation, use of surfactant which are becoming more and more important to the pharmaceutical sector by opening up pathway to prepare effective and marketable drugs are discussed in present review article.

Key Words: *Solubility, Solubility enhancement, Bioavailability, Novel methods, Dissolution.*

INTRODUCTION:

Solubility is a property of substance in a particular solvent. In quantitative terms it is concentration of dissolved solute in a saturated solution at a specific temperature. In qualitative terms it means continuous interaction of two or more compound to form one phase, clear homogeneous molecular dispersion. It is measured as maximum amount of solute dissolved in a solvent at equilibrium. The resulting solution is called a saturated solution. A solubility chart gives a list of ions and how, when mixed with other ions, they can become precipitates or remain aqueous. [1, 2] Solubility equilibrium is a dynamic equilibrium that occurs when a chemical compound in the solid state exhibits chemical equilibrium with a solution of that compound. Solubility equilibria are important in pharmaceuticals. Drug with poor aqueous solubility (in other words Class II or even Class IV compounds of BCS) presents dissolution related absorption problems. In pharmaceutical sciences, when quantitative data are available solubility may be expressed as parts, molarity, normality, formality, mole fraction percent solution, volume fraction and molality.

molecules of the solvent to provide space in the solvent for the solute, interaction between the solvent and the solute molecule or ion

Step 2 Molecule of the solid breaks away from the bulk.

Step 3 The feed of solid molecule is integrated into the hole in Solvent.

Biopharmaceutics classification system (BCS) was introduced by US Food and Drug Administration (FDA) and it classify the drug in to four classes according to permeability and solubility. Solubility impediment are faced in the Class II and Class IV of the system facing dissolution as the rate limiting step for the absorption of drug due to low solubility.

BCS Classification of Drug. [6]

Class	Permeability	Solubility
I	High	High
II	High	Low
III	Low	High
IV	Low	Low

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HEATING THE MATRIX TABLETS OF ACECLOFENAC ABOVE GLASS TRANSITION TEMPERATURE OF THE POLYMER TO ACHIEVE SUSTAINED RELEASE

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ABSTRACT

The present research was aimed to develop sustained release formulation of aceclofenac by a simple and economic means of heating Eudragit RS matrix tablets containing aceclofenac above the glass transition temperature of Eudragit RS and to study the effect of duration of heat treatment on drug release. The matrix tablets of aceclofenac were formulated using Eudragit RS and were subjected to heat treatment at temperatures 45^0 C and 60^0 C for 6, 12 and 24 hours, in oven. Dissolution studies were carried out to investigate effect of temperature and duration of heat treatment. The results of in vitro dissolution study showed that heating matrix tablets above glass transition temperature of the polymer Eudragit RS caused reduction in the drug release than untreated matrix tablets and tablets heated below glass transition temperature. Also it was evident that as the duration of heat treatment was increased, the drug release decreased significantly. This was related to formation of tight polymer network and better entrapment of drug in the polymer matrix due to heating above glass temperature. The research was successful in development of better sustained release drug delivery of Aceclofenac.

KEYWORDS: Aceclofenac, Eudragit RS, glass transition temperature, sustained release.

INTRODUCTION

Aceclofenac is a Non-steroidal anti-inflammatory drugs (NSAIDs) which is considered to be one of the drug of choice in the symptomatic relief of conditions like rheumatoid arthritis, osteoarthritis and spondylitis.[1] The short biological half-life (3- 4h) and dosing frequency more than once per day make Aceclofenac an ideal candidate for sustained release.[2] Over the last few decades, greater attention has been focused on design and development of sustained release drug delivery systems due to its many advantages. The goal of designing a sustained release drug delivery system is to prolong the drug release, reduce frequency of dosing, reducing the dose required and to provide uniform drug delivery.[3]

There are many techniques available for design of sustained release formulations. Out of which controlling the drug dissolution is one of the best and most successful methods due to its simple design and economic aspects. In order to achieve this, a lot of methods have been investigated

REVIEW ARTICLE

General Considerations of Design and Development of Dosage Forms: Pre-formulation Review

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Abstract

Goal of formulation development is to convert active drug moiety into suitable dosage forms. This can be achieved by investigating of physicochemical properties of a drug substance alone and along with excipients before the formulation. The main objective of pre-formulation testing is to collect the information useful to develop stable, bioavailable dosage forms with safety consideration. Pre-formulation investigations are designed to collect all necessary data, especially physicochemical, physico-mechanical, and biopharmaceutical properties of drug substances, excipients, and packaging materials. This review provides information about pre-formulation parameters such as physical, chemical, solubility, stability, storage, and precaution to be taken for ensure the quality of product.

Key words: Flow properties, Fourier transform infrared spectroscopy, preformulation, solubility, stability

INTRODUCTION

Drug is any chemical entities intended to its therapeutic purpose but it cannot be taken in its pure form, so it is formulated into suitable dosage forms for their safe and compatible administration into the body.

GOAL OF DRUG/DOSAGE FORMS[1]

Following qualities of features are required in drug and dosages form design:

1. Drug would produce specifically desired (therapeutic) effect
2. Be administered by most desired route at minimal dose and dosing frequency
3. Drugs have short onset and optimum duration of activity, without any side effect
4. Would be completely eliminated from the body efficiently without any residual effect
5. Pharmaceutically dosage forms should be elegant, physically, and chemically stable at various conditions of use and storage.

Biopharmaceutical aspects, therapeutic consideration, drug factors (pre-formulation) aspects to be considered for achieving the above goal.[1]

Biopharmaceutical aspects of dosage form design

A route of administration varies with pharmacokinetic parameters of drug, such as, absorption, distribution, metabolism, and elimination (ADME). Drug is administered into body by various routes such as oral, topical, parentral, respiratory (inhalation), rectal, nasal, ear, and eye. According to drug candidate pharmacokinetic profile (ADME) and type of illness (disease condition), route of administration is preferred.

Therapeutic consideration

Nature of clinical indication, disease/illness for that drug is intended is an important factor for selection of dosages form and route of administration. In case of emergency sublingual, an injection is given. In infants: Liquid drops, children's: Liquid dosage forms (e.g., syrup), in geriatric and patients

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Original Article

Development and Validation of UV-Spectrophotometric Method for Estimation of Metformin in Bulk and Tablet Dosage Form

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ABSTRACT

Introduction: Diabetes mellitus, a metebolic disorder characterized by increased blood sugar level. Metformin hydrochloride is used to treat type I Diabetes mellitus. Metformin hydrochloride chemically 1, 1-dimethylbiguanide hydrochloride, is white crystalline powder, hygroscopic and freely soluble in water. Officially UV spectrophotometric method used for estimation of Metformin Hydrochloride from the bulk and tablets formulations. **Objective:** Develop and validate a simple, rapid, accurate, economic and precise UV/VIS method for Metformin Hydrochloride in bulk and tablets formulation. **Methodology:** Choices of a common solvent were essential so various solvent ranges including methanol, ethanol, acetonitrile and phosphate buffer and various concentrations ranges of various buffers were analyzed. **Conclusion:** Among different solvents water has showed better results, hence water was selected as a solvent for the proposed method. Metformin Hydrochloride showed maximum absorbance at 234 nm. The percentage recoveries for Metformin Hydrochloride were found in the range of 99-101 %. Method was quantitatively evaluated in terms of linearity, accuracy, precision, ruggedness, robustness and recovery. The method was simple, convenient and suitable for the determination of Metformin Hydrochloride from bulk and tablet dosage forms.

Key Words: Metformin HCl, UV-Spectrophotometry, Tablet.

INTRODUCTION

Chemically Metformin Hydrochloride (HCl) is a (*N, N*-dimethyl imidodicarbonimidic diamide monohydrochloride as shown in Figure 1. Metformin HCl is used in the treatment of diabetic's mellitus–II, which works to decrease the glucose absorption in the small intestine, increase of glucose transport into cells, decrease the plasma frees fatty acid concentrations and inhibition of gluconeogenesis. Activation of AMPK plays a vital role in these processes.[1,2]

Literature survey revealed that reports on analytical methods such as UV-Visible, HPLC, LC-MS, LC-MS/MS and HPTLC for the determination of Metformin HCl from the bulk and dosage form, very few analytical methods reported for Metformin HCl[3-18] Moreover reported methods were not much cost-effective in terms of solvent consumption. The present investigation was carried out in the view of establishing a simple, rapid, accurate, economic, precise and robust UV method for estimation Metformin HCl in bulk and tablet dosage form using water as the solvent.

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MATERIALS AND METHODS[19,20,21]

Instrument

A Shimadzu UV-1800 240V UV/VIS spectrophotometer was used having two matched 1 cm matches quartz cell.

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SOLUBILITY AND DISSOLUTION ENHANCEMENT OF A BCS CLASS II DRUG BY CO-GRINDING WITH SUPERDISINTEGRANTS

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ABSTRACT

Majority of drugs administered by oral route exhibit low bioavailability because of their limited water solubility. Atorvastatin calcium (ATR)-a potent antihyperlipidemic drug- is a poorly soluble BCS class II drug. Present investigation was aimed at solubility and dissolution enhancement of ATR by co-grinding it with superdisintegrants. Atorvastatin calcium was milled with crospovidone(CP), croscarmellose sodium (CCS) and sodium starch glycolate (SSG) in different ratios using a ball mill. Prepared co-ground mixtures were evaluated by saturation solubility studies, Fourier Transform Infrared (FTIR), X-Ray Diffraction (XRD), Differential Scanning Calorimetry (DSC), and Scanning Electron Microscopy (SEM). Infrared spectrum ruled out any chemical interactions between drug and superdisintegrant. DSC and XRD studies proved that the co-grinding has caused reduction in drug's crystalline characteritics. Also, SEM study indicated micronisation and intimate mixing of drug particles with superdisintegrant. Solubility studies revealed significant solubility enhancement in all co-ground mixtures than that of pure drug and drug milled alone. Tablets were formulated from all co-ground mixtures and evaluated. All the tablet formulation containing co-ground mixture exhibited improved *in-vitro* dissolution. Co-ground mixture with superdisintegrant CCS showed highest solubility and dissolution enhancement in the ratio 1:3. The optimized tablet formulation (F6) displayed better dissolution profile than a marketed formulation. Thus, solubility and dissolution of ATR was successfully enhanced by co-grinding it with superdisintegrants. Co-grinding with superdisintegrant could be concluded as a simple, novel and effective tool for solubility and dissolution enhancement of BCS class II drugs.

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Research Article

Formulation and Evaluation of Particulate Nasal Drug Delivery System for the Treatment of Migraine

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ABSTRACT

The intranasal delivery is preferable route for the administration of the drug for local systemic as well as central nervous system drug delivery. Microparticulate drug delivery system provides numerous advantages like, increased surface area, modified release pattern, improved bioavailability etc. The aim of the present study is an attempt to formulate and evaluate microspheres drug delivery system of Zolmitriptan by using Ethyl Cellulose as polymer for the treatment of migraine. The Zolmitriptan microspheres were prepared by quasi emulsion solvent diffusion method using methanol and dichloromethane system. The formulation parameters and processing parameters like ratio of drug polymer (1:2, 1:3, 1:4, 1:5, 1:6, 1:7), volume of water and stirring speed, time were optimized. The prepared microspheres were characterized for its drug content, percentage yield, compatibility study, powder characteristics, percent moisture content, *in-vitro* drug release, Ex-vivo mucoadhesion study. Based on In-vitro drug release the batch F4 is selected as optimized batch. Having drug: polymer ratio is 1:5 (Zolmitriptan 50 mg: ethyl cellulose 250mg). The *in-vitro* % drug release of batch F4 was 99.6.

Keywords: Zolmitriptan, mucoadhesion

1. INTRODUCTION

Intranasal drug delivery system is suitable for the local and systemic delivery of diverse therapeutic compounds. Among the non-invasive routes, nasal administration offers promising potential as a variable alternative for the delivery of some drugs. Hence, a surge of interest led to many investigations involving the cavum as a possiblewebsite for the administration of a lot of therapeutic agents. The nasal route is conventionally used for drug delivery for treatment of local disease. Now a days this route has received special attention as a conventional and reliable method for systemic delivery of drugs, especially those that are ineffective by route due to their metabolism in the GI tract being prone to first pass metabolism. The objective of present study is to prepare the sustained release microspheres. A sustained, constant drug level at the therapeutic optimum is needed in the blood in number of pathological conditions. Therefore the preparation of controlled and targeted drug delivery system is most important. The microparticulate delivery systems include mainly microspheres, liposomes, suspension and microemulsion.

Biodegradable and biocompatible polymer materials as drug carriers have been investigated in the recent 15 years in large number of studies in various drug delivery systems. Microparticles, have controlled diffusion through the matrix structure and also sensitive materials (drugs, peptides, hormones, vaccines, pDNA) can be protected against the external environment. The present work was aimed to formulate and evaluate

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NASAL DRUG DELIVERY SYSTEM: A ROUTE FOR BRAINE TARGETTING

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ABSTRACT

Present review highlights the potential of nasal mucosa as an administration route for targeting the central nervous system, the brain. Targeted drug delivery seeks to concentrate the medication in the tissues of interest while reducing the relative concentration of medication in the remaining tissues. Thus improving efficacy of the drug and reducing side effects. The nasal mucosa when compared to other mucous membranes is easily accessible and provides a practical entrance portal for small and large molecules. Intranasal administration offers rapid onset of action, no first-pass effect, no gastrointestinal degradation or lung toxicity and non-invasiveness application and also improves bioavailability. It is thought that olfactory route of drug transport, by pass the blood-brain barrier and allows the direct transport of drug from the nose to the brain. This review provides an overview of strategies to improve the drug delivery to brain via nasal mucosa and recent advances in this field.

KEYWORDS: Nasal Delivery, Brain targeting, Blood-Brain barrier (BBB), Central nervous system (CNS), Cerebrospinal fluid (CSF).

1. INTRODUCTION

Earlier the Nasal route has been used for the delivery of drugs in the treatment of local diseases. Nasal therapy has been recognized form of treatment in the Ayurvedic system of Indian medicines.[1] The early 1980s saw the introduction of nasal route as a promising systemic delivery alternative to other conventional drug delivery routes.[2] The delivery of

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PRONIOSOMES: PENETRATION ENHANCERS IN TRANSDERMAL DRUG DELIVERY SYSTEM

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ABSTRACT

The aim of the drug delivery system is deliver the therapeutic agent into the desired site of action. The transdermal route is most important but the stratum corneum acts as barrier which is present on the top of the epidermis and also acts as the rate limiting membrane of penetration of drugs. Vesicular drug delivery system such as niosomes and liposomes are promising systems to cross this permeation barrier. The provesicular niosomes is the colloid carrier in the early stage of developed it may need to exploit more in field of drug delivery. They are non-toxic and non-immunogenic bilayer that be changed to niosomes once applied to skin by absorption of water and interacts with the strong hydrogenbond of stratum corneum and loosens it, thereby permitting the diffusion of drug into the skin. The provesicular system is the new emerging concept and it provides the solution to gel of the stability and also provides the higher entrapment efficiency over conventional systems.This review provides a very important summary of preparation, formulation, characterization and application of proniosome gel as a drug carrier.

KEYWORDS: Provesicular systems, proniosomal gel, non-ionic surfactant, penetration, entrapment efficiency, transdermal.

INTRODUCTION

In the past few decades, reasonable attention has been centered on the improvement of novel drug delivery system. Several novel approaches emerged covering numerous routes of administration, to attain either controlled or targeted delivery. The prime aim of novel drug

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Review Article

LIQUISOLID COMPACTS: A PROMISING APPROACH FOR SOLUBILITY ENHANCEMENT

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ABSTRACT

At present 40% of the drugs within the development pipelines, and approximately 60 % of the drugs coming directly from synthesis area unit poorly soluble. Solubility is one of the important parameter to obtain desired concentration of drug in systemic circulation. Liquisolid compacts technique is a new and promising approach to overcome this consequence and that can change the dissolution rate of water insoluble drugs and increase the bioavailability of the drugs. This technique is an efficient method for formulating water insoluble and water soluble drugs. This technique relies upon the admixture of drug loaded solutions with applicable carrier and coating materials. Liquisolid system is characterized by flow behaviour, wettability, powder bed hydrophilicity, saturation solubility, drug content, differential scanning calorimetry, Fourier transform infra-red spectroscopy, powder X-ray diffraction, scanning electron microscopy, in-vitro release and in-vivo evaluation. This review article explains the preparation, classification and application of liquisolid system.

Key word: Liquisolid system, water insoluble drug, carrier material, coating material.

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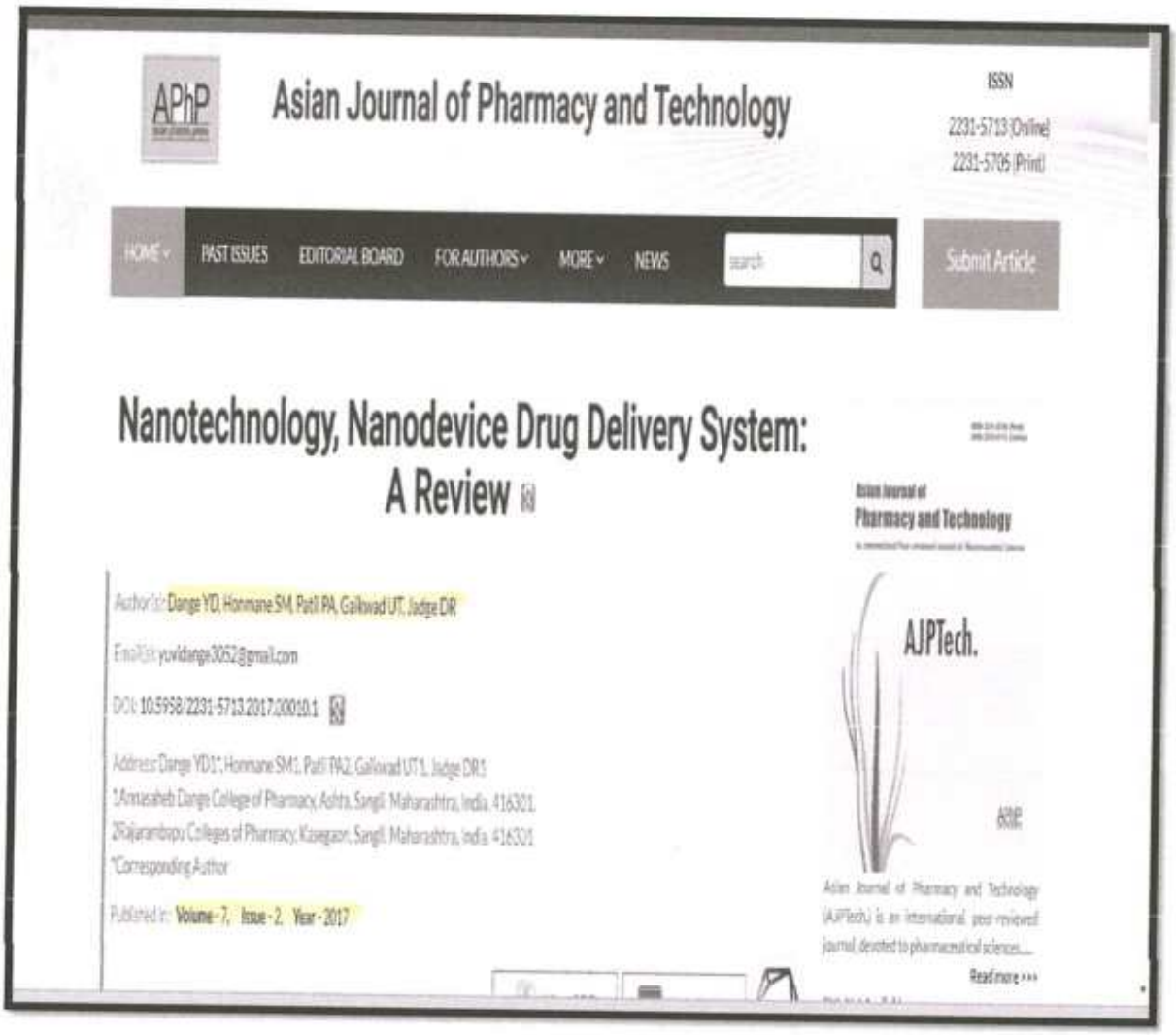
INTRODUCTION

The oral route is the most preferred route of drug administration due to the ease, high patient acceptance, and low cost production. The drug must be presented in solution form for absorption through gastrointestinal tract (GIT) when given orally.The solubility and dissolution behaviour of a drug is the key determinants of its oral Bioavailability [1]. Release improvement of poorly soluble drugs is rise achieved by a rise of the drug surface area, the drug solubility, or by formulating the drug in its dissolved state. Numerous techniques are used to formulate oral drug delivery system that might enhance the dissolution profile and successively, the absorption potency of water insoluble drugs likes micronization, adsorption onto high surface area transporters, lyophilization, co-grinding, formulation of inclusion complexes, solubilization by surfactants, solid dispersions, solid solutions, hydrotrophy, inclusion of the drug resolution or liquid drug into soft gelatin capsules, and cosolvency and liquisolid compact technology[2]. The Liquisolid compact concept described by Spireas *et. al.* in this system oily liquid drug and solution or suspension of water insoluble drug in to non-volatile solvent [3]. Liquisolid technology, a liquid is also reworked into a free flowing, without delay compressible and apparently dry powder by easy physical mixing with elect excipients named the carrier and coating material. The liquid portion, which can be a liquid drug, a drug suspension or a drug solution in to suitable non-volatile liquid vehicles, is combined into the carrier material. The foremost promising and new technique for supporting dissolution is that the formation of liquisolid tablets among the numerous novel



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Nanotechnology, Nanodevice Drug Delivery System: A Review

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Review on Fast Dissolving Buccal Film: An Emergency Treatment

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Abstract:- Orally fast dissolving films (OFDFs) have been introduced in the market recently as they provide convenience and ease of use over other dosage forms such as orally disintegrating tablets. Fast-dissolving drug-delivery systems is an alternative to tablets, capsules, and syrups for paediatric and geriatric patients which rapidly disintegrate and dissolve in saliva and then easily swallowed without need of water.Mouth dissolving buccal films are advantageous particularly for pediatric, geriatric and mentally ill patients who have difficulty in swallowing conventional tablets. This approach increase therapeutic efficiency of pharmacentical actives by avoiding hepatic first pass metabolism, deliver drug molecule in control manner, enhance absorption and improves patient compliance.

Keywords: Oral route, Fast dissolving film, pediatric and geriatric patients, rapid absorption, enhanced Bioavailability.

I. INTRODUCTION

Fast-dissolving drug-delivery systems were first developed in the late 1970s as an alternative to tablets, capsules, and syrups for paediatric and geriatric patients which rapidly disintegrate and dissolve in saliva and then easily swallowed without need of water. A film or strip can be defined as a dosage form that employs a water-dissolving polymer(generally a hydro colloid, which may be a bioadhesive polymer),which allows the dosage form to quickly hydrate, adhere, and dissolve when placed on the tongue or in the oral cavity(i.e. buccal, palatal, gingival, lingual, or sublingual) to provide rapid local or systemic drug delivery[1]. These oral strips may be flexible or brittle, opaque or transparent.

Buccal mucosa is an attractive route for systemic delivery of drugs since it is relatively permeable with a rich blood supply. A drug can be easily applied and localized to the application site, and can be removed from there if necessary. Attempt has been made earlier to formulate various mucoadhesive buccal devices, including tablets, films, patches, disks, strips, ointments and gels[2].

Formulation of fast dissolving buccal film involves the application of both aesthetic and performance characteristics such as strip-forming polymers, plasticizers, active pharmaceutical ingredient, sweetening agents, saliva stimulating agent, flavoring agents, coloring agents, stabilizing and thickening agents. From the regulatory perspectives, all excipients used in the formulation of oral drug strips should be approved for use in oral pharmaceutical dosage forms, be approved for use in oral pharmaceutical dosage forms.

A. Need of Fast Dissolving Film

- Convenient dosing
- No water needed
- No risk of chocking
- Taste masking
- Enhanced stability
- Improved patient compliance
- The drug enters the systemic circulation with reduced hepatic first pass effect.
- Site specific and local action
- Availability of large surface area that leads to rapid disintegration and dissolution within oral cavity.

B. Special Features of Fast Dissolving films [4]

- Film should be thin and elegant.
- Films are available in various size and shapes.
- It should be Unobstructive.
- It should be easily adhere to the oral cavity.
- Fast disintegration without water and Rapid drug release.

C. Ideal Characteristics Of A Drug To Be Selected [3]

- The drug should have pleasant taste.
- The drug should preferably have a minimum dose.
- The drug should have small or moderate molecular weight.
- The drug should have good stability and solubility in water and in saliva.
- It should be partially unionized at the pH of oral cavity.
- It should have the ability to permeate oral mucos.