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New class of fused [3,2-b][1,2,4]triazolothiazoles for targeting glioma *in vitro*

Papisetti Venkatesham [a], Nikhil Ranjan [b], Anwita Mudiraj [b], Vinutha Kuchana [c], Raju Chedupaka [a], Vijjulatha Manga [c], Phanithi Prakash Babu [b], Rajeswar Rao Vedula [a]

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Abstract

Glioma is aggressive malignant tumor with limited therapeutic interventions. Herein we report the synthesis of fused bicyclic 1,2,4-triazolothiazoles by a one-pot multi-component approach and their activity against C6 rat and LN18 human glioma cell lines. The target compounds 2-(6-phenylthiazolo[3,2–b][1,2,4]triazol-2-yl) isoindoline-1,3-diones and (E)-1-phenyl-N-(6-phenylthiazolo[3,2–b][1,2,4]triazol-2-yl) methanimines were obtained by the reaction of 5-amino-4H-1,2,4-triazole-3-thiol with substituted phenacyl

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Original Article

Design Formulation and Statistical Evaluation of Gastroretentive Microspheres of Rasagiline Mesylate for Parkinson's Disease Using Design Expert

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ABSTRACT

Introduction: Rasagiline mesylate is primarily prescribed to treat the symptoms of idiopathic Parkinson's disease works as irreversible inhibitor of mono amino oxidase. The microspheres were designed for extended retention of drug in gastrointestinal tract, resulting in superior absorption and enhanced bioavailability by oral route. **Materials and Methods:** The ionotropic gelation method was used to prepare the formulations RM1 to RM14 mucoadhesive microspheres with Sodium alginate, Calcium chloride, Carbopol 934, Xanthan gum, Chitosan of different concentrations were formulated in preliminary trials after performing preformulation studies such as FTIR, DSC. Optimization of Rasagiline mesylate mucoadhesive microspheres (RMS1 to RMS11) were done by optimizing independent variables such as polymer concentration i.e. Xanthan Gum (5 mg, 20 mg and 35 mg), a Stirring speed (500, 1000 and 1500 rpm) and dependent variables such as percentage entrapment efficiency, particle size and cumulative percent drug release. Optimization was done by using Design export 13 software by Central composite design from Response surface methodology. ANOVA explains the impact of independent variables on the dependent variables. For optimized formulation structural features determined by SEM and XRD. **Results:** In preliminary studies it was found that, apart from Chitosan, the formulations with Carbopol 934P had shown best mucoadhesion and drug release. The optimized formulation RMS12 (given by Design expert software) having 32.12 mg of Xanthan gum at 1500RPM showed 86.84% entrapment efficiency, 440µm particle size and 96.43 Cumulative percent drug release. **Conclusion:** It was concluded that the formulated Gastro retentive mucoadhesive microspheres of Rasagiline mesylate was found to be having best *in vitro* drug release.

Keywords: Rasagiline mesylate, Parkinson's disease, Mucoadhesion, Microspheres, Design expert, Response surface methodology.

INTRODUCTION

The diameter of a microsphere ranges between 1 µm and 1000 µm. The particles are spherical free-flowing made up of proteins or polymers.[1] In addition to natural polymers, waxes, biodegradable synthetic polymers are also used to make them. As a strategy for controlling drug delivery, mucoadhesive microspheres were designed to extend the duration of the dosage form remains at the site of absorption, thus improving and enhancing the bioavailability of the drug.[2]

Rasagiline mesylate is a irreversible, selective second-generation monoamine oxidase type B inhibitor which is primarily responsible for inactivating dopamine in the central nervous system. Rasagiline mesylate has been used to treat motor complications caused by Parkinson's disease. However, the Rasagiline mesylate undergoes first-pass metabolism, has low bioavailability (36%) and short half-life of 1.5 to 3.5 hr. So, there is a need to make gastro retentive formulation due to the short half-life, poor bioavailability and to maintain therapeutic levels of the drug.[3-5]

Design of Experiments (DOE) is an active means in order to optimise the formulation with the fewest possible runs and identify the factors that have the greatest influence on the formulated microspheres. The relationship between factors (independent variables) selected and the responses (dependent variables) noticed by DOE and the variability in responses were notified.[6,7]

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Research Article

AN OVERVIEW ON ORO DISPERSIBLE TABLETS

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A B S T R A C T

In the design of delivery method, convenience in administration as well as improved patient compliance find predominance. Oral dispersible tablets (ODTs) are solid dosage forms which disintegrate in the oral cavity in below 60seconds and have been taken without water. Swift disintegration followed by fast dissolution and rapid commencement of action are advantages of ODTs. Other advantages include improved stability and bioavailability. ODTs are suitable dosage forms in pediatrics, geriatrics, the mentally sick, nausea patients, and patients having trouble in consuming tablets and capsules. When ODTs in the tongue, they disintegrate immediately, delivering the drug, that breaks down in the saliva. Few medications are absorbed from the mouth, oesophagus, and pharynx, as the saliva passes through the stomach. In such instances, the bioavailability of a drug is remarkably greater than those noticed from conventional tablet dosage forms. Various methods in ODT manufacturing include – direct compression, spray drying, sublimation, melt extrusion, cotton candy process, etc.

INTRODUCTION

Despite enormous innovations in delivery of drug, the oral route continues to be the preferred route for administering therapeutic agents because of precise dosage, inexpensive therapy, non-invasive method, self-medication, ease of management, giving rise to patient compliance[(1)]. Paediatric patients can have ingestion problems due to poor muscular and nervous control. Besides, patients travelling with less or no access to water restrict the use of orally administered conventional dosage forms [(2,3)]. Traditional oral dosage forms such as tablets and capsules have a swallowing problem for geriatrics and paediatrics [(4)]. Approximately 35% of the overall population suffers from dysphasia. Oral disintegrating tablets (ODTs) are tablets which are placed in the mouth and then they get dispersed in mucus without the water[(5)]. ODTs are investigated for their potential to improve the bioavailability of less water-soluble drugs by altering the drug's dissolving profile and increasing patient compliance[(6)]. The excipients used in ODT mechanism are generally hydrophilic and can be chosen based on the drug's physicochemical nature, like hydrophilicity or hydrophobicity[(7)]. In case the drug is hydrophobic, the dosage form is known as disintegrating tablet, and if it is hydrophilic, it is a fast-dissolving tablet[(8,9)].

Advantages of Oro dispersible tablets

- These are given to geriatric, paediatric, and psychologically disabled patients.
- Water is not required to swallow the tablet[(10)].
- After oral administration, no residue should be left in the oral cavity.
- Compatible with taste concealing and have a pleasant mouth feel[(11)].
- High drug loading.
- A precise dose is possible as compared to liquids.
- Fast dissolution and drug absorption, contributing a rapid onset of action.
- No risk of suffocation due to physical barrier when swallowed, thus offering enhanced safety[(12)].

Need to formulate mouth-dissolving tablets

The non-invasive drug delivery systems proceed on the basis of poor patient compliance with current delivery regimes and restricted market area for drug companies. FDTs are those dosage forms which are valuable for:

- Geriatric patients mostly suffer from conditions such as hand quakes and dysphasia.
- Pediatric patients cannot swallow easily as their internal muscles and central nervous system are not fully developed.
- Lack of access to water, to patients suffering from diarrhoea and motion sickness while travelling.
- Patients with continuous nausea for an extended period face difficulty in swallowing. Especially cancer patients, post chemotherapy, causes nausea after swallowing the H2 blockers prescribed to bypass gastric ulceration[(13)].

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Review Article

A REVIEW ON SELF-NANO EMULSIFYING DRUG DELIVERY SYSTEMS (SNEDDS)

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ABSTRACT

Lipid based drug delivery formulations have been widely reported in the literature for improving drug solubility, permeability and bioavailability. The systems involve simple oil solutions, multiple, dry and coarse emulsions, nano, micro emulsifying systems and complex emulsifying drug delivery systems. Self-emulsifying systems are further classified as-SNEDDS, SMEDDS which are widely prevailing and commercially viable oil-based approach for those drugs which exhibit low rate of dissolution and inadequate absorption. Since development of SNEDDS, researchers drew interest in this field to deal with challenges of poorly hydrophilic drugs. SNEDDS is an established method for increasing solubility and bioavailability of lipophilic compounds. Due to their large scale production and robustness of SNEDDS, they show improved patient compliance with high drug loading capacity. The presence of biocompatible and biodegradable ingredients along with drug targeting opportunities allow SNEDDS to be used in solubility enhancement techniques. In this article, an attempt was made to give an overview of SNEDDS, formulation excipients, mechanism along with recent advancements, their advantages, disadvantages, applications and future perspectives.

INTRODUCTION

In recent era, the design of poorly soluble complexes posed challenges for formulation in pharmaceutical industry. Up to 40% of newer chemical entities developed by the pharmaceutical industry are sparingly soluble or lipophilic compounds, that leads to poor oral bioavailability, high inter and intra subject variability and lack of dosage regimen[(1)].

Self-nanoemulsifying drug delivery systems (SNEDDS) are considered as nano emulsion as anhydrous forms or preconcentrates of the nano emulsion. Self-nanoemulsifying Drug Delivery system (SNEDDS) is an isotropic combination of the synthetic or natural oil, surfactants, co-surfactants and, on the other hand, aqueous media consists of one or more hydrophilic solvents and co-solvents/surfactant's capacity to generate fine oil-in-water (O/W) type nano-emulsions inslight agitation environment[(2)]. The globules size range in the SNEDDS is below 100nm when dispersed in water. Current studies on Self-Nano emulsifying Drug Delivery System (SNEDDS), is working on enhancement of aqueous solubility of BCS Class II and Class IV drugs which are sparingly water-soluble in nature[(3).]

Using non-ionic surfactant and medium chain tri glycerides oils the SNEDDS were formulated as its oral ingestion is critical[(4)]. To overcome the dissolution barrier and to enhance reproducibility of plasma drug concentration and absorption rate, the drug is formulated as SNEDDS [(5)].

SMEDDS are formulations, which produce a transparent microemulsion of water-in-oil or oil-in-water with a diameter of < 250 nm. SNEDDS have a droplet size of 20 to 200 nm that is translucent and thermodynamically stable[(6)]. SNEDDS is a competent, well-designed, and patient compliant technique for sparingly soluble drugs, as it enhances the solubility and permeability, enhances absorption and dissolution patterns in the GI tract[(7)].

Drug selection criteria for SNEDDS

The SNEDDS system is a novel approach to enhance oral bioavailability of drugs that are poorly water-soluble drugs. in the Biopharmaceutical classification system (BCS) can categorize into four classes, comparison to class i and class iii drugs, class ii and class iv drugs have lower aqueous solubility[(9)]. Under the self-nanoemulsifying drug delivery system, class ii and class iv drugs can increase their aqueous solubility and oral bioavailability. the SNEDDS is important to prevent problem of enzymatic degradation associated to class i drugs and class iii drugs and improved solubility and bioavailability [(10)]. based on the solubility and permeability analysis a schematic representation about biopharmaceutical classification system (BCS) having four classes of system.

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Research Article

NANOSUSPENSIONS - A NOVEL APPROACH FOR VARIOUS DRUG DELIVERY SYSTEMS AND ENHANCED SOLUBILITY

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ABSTRACT

Nanosuspensions refer to pharmaceutical active ingredient particles that are present in a liquid phase and are dispersed in a size below 1µm. The development of new drugs is happening rapidly, resulting in a variety of promising drug candidates that work well, but do not dissolve easily in water. Nanosuspension is a possible solution to the issues that arise when working with drugs that are poorly water- and lipid-soluble because of its unique properties and submicron particle size. BCS Class II drugs have low solubility, but the use of nanotechnology increases their solubility and bioavailability. Preparing nanosuspension is a straightforward process applicable to all drugs that are insoluble in water. A nanosuspension offers a comprehensive solution to the issue of limited solubility and availability of drugs. Apart from that, its impact on pharmacokinetics paves the way for better efficacy and safety of medicines. The interaction of this technology takes place at a molecular level, making it highly specific in targeting cells and tissues, with the possibility of clinical applications yielding the most favourable therapeutic outcomes with minimal adverse effects. In this article review, the ways of preparing, characterizing and application of nanosuspensions are discussed.

INTRODUCTION

Advancements in the field of drug discovery have led to the development of new and effective ways to deliver drugs to the body, such as through nanosuspensions. Due to its unique properties and sub-micron particle size, these materials can be used to address various formulation and delivery issues[1]. Some of the techniques that can be utilized to formulate these are media mills, high-pressure homogenizer, and emulsion-solvent evaporation.

The stability of the solution and the resuspendability of the nanosuspension are some of the factors that are considered when it comes to the production and scale-up of these materials. Currently, the research in this field is focused on the development of new and effective drug delivery systems for multiple applications, such as oral, nasal and ocular[2].

This article provides an overview of the various steps involved in the production of nanosuspensions, including the characterization, preparation, and post-production procedures. It also covers the clinical applications of these materials.

Benefits of Using Nanosuspensions:[3-5]

1. Improve the ability of drugs to dissolve and be absorbed by the body.
2. Hydrophilic medications are appropriate for use.
3. It is possible to increase the drug loading capacity.
4. Modifies the drug regimen, adjusting the frequency of medication administration, or switching to a lower dose form of the drug.
5. Increase the durability and steadiness of medications through improvements in their physical and chemical properties.
6. Passive drug targeting is made possible with this.

Drawbacks of Nano Suspensions

1. Sedimentation and physical stability.
2. During handling, one must exercise caution as it is quite large and cumbersome.
3. It is essential to take the correct dosage of medication. Taking an incorrect dose of medicine can have negative consequences.
4. Uniformity in dose cannot be attained.

Preparation Techniques for Nanosuspension

Nanosuspensions offer a simpler and more cost-effective alternative to conventional drug carriers like liposomes. They are particularly useful for poorly soluble drugs and result in a more physically stable product. The two methods of manufacturing nanosuspensions are the Top-down process technology and the Bottom-up process technology.

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Solid Lipid Nanoparticles For Oral Drug Delivery- Advancements, Challenges And Future Perspectives - A Review

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ABSTRACT: Solid lipid nanoparticles (SLN) have a number of possible uses in research and in drug delivery. They are at the forefront of the quickly evolving field of nanotechnology. Solid-Lipid nanoparticles present a chance to create novel therapeutics because of their special size-dependent characteristics. Drug targeting is made possible by the ability to incorporate drugs into nanocarriers, which provides a new drug delivery prototype. Thus, solid lipid nanoparticles are generating a lot of interest from researchers due to their great potential for achieving the aim of controlled and site-specific drug delivery. This review covers introduction,advantages,disadvantages,aim,methods of preparation, characterization, evaluation and applicationThe analytical methods for characterizing SLN, are Measurement of particle size and zeta ,electron microscopy, and photon correlation spectroscopy, Atomic Force Microscopy are emphasized. Aspects of SLN route of administration and the in vivo fate of the carriers are also discussed.

Key words: solid lipid nanoparticles, oral drug delivery, drug targeting, applications.

INTRODUCTION:

Solid lipid nanoparticles (SLNs) were discovered by Gasco and Muller in 1991. In the up-and-coming scientific world nanotechnology is nowanovel technology for upcoming generations. SLNs are sub-micron colloidal carriers ranging from 50 to 1000 nm, which are composed of physiological lipid, dispersed in water or in aqueous surfactant solution. SLN offer unique properties such assmall size,large surface area, high drug loading and the interaction of phases at the interface and are attractive for their potential to improve performance of pharmaceuticals(1,2,3).SLNs are spherical in shape anddiameter ranging from 10 to 1000nm.

In order to overcome the disadvantages associated with the liquid state of the oil droplets, the liquid lipid was replaced by a solid lipid, which eventually transformed into solid lipid nanoparticles.

The reasons for the increasing interest in lipid based system are many fold which includes.

1. Lipids enhance oral bioavailability and reduce plasma profile variability.
2. Better characterization of lipid excipients.
3. An improved ability to address the key issues of technology transfer and manufacture scale-up.

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Research Article

DESIGN AND INVITRO EVALUATION OF MONTELUKAST SODIUM EFFERVESCENT FLOATING TABLETS

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Montelukast sodium, Effervescent floating tablets, guar gum, karaya gum, Xanthan gum, *In-vitro* evaluation.

ABSTRACT

The aim of present research work is to develop an ideal floating drug delivery system using montelukast sodium to increase the gastric residence time in stomach and to assess the *in-vitro* quality control tests for prepared tablet formulation. Materials and Methods: In this study montelukast sodium tablets were prepared using xanthan gum, guar gum, karaya gum as polymers, sodium bicarbonate as gas releasing agents, citric acid as acidifying agents, and magnesium stearate as flow promoters and SMCC HD 90 as a diluent. The direct compression method was used by using a rotary compression machine. Before compression, granular material was evaluated for precompression parameters such as angle of repose, bulk density, tapped density, carr's index and hausner's ratio. After punching, tablets were evaluated for weight variation, friability, hardness, drug content, floating lag time, buoyancy, and cumulative percent drug release. The formulations were optimized for different concentrations of guar gum, karaya gum, and xanthan gum and their formulations. Optimized formulations were subjected to stability studies and characterization by FTIR. Results and Discussion: All prepared tablets showed good *in-vitro* buoyancy for >9 to>24hours. Optimized formulation showed cumulative percent drug release of 99.8±0.14 %, buoyancy lag time 39.06±0.03sec and duration of buoyancy >24±0.3. Release kinetics of optimized formulation showed zero order with non-fickian diffusion. Conclusion: Out of all nine formulations, F3 has 40mg of xanthan gum and was considered as best formulation based on buoyancy, swelling studies and drug release mechanism corresponds to zero order and non-fickian diffusion.

INTRODUCTION

The aim of the present work was to formulate and evaluate the gastro retentive drug delivery system (Floating tablet) of Montelukast sodium using combination of polymersto increase their retention in stomach, which ultimately results in the increase of bioavailability along with extended duration of action resulting in possible reductionin dose, less side effects, low overall cost of therapy and hence better patient compliance. The current research was aimed to formulate, evaluate, and optimize gastro retentive formulations of Montelukast sodium using a combination of natural polymers such as guar gum and xanthan gum. Montelukast sodium is a leukotriene receptor antagonist (LTRA) administered as oral tablets at high doses 2-3 times per day. Hence in the present investigation, it is aimed to develop effervescent floating tablets of montelukast sodium to reduce frequency of dosing, achieve maximum gastric residence time and to improve drug availability [1,2,3].

Mechanism of Floating Systems

Various attempts have been made to retain the dosage form in the stomach as a way of increasing the retention time. These attempts include: 1) Introducing floating dosage forms (gas generating systems or swelling or expanding systems), 2) Mucoadhesive systems, 3) High-density systems,4) Modified shape systems, 5) Gastric-emptying delaying devices and 6) Co-administration of gastric emptying delaying drugs. Among these the floating dosage forms are the most used dosage forms [4,22,23]. Floating dots have been made to retain the dosage form in the stomach as a way of increasing the retention time. These attempts include: 1) Introducing floating dosage forms (gas generating systems or swelling or expanding systems), 2) Mucoadhesive systems, drug delivery systems (FDDS) have a bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the system. After release of the drug,

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Research Article

FORMULATION AND EVALUATION OF ATORVASTATIN CALCIUM EFFERVESCENT FLOATING TABLETS

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Atorvastatin calcium, Effervescent floating tablets, HPMC, Xanthan gum, *In-vitro* evaluation.

ABSTRACT

The aim of present research work is to develop an ideal floating drug delivery system using Atorvastatin calcium to increase the gastric residence time in stomach and also to assess the *in-vitro* quality control tests for prepared tablet formulation. Materials and Methods: In this study Atorvastatin calcium tablets were prepared using xanthan gum, PVPK30 and HPMCK4M as polymers, sodium bicarbonate as gas releasing agents, citric acid and tartaric acid as acidifying agents, talc and magnesium stearate as flow promoters and avicel pH 101 as a diluent. Direct compression method was used by using a rotary compression machine. Before compression, granular material was evaluated for precompression parameters such as angle of repose, bulk density, tapped density, carr's index and hausner's ratio. After punching, tablets were evaluated for weight variation, friability, hardness, drug content, floating lag time, buoyancy and cumulative percent drug release. The formulations were optimised for different concentrations of HPMCK4M and xanthan gum and their formulations. Optimized formulations were subjected to stability studies and characterization by FTIR. Results and Discussion: All prepared tablets showed good *in-vitro* buoyancy for >9 to>24hours. Optimized formulation showed cumulative percent drug release of 92.8±0.12%, buoyancy lag time 41±0.09sec and duration of buoyancy >24±0.3. Release kinetics of optimized formulation showed zero order with non-fickian diffusion. Conclusion: Out of all nine formulations, F6 has 80mg of xanthan gum was considered as best formulation based on buoyancy, swelling studies and drug release mechanism corresponds to zero order and non-fickian diffusion.

INTRODUCTION

The oral route best and most popular way to distribute medications to the systemic circulation is orally [1]. Drugs having a well-controlled release profile and a longer period of action are the subjects of ongoing research. Increasing the dosage in the gastrointestinal tract by lengthening stomach residence time poses the greatest obstacle, even though it is less intrusive. The main routes for medication absorption are the stomach and upper small intestine [2]. By increasing the residence duration, which increases drug bioavailability, repeated administration of These are the dose forms that are utilised the most frequently. They offer good physicochemical stability and simple methods of administering active pharmacological ingredients (API) [3,4]. medicine is released slowly at the desired pace because the device floats over the gastric contents, prolonging gastric retention duration and reducing dose frequency [5]. Local drug administration to specific areas, such as the stomach and proximal small intestine, is made possible via floating drug delivery systems. It exhibits high absorption, improved therapeutic action, and significant patient advantages [6]. Effervescent tablets are tablets which are developed to dissolve in water, and release carbon dioxide. To use them, they are dropped into water to make a solution [6]. These tablets along with the active medicament, also contain ingredients like sodium bicarbonate, citric acid, and tartaric acid. when tablets are dropped in the presence of water, liberating carbon dioxide, and producing effervescence leading to the dissolution of the tablet, thus fastening solution formation and increasing the palatability.

Atorvastatin is a benzimidazole derivative and is a It is a type of HMG-CoA reductase inhibitor and a type of statin and called as Lipitor. Atorvastatin Calcium is absorbed orally about 15 percent [4]. It shows the first pass effect in liver and gastro-intestinal metabolism. It helps to stop feeling or being sick, nausea or vomiting.

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Synthesis and Evaluation of Some New Pyridines as Possible P-gp Inhibitors with Reduced Calcium Channel Blocking Activity

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ABSTRACT The 1,4-dihydropyridine derivatives (DHPs) **(3a-b** and **4a-c)** were oxidized with iodine in methanol to produce five new, hitherto unreported pyridine derivatives **(5a-b** and **6a-c).** The "Everted sac method" was used to assess the DHPs and their pyridines for potential p-glycoprotein (P-gp) inhibitory or multidrug resistance reversal action. Domperidone, a P-gp substrate, was examined for intestinal absorption in everted rat jejunal segments in the presence and absence of DHPs **(3a-b** and **4a-c)** and pyridines **(5a-b** and **6a-c)** at doses of 30 µg/mL and 100 µg/mL. The standard was Verapamil, a known P-gp inhibitor (30 µg/mL and 100 µg/mL). The P-gp inhibition of all the tested compounds was higher than Verapamil. The P-gp inhibition of compounds **5b** and **6b** was the highest. Utilizing isolated rat ileum, the newly synthesized pyridine derivatives calcium channel blocking efficacy was also investigated. The strongest Ca^{2+} channel-blocking action was seen with compound **5b**. It was determined to be equivalent to Nifedipine, the gold standard. Strong P-gp inhibitor compound **6b** has little calcium channel-blocking action.

KEYWORDS Dihydropyridines, Everted sac method, Multidrug resistance, p-glycoprotein, Pyridines.

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INTRODUCTION

Multi-drug resistance (MDR) is a major obstacle towards the chemotherapy of several diseases, hindering effective treatment. ATP-binding cassette (ABC) transporters are mainly involved in the active efflux of drugs from cells leading to MDR. MDR1 or p-glycoprotein (P-gp) is a 170KDa protein belonging to ABC family. It is overexpressed on MDR cells.[1-3] For the past few decades, much work has been reported on various chemical classes as P-gp inhibitors to overcome MDR.[4] The 1,4-dihydropyridine (DHP) **[Figure 1]** calcium channel blockers are widely studied as P-gp inhibitors, in analogy to Verapamil.[5]

However, due to their cardiovascular side effects, several structural modifications have been made on DHPs to enhance their MDR inhibitory activity and reduce their calcium channel-blocking activity.[6,7] Literature on DHPs reveals extensive work on DHP ester derivatives.[8] In contrary to this, the reports on DHP carboxamide derivatives are meager. Therefore, in continuation to our work on 1,4-DHP carboxamides,[9-15] five new symmetric and asymmetric pyridine carboxamides **(5a-b** and **6a-c)** were synthesized from the potent DHP carboxamides **(3a-b** and **4a-c)** and evaluated for their possible *in vitro* P-gp inhibitory and calcium channel-blocking activities.

RESULTS AND DISCUSSION

Chemistry

The 1,4-DHPs **(3a-b** and **4a-c)** were synthesized as per our earlier reported procedure.[10,15] The reaction of an

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EFFERVESCENT TABLETS- AN OVERVIEW

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ABSTRACT

Oral dosage forms are the most popular of medication, although there are disadvantages when compared to other medications. But these disadvantages can be masked by manufacturing the medicament in its liquid dosage form. But the problem with liquid dosage form is that there are certain drugs which are unstable in liquid dosage form. Effervescent technique is alternative method to develop such dosage form which can accelerate the dispersion and deterioration of drugs. This technique is usually applied in quick release preparation. The tablets produced by effervescent technique are broadly significant in superior and rapid absorption, increasing patients liquid intake. These tablets also control drug release, sustained and controlled release preparations. This review reflects new application of effervescent technique in preparation of effervescent tablets.

Key Words: Effervescent, Dry granulation method, Tablets, Acid source.

INTRODUCTION

Oral route of administration is the most widely preferred route of administration. This is most utilized among all the routes which are route of administration employed for systemic delivery.

According to USFDA, effervescent tablets are intended to dissolved or dispersed in water before administration. Effervescent tablets release CO_2 when the acid is reacted with bicarbonates in the presence of water. Most common acids used are adipic acid, citric acid, tartaric acid and fumaric acid. Bicarbonates used are sodium bicarbonate and the potassium bicarbonate. In these tablets polyvinylpyrrolidone is used as binder.[1]

Effervescent tablets have special property which allows faster adsorption of the drug. Effervescent tablets are designed in a way to break down when they come in contact with the liquid like water or any juice, which makes the tablet to dissolve into a solution.

$$3NaHCO_3 + H_3C_6H_5O_7 \rightarrow 4H_2O + 3CO_2 + Na_3C_6H_5O_7$$

Sodium bicarbonate + Citric acid →Water+ Carbon dioxide+ Sodium citrate

$$C_4H_6O_6 + 2\ NaHCO_3 \rightarrow Na2C4H4O6 + 2H2O + 2CO2\ (g) \uparrow$$

Tartaric acid + Sodium bicarbonate → Sodium tartrate + Water + Carbon dioxide.

These reactions are the most common drug reactions utilised for pharmaceutical purpose.

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SYNTHESIS, CHARACTERIZATION, MOLECULAR DOCKING STUDIES AND ANTHELMINTIC AND ANTI-CANCER ACTIVITY OF PYRAZOLE CONTAIN NOVEL INDOLIN-2-ONE DERIVATIVES

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Keywords:

Isatin, Pyrazole, Anthelmintic, Anticancer activities, Molecular Docking

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ABSTRACT: Background: Imidazole-5-one scaffold has been predicted in the important synthetic drug analogs, which gave valuable information for treatment and high binding affinity to the multiple receptors helpful drug development. **Objective:** To synthesize and evaluate the anthelmintic, anticancer, and Insilco docking studies of pyrazole contain novel Indole derivatives (4a-4h). **Methods:** In the present work, we intended to synthesize pyrazole containing novel Indole derivatives (4a-4h) by a conventional method. **Results:** All the newly synthesized molecules (4a-4h) were characterized by FTIR, ^{1}HNMR, and Mass spectral analysis. The compounds 4c and 4f showed high anthelmintic activity compared with Albendazole as a standard and the compounds 4b, 4e, 4f, and 4g exhibited good anticancer activity against MCF-7 cell line. In molecular docking research, dock rankings of all the synthesized derivatives ranged from -5.972 (compound 4h) to -3.127 (compound 4d). **Conclusion:** The literature reveals that Imidazole-5-one derivatives have diverse biological activities and a cytotoxic potential to be explored for newer therapeutic possibilities.

INTRODUCTION: Medicinal chemistry is a chemistry- grounded discipline involving aspects of birth, medical and knowledge. It's concerned with the invention, discovery, design, identification, and physic of biologically active amalgams, the interpretation of their mode of action at the molecular place, and the construction of the relationship between chemical structure and pharmacological exercise.

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Indole and its by-products, a class of well- known nitrogen and Sulphur containing heterocyclic admixtures, absorb an important position in medicinal and Acaridae chemistry with a wide range of bioactivities. Pyrazole spin-offs have a long history of use in agrochemicals as manures and manures and in pharmaceutical sedulousness as antipyretic and anti-inflammatory [1].

Antipyrine is one of the virgin synthetic specifics and is named after its antipyretic tracts. Benzo pyrrole heterocyclic combinations represent important edifice blocks in organic and medicinal chemistry. Multiple significant inquest exercise was carried out towards this structure. The heterocyclic Indole and its derivations show

Research Article

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Novel Imidazole 2-Amino Pyrimidine Derivatives: *In silico* Studies, Evaluation of Their Anti-Cancer Activity Against Human-CDK2

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ABSTRACT

In drug discovery process the identification of lead compounds by virtual screening is a novel approach. From the literature it is understood that imidazoles and pyrimidines have gained much importance among the medicinal chemists because of their flexible structure and varied pharmacological activities. In present study imidazole and 2-amino pyrimidine derivatives were designed, subjected to the structure based virtual screenings in order to find the novel anticancer agents against human CDK2 protein. The molecular properties and molecular toxicity prediction was done using various online softwares like Molinspiration, Molsoft, OSIRIS, pkCSM along with bioactivity properties. The derivatives which exhibited drug like property were further subjected to molecular docking studies using Autodock Vina. Hits are identified, the basic pharmacophoric features responsible for the anticancer activity were predicted. Based on docking results the compound 24, which exhibited highest binding interaction with receptor will be further synthesized and can be novel lead for the development of anticancer agents.

Keywords: Virtual Screening, Autodock Vina, pkCSM, Anticancer Activity, Human CDK2

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SELF MICROEMULSIFYING DRUG DELIVERY SYSYTEM - AN OVERVIEW

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Abstract

Self- Micro Emulsifying Drug Delivery System (SMEDDS) are formulated to improve the oral bioavailability of lipophilic drugs. It is an isotropic mixture of compounds like oil, surfactant, co-surfactant, and drug having the unique ability to form fine o/w micro-emulsion by agitation and diluted with GI fluid. Its liquid formulation technique enhanced the absorption and bioavailability of poorly water-soluble drugs but also had a few drawbacks like long time period stability issues and storage conditions. Some special techniques convert the liquid form into solid dosage form to overcome these problems. The present paper gives exhaustive information about formulation design by screening excipients. We study the selection and solubility of excipients, its preparation and characterization, and the mechanism by which bioavailability can be improved. This discussion is useful for a better understanding of SMEDDS for its recent advancements, marketed formulation, and patents on SMEDDS. The poorly water-soluble drugs having dissolution rate absorption limited can be effectively formulated in the form of SMEDDS causing a stable plasma profile. The plasma levels of the poorly aqueous soluble medicament show the critical passage of drug absorption, i.e., dissolution. Surfactants with a high HLB value, such as Tween 80 are said to increase the permeability of active ingredients when administered in conjunction with the formulation due to their loosening effect on tight junctions.

Key words: Self Micro Emulsifying Drug Delivery System, Surfactant, Co-Surfactant, Pseudoternary Diagram

INTRODUCTION

The oral route of administration is preferred for persistent drug therapy. The issues of low oral bioavailability afflict several therapeutic molecules including lipophilic drugs. Improvement in their bio-availability and simultaneous prevention of the oral degradation of the susceptible molecules seems to be challenging. Approximately 40 % of modern drug applicants have poor water solubility and hurdles to their successful oral delivery due to a complex web of physical, chemical, physiological, and anatomical factors that act independently and in concert to limit drug bioavailability. The feasible accumulation and their poisonous metabolite product have also been studied.

Self-Micro emulsifying Drug Delivery System (SMEDDS) is a lipid-based system designed to enhance oral bioavailability of lipophilic drugs. Few researchers have stated enhancement in bioavailability of poorly soluble capsules while formulated as SMEDDS. Researchers have tried lipid-based delivery of lipophilic drugs like cyclosporine and concluded that cyclosporine is capable for such delivery. Self- micro emulsifying drug delivery systems (SMEDDS) are described as isotropic combinations of natural or synthetic oils, surfactants, and cosurfactants which have a completely unique capacity of forming splendid oil-in-water (o/w) micro emulsions upon slight agitation observed through dilution in aqueous media, together with GI fluids. Droplet sizes of SMEDDS ranging from 300-500 nm, even much less than 500 nm

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MUCOADHESSIVE MICROSPHERES – AN OVERVIEW ON METHODS, EVALUATION PARAMETERS AND APPLICATIONS

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ABSTRACT

Microspheres are free-flowing spherical particles made up of either proteins or synthetic polymers that are having sizes between 1 and 1000 µm. Microspheres are manufactured to obtain extended or controlled drug delivery to increase bioavailability and activity at the targeted site to a predetermined rate. Microspheres are prepared by using various methods. mucoadhesive drug delivery systems retain in stomach for longer period and avoid first pass effect. Microspheres evaluated for size determination, flow properties, percentage yield, entrapment efficiency, swelling index, and drug excipient compatibility studies by DSC and FTIR.

Keywords: Microspheres, Mucoadhesive drug delivery system, Ionic gelation method.

INTRODUCTION

Microspheres are solid sphere-shaped particles with a diameter ranging from 1-1000 micrometers. They are freely moving spherical particles made up of proteins or artificial biodegradable polymers. Microspheres are divided into two categories**:**

Microcapsules and Micrometrics

Microcapsules are having a unique capsule wall around the encapsulated material, whereas micrometrics have the encapsulated substance dispersed throughout the microsphere's matrix. [1]

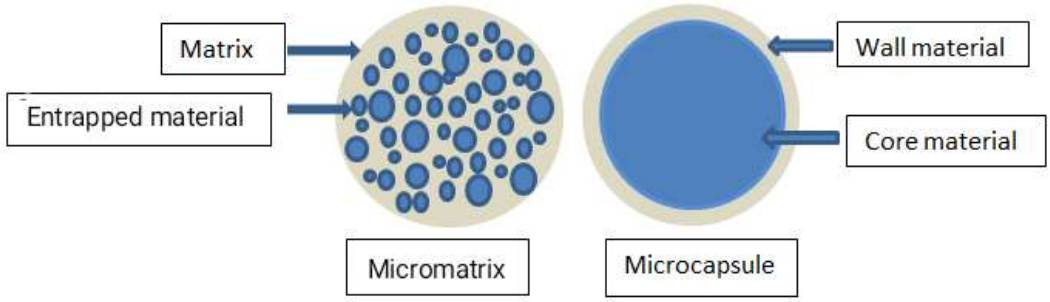

Fig.1: Types of Microspheres

GREEN SYNTHESIS AND PREPARATION OF COLD CREAM WITH SILVER NANO PARTICLES WITH LEAF EXTRACT OF *ALOE BARBADENSIS MILLER*

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Abstract:
In nanotechnology, nano materials are created at molecular level which exhibit qualities quite different from the bulk material. Bulk silver, when reduced to nano-level, shows remarkable changes in the properties making it more environments friendly and useful. Nano silver exhibits unique physical and chemical properties compared to "conventional" silver (e.g., macro scale "bulk" silver). Nano silver of different shapes can be synthesized using various synthesis processes. such as electron irradiation, laser ablation, chemical reduction, biological artificial methods, photochemical methods and microwave processing.
In present work firstly we prepared the ethanolic extract of Aloevera and Silver nanoparticles (AgNPs) were synthesized by bio reduction of Ag^+ ions (from silver nitrate $AgNO_3$), using aqueous or ethanolic *Aloe vera* extracts as reducing, stabilizing, and size control agent and characterized by microscopy and UV. With prepared silver nano particles cold cream was prepared and compared physicochemical parameters i.e viscosity, globule size ,spredability with the control cold cream which is prepared without silver nano particles

Keywords: Nanomaterials, Silver nanoparticles (AgNPs), ethanolic extract, *Aloe vera*, reducing agent, stabilizing agent, Microscopy, UV, cold cream, viscosity, globule size, spredability.

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Phytochemical investigation and Antidiabetic activity screening of Bennincas Hispida (THUNB.)

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Abstract
The crude extracts of *Benincasa hispida* i.e. ethanolic extract and aqueous extract were studied for the presence and detection of phytochemical such as of flavonoids, sterols, terpenoids, carbohydrates and phenolic compounds using standard procedures. On the basis of the results, the extracts were further used for in vivo evaluation of antidiabetic activity. The present study was designed to study the phytochemical screening and to investigate the antidiabetic potential of aqueous and ethanolic extract of dried leaves of *Benincasa hispida*. The antidiabetic potential was evaluated by Streptozotocin-Nicotinamide induced diabetic in rat model. The extracts showed significant potential in a dose dependant manner when compared with the Glibenclamide. The aqueous extract shows good glucose lowering ability than ethanoloc extract on day 15. Thus both the ME and AE may be useful as a natural antioxidants in the near future.

Keywords: *Benincasa hispida*; Streptozotocin, Nicotinamide; Type 2 diabetes; Flavonoid

Introduction

The number of diabetic patients is steadily increasing worldwide, and type 2 diabetes, especially among young people such as children and adolescents, is becoming a problem [1].

The causes of type 2 diabetes include environmental exposure and genetic factors [2]. Early diagnosis and management of risk factors are important because diabetes causes various serious complications. Blood sugar management is important for the prevention and management of type 2 diabetes [3], and agents with -glucosidase inhibitory activity are used as oral hypoglycemic drugs [4]. In the state of hyperglycemia, a sugar-derived substances called advanced glycation end-products (AGEs) are actively produced and accumulate in the blood and tissue [5, 6]. AGEs are a heterogeneous group of molecules formed by the Maillard reaction [7]. The reaction is a non-enzymatic reaction of reducing sugars with free amino groups of proteins, lipids, and nucleic acids [5]. Methylglyoxal (MGO) is one of the most reactive AGE precursors [8]. During aging and diabetes, increasing amounts of AGE-modified proteins can be detected. In other words, they are involved in the development of degenerative diseases such as diabetes [9]. Therefore, controlling the formation of AGEs is important for the prevention and treatment of diabetes and diabetic complications.

Agents that inhibit or reduce AGE formation include aminoguanidine, pyridoxamine, and OPB-9195. Aminoguanidine has been reported to be toxic during clinical evaluation [6]. Therefore, it is necessary to identify a safe anti-glycation agent. To find novel synthetic AGE inhibitors, scientists are focusing on researching anti-glycation compounds from natural products [7-10].

Benincasa hispida (Synonym: *Benincasa cerifera*) which usually known as (winter melon, ash gourd, ash guard, winter gourd, white pumpkin and wax gourd. white gourd, animal oil gourd, gourd melon and Chinese watermelon) belongs to the family Cucurbitaceae. it's common vegetable crop, notably among Asian countries both for biological and medicative purposes [11, 12]. All part of the plant is used medicinally. The plant grows annually. This plant could be a crawling with branched tendrils which

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A REVIEW ON THE PREPARATION, MECHANISM OF ACTION AND CHARACTERIZATION OF NIOSOMES FOR THE NOVEL DRUG DELIVERY SYSTEMS

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ABSTRACT

Niosomes are a type of non-ionic surfactant vesicles that have gained significant attention in recent years as novel drug delivery systems due to their ability to encapsulate both hydrophilic and hydrophobic drugs. In this review, we present an overview of the preparation methods and characterization techniques used for niosomes, along with a discussion of their mechanism of action. We also highlight the advantages of niosomes over other conventional drug delivery systems, such as liposomes, and discuss their potential applications in various fields, including cancer therapy, gene delivery, and cosmetic formulations. Finally, we provide a critical analysis of the current challenges and future directions for the development of niosomes as effective drug delivery systems. Overall, this review aims to provide a comprehensive understanding of the potential of niosomes in the field of drug delivery and encourages further research in this area.

IndexTerms: **Niosomes, cancer therapy, novel drug delivery systems, non-ionic surfactant, gene delivery**

I.INTRODUCTION

As we know, designing and developing a new drug is expensive, difficult and time consuming. This process includes preclinical testing, Investigational New Drug application (IND), Clinical trials- Phase I, II, III & IV, New Drug Application (NDA) and FDA approval. Many attempts to improve the safety and efficacy of the already existing drugs was done using various methods like customizing drug therapy, dose titration and therapeutic drug monitoring among these the most important parameter is the delivery of drugs at controlled rates at the target sites.[1] Here, Drug delivery systems play a vital role. Drug delivery systems provide extended circulating half lives so that low amount of drug is used for the therapeutic effectiveness, relieving

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ORIGINAL ARTICLE OPEN ACCESS

FORMULATION OF METRONIDAZOLE CONTAING THERMOSENSITIVE BIOADHESIVE GEL FOR VAGINAL DRUG DELIVERY SYSTEM

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ABSTRACT

The aim of the present study was to formulate and evaluate metronidazole containing thermosensitive bio adhesive gel for vaginal drug delivery to achieve a better therapeutic efficacy and patient compliance in the treatment for vaginosis. Here metronidazole (1%) was formulated as a vaginal gel using thermosensitive polymer, pluronic F127 (20%) along with bioadhesive polymers such as carbopol 934, HPMC, SCMC and polycarbophil. The drug polymer compatibility was studied using FTIR. The prepared formulations were evaluated for parameters such as gelation temperature, gelation time, viscosity, bioadhesive strength and drug release. Gelation temperatures for various formulations were found in the range of 30-38 ºC with gelation time varying from 1-5 min. The developed formulations had optimum viscosity, good bio adhesive strength and hence will have high retention property which is required for convenience at the site of application. Among the prepared formulations, one with the combination of pluronic F127, polycarbophil and carbopol 934 showed optimum gelation temperature, gelation time, viscosity, bioadhesive strength with sustained drug release for 12 hrs. The optimized formulation (F8) showed insignificant change in physical property and drug content when stability testing was carried out at 25ºC/60%RH for 3 months.

Keywords: *Metronidazole, Thermosensitive, Bioadhesion, Gel, Bacterial Vaginosis.*

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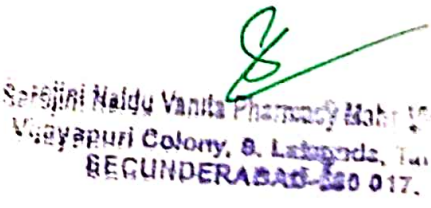
INTRODUCTION

The vagina has been studied as a favorable site for the local and systemic delivery of drugs, specifically for female-related conditions. Traditionally, the vaginal cavity has been used for the delivery of locally acting drugs such as antibacterial, antifungal, antiprotozoal, antiviral, labor-inducing, spermicidal agents, prostaglandins and steroids[1]. Compared with other mucosal tissues, which are of interest for noninvasive drug administration, the vagina offers various advantages from a delivery point of view. The delivery system can be localized on the vaginal mucosa for many hours without causing a pronounced irritation unlike most other mucosal absorption membranes, such as the buccal or ocular mucosa. Intravaginal enzymatic activity is comparatively lower in the vagina than in the gastrointestinal tract[2]. Recently, increased interest in the development of localized drug delivery systems within the vaginal cavity has been shown due to the advantage of localized drug levels, which reduces dosing frequency, drug administration, and side effects[3]. Topically administered agents are generally very well tolerated and systemic side effects can be overcome. Topical therapy is also safe for pregnant and nursing women under medical supervision, and there is no risk of damage to the



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A Study on Granules for Oral Suspension of Fixed Dose Combination of Analgesic Activities

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Keywords: Paracetamol, Mefenamic acid, Granules, wet granulation, analgesics etc.

Abstract:

Paracetamol and Mefenamic acid Granules for Oral Suspension formulation was prepared by granulation method. These two drugs are used as analgesics and the combination of the drug will increase the pharmacological activity. The formulations were prepared based on the release of the drug and taste of the suspension. These granules have shown increased bioavailability. The solubility of the drug can be increased. The granules formed by wet granulation using rapid mixer granulator have greater drug release. This type of formulation is not available in market. The drugs Paracetamol and Mefenamic acid are compatible with each other. The dosage form is Granules for Oral Suspension, so it should be dispensed in sachet, a readily available dosage form, which does not Effect the stability of drug. It is a unit dosage form, so it avoids over dosing. The drug release was rapid and has good pharmacological action.

Introduction

The Granules and powders are themselves in dosage forms. Powders and granules can be filled into sachets and be administered as a dosage form. They can also bean intermediary for drugs normally administered as a solution or suspension in an aqueous vehicle. They are also the intermediate products in the manufacture of other dosage forms. Most pharmaceutical granules have a short lifetime before being incorporated into tablets or hard-gelatin capsule dosage forms. Granules are agglomerates of powdered materials prepared into larger, free flowing particles. The shape of granules is generally irregular,[1,2]

Formulation of Granules:

Granulation is the process in which dry primary powder particles (i.e. single, discrete powder particles) are processed to adhere to form larger multi-particle entities called granules. Pharmaceutical granules typically have a size range between 0.2 and 4.0 mm, depending on the subsequent use of the granules. In the

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A REVIEW ON MICRO NEEDLE BASED TRANSDERMAL DRUG DELIVERY SYSTEM

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ABSTRACT

Micro needle could be a metric linear unit sized needle its height of 10- 2000µm and also the dimension has 10-50µm, which might penetrate through the cuticle layer to dermal tissue directly while not pain. Microneedles are the wide utilized in the transcutaneous drug delivery system they're painless, efficient, safe, convenient, less invasive, and simple to self-administer with a high drug bioavailability. They're divided in to 4types solid microneedles, coated microneedles, dissolving microneedles, hollow microneedles. Differing kinds of microneedles play totally different roles in numerous analysis fields. Within the recent years, microneedles have oftentimes wont to deliver medication, genes, proteins, RNA & vaccines & have achieved wonderful therapeutic result. In addition, recent biological applications & clinical trials are introduced. Small needles are often improved 3D printing & digital technology contribute to the development of microneedle fabrication technology.

KEYWORDS: Microneedles Transdermal Fabrication techniques.

INTRODUCTION

Microneedles carries with it a plurality of micro-projections, usually starting from 25-2000µm tall, of various shapes, that area unit hooked up to a base support. Application of MN arrays to biological membranes will produce transport pathways of micro meter dimensions.[1] MNs even be used for sampling body fluids, such for measurement the glucose levels in diabetic medical aid transdermic delivery has the advantage of by passing the primary pass impact & permitting sustained unleash of the drug but drug delivery is tough because of the barrier created by the horny layer. Microneedle area unit platform for transdermic drug delivery, it's simple to self-administer, & it exhibits a high drug bioavailability. The dose, delivery rate, & effectuality of the medication will be controlled by the microneedle style & drug formulation.

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A REVIEW ON NITROSAMINE IMPURITY- SOURCES, ANALYTICAL METHODS, CARCINOGENICITY AND PRESENCE IN VARIOUS DRUGS

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Abstract:

The presence of N-nitrosamines in pharmaceutical products has caused concern among health regulators and pharmaceutical companies. When nitrates or nitrites react with amines, nitrosamines are formed. Nitrosamines and/or their precursors are present in a variety of consumer items. Some sartan pharmaceutical products were discovered to be contaminated with nitrosamine compounds, which are very carcinogenic. Special emphasis was paid to N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA). The most prevalent Nitrosamines detected are NDMA and NDEA, however there are numerous more Nitrosamines as well. Certain nitrosamines may increase the risk of cancer if people are exposed to them at higher-than-safe levels for an extended period of time. People who consummate NDMA-containing drugs at or below the permissible consumption limits on a daily basis for 70 years are unlikely to get cancer. They can be present in medications, cosmetics, water, and food. Many variables contribute to the development of N-nitrosamine. The Food and Drug Administration classifies two Tobacco Specific Nitrosamines (TSNA) as dangerous and potentially harmful components (HPHCs) in tobacco products and tobacco, N-nitrosonornicotine (NNN) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK). Many approaches for detecting nitrosamine have been developed since 1954.

Keywords: *Nitrosamine**;** NNK; NDMA; NDE; NNN; TSNA*

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A REVIEW ON THE NOVEL COVID-19 VACCINE: TYPES OF VACCINE PLATFORMS

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ABSTRACT
The mishap of the peculiar severe acute respiratory syndrome by coronavirus, SARS-CoV-2 is still a worldwide human setback. So far, no particular antiviral drug or therapy has been capable to break the extensive SARS-CoV-2. During this span, a phenomenal effort by the scientific coterie has led to the evolution of over 300 vaccine projects. Out of which 40 vaccines are subjected to the clinical evaluation and around 10 vaccines are going through phase 3 clinical trials also three vaccines have winded up the phase 3 clinical trials with effective results. In addition to these a couple of vaccines were consented for emergency use. It has been basically presumed that reviving protective immunity through the universal vaccination is a discrete strategy to survive this pandemic. To ease the consequence of the virus on the world's population and the international wealth vaccines were rapidly evolved. In not more than a year corresponding to usual clinical development rules, many vaccines were released on the market and many vaccine drives were brought into action. To develop a vaccine, it is necessary to know the patient's well-being associated behaviours and perceptions to manage the public health vaccination policy. It also involves attention towards the immunological and non-immunological perspective.

KEYWORDS: SARS-CoV-2 vaccinations, Technological problems, Vaccine drives, Clinical Trials, Efficacy, Types of vaccines, Perceptions, Immunological and non-immunological.

INTRODUCTION
In view of the fact that SARS-CoV-2 has led to the novel CoViD-19 pandemic since the early February of 2020, several scientists across the globe have been working on different types of vaccines. With the help of today's technological platforms our scientists came up with over 200 vaccine programmes in which almost 10 vaccines have ended phase 3 trials with positive results and a few vaccines like Covishield and Covaxin were approved for emergency cases. Since the pandemic won't stop spreading it is becoming difficult for the pharmaceutical industry to produce mass number of vaccinations at once. SARS-CoV-2 is a single stranded RNA virus belonging to the family Coronaviridae.[1] Since the virus being RNA virus, it undergoes high-rate mutations giving rise to various virus mutants which are stronger and even more resistant to the medications. To design and develop a vaccine one should know about the immunological and non-immunological standpoints of the patient. The already healed person contains higher range of antibodies that neutralize the SARS-CoV-2 virus. Also it is important to know the efficacy and potency of the vaccines. There is a lot of pressure from the media and also the global public health for the development of the vaccines. This article is going to be about the types of vaccines produced or under production or undergoing clinical trials, about the efficacy and the availability of the vaccine, technological platforms involved in the development of the vaccine, about the role of pharmacovigilance and pharmacoepidemiology in the safety guidance of the vaccines, also the predictions and perceptions of the vaccines in the long run and last but not the least alternative medications involved in the treatment of the Covid-19 virus.[2-4]

A brief explanation on the structure of the virus
The SARS-CoV-2 is basically a large enveloped, single stranded, positive sense RNA virus. Their membrane looks like a crown in shape as there are spike proteins present on the structure. The structural proteins are: a) Spike Glycoproteins(S), b) Small envelop proteins(E), c) Membrane or matrix proteins(M) and d) Nucleocapsid proteins(N).

The mechanism of action of sars-cov2
The SARS-CoV-2 acts by binding to the ACE2 receptors that is Angiotensin Converting Enzyme 2 receptors. These receptors are generally observed in the main organs like heart, kidneys and the intestine. To go into further more depth, the Spike(S) proteins is further

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NOVEL STRATERGY:A REVIEW OF LIQUISOLID COMPACTS FOR ENCHANCING DRUG SOLUBILITY

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ABSTRACT
Drug solubility may be an important consideration when developing pharmacological formulations, resulting in varied bioavailability. Spire's novel Liquid-solid system technique improves the dissolving qualities of water-insoluble or weakly soluble medicines. Liquisolid systems (LS) are powdered forms of liquid drugs created by converting liquid lipophilic drugs or drug suspensions or solutions of water-insoluble solid drugs in suitable non-volatile solvent systems into dry looking, non-adherent, free-flowing, and readily compressible powders by blending with selected carrier and coating materials. These systems have been tested utilising contact angle measurements and water rising times. DSC analyses are used to examine the thermal behaviour of pure components and liquid-solid compacts. XRD is used to determine the crystalline characteristics of liquidsolid compact.

Key Words
Liquidsolid systems, suspensions, solutions, microsystems, carrier material, coating material, disintegrant, Non-volatile solvents.

INTRODUCTION
Bioavailability refers to the extent and rate at which the active pharmaceutical ingredient (drug or metabolite) enters systemic circulation, thereby gain access to the site of action. Bioavailability of a drug is chiefly determined by the properties of the dosage form, which depend partly on its design and manufacture. Differences in bioavailability among formulations of a given drug can have clinical significance; thus, knowing whether drug formulations are equivalent is essential. Drug solubility could be a vital consideration the planning of pharmaceutical formulations result in variable bioavailability. Dissolution is a very crucial issue for absorption of medicine specially in case of water insoluble or less soluble medicine. The recently emerging drugs which are given for oral administration half of them are poorly soluble in water which affects the formulation development process. Many

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A REVIEW ON IN-SITU GELLING IN OCULAR DRUG DELIVERY SYSTEM

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ABSTRACT
Polymeric formulations known as "in situ gelling systems" transition from their sol state before entering the body to their gel state once inside it. The pH shift, temperature modulation, solvent exchange, UV radiation, and the presence of certain ions or molecules are only a few of the stimuli that can cause the sol-gel transition. Such characteristics make drug delivery systems well suited for preparing bioactive compounds for sustained distribution. The eye is the body's most sensitive organ. There are significant efforts being made to develop innovative drug delivery systems for ophthalmic administration in order to increase the bioavailability of ophthalmic medications. The efficiency of drug administration is increased by altering the release profile, and these innovative drug delivery methods also lessen drug toxicity, giving them a number of advantages over conventional systems. There is a lot of research being done in this field that supports the idea that in situ gelling systems can be useful for the administration of ocular medications. This study will provide a brief overview of in situ gels, distinct in situ gelling system techniques, the many types of polymers utilised in in situ gels, their gel formation mechanisms, and evaluation of polymeric in situ gels.

KEYWORDS: In situ gels, ophthalmic administration, Polymers, pH shift.

INTRODUCTION
One of the most vital and intricate organs in the human body is the eye. It is a sensory organ with distinct physiological and anatomical functions. Due to the eye's robust mechanism and barrier protection, drugs for the eyes are administered using a variety of preparations. Medication is absorbed and penetrated through the posterior portion of the eye. At the cornea sclerotic junction, conjunctiva is placed on top of the epithelial layer that makes up the cornea of the eye.[1,2]

Endothelium covers the posterior surface of the body. There are plenty of nerve endings in the cornea. The opaque white sclera, a stiff fibrous tissue, is present to the posterior region of the cornea. The stroma of the cornea has 200–250 lamellae as well. The lamellae that make up the stroma have lagged down collagen. Epithelial, endothelial, and stromal cells act as the primary obstacles to the absorption of ocular medicines. Drugs that are hydrophilic can pass through the outer epithelial membrane, but those that are hydrophobic must pass through the stroma, which serves as a barrier. Human lacrimal glands are fully filled with fluid. This fluid's presence hinders the elimination of foreign particles and eye dryness. When a small amount of medication is administered to the eye, the majority will be the last to enter the fluid in the anterior chamber. The most popular methods for making eye medications are solutions and suspensions, although these types of formulations have a low or poor bioavailability. In-situ hydrogel preparations are being created as part of more recent research in ocular medication delivery systems to increase ocular bioavailability.[3,4]

Natural or synthetic polymer has led to the development of numerous in-situ gel delivery techniques. Gels are typically semi-solid by nature, heavier than liquids despite being greater in size. The primary advantage of the in-sites polymer delivery technology is increased patient convenience. Sol-to-gel transitions in polymers occur as a result of the alteration in their physiochemical characteristics. The three types of systems - PH triggered system, temperature dependent system, and ion-activated system are recognised based on the technique utilised to induce sol-to-gel transition. For the treatment of various disorders, the topical application of in-sites gels to the eyes is a well-established route of administration. The duration of the drug's action is prolonged by this method of delivery. Due to the inclusion of both natural and synthetic polymers, they are taken via a variety of routes, including intraperitoneal, rectal, vaginal, oral, and ocular.[5,6]

Section A-Research paper

Exploring the Anti-inflammatory potential of *Sarcostigma kleinii* Wight & Arn.: An Endemic plant to Western Ghats of India

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ABSTRACT

Conventional approaches addressing chronic & acute pains and inflammations are associated with fewer side effects, and there is a need to explore plant-based medicine to mitigate this issue. *Sarcostigma kleinii* Wight & Arn.is a plant of Western Ghats and not been explored much for its pharmacological and phytochemical profile. Since cellular stress is also involved in the inflammation, various extracts of *Sarcostigma kleinii* Wight & Arn.seeds were screened for total phenolic, total flavonoid content followed by antioxidant studies by DPPH and Nitric oxide free radical assay. The extracts were also screened for both *In vitro* and *In vivo* anti-inflammatory activity. The results suggest that the ethanol extract is moderately safe and exhibited potent inhibition against COX-2 and COX-1 enzymes. The oral administration of the extract was found to significantly reduce the inflammation caused by carrageenan treatment. Compared to the standard Diclofenac the ethanol seed extract effectively reverts the paw edema volume of the inflammatory animals.The phenolic and flavonoid compounds can be interrelated to the antioxidant and anti- inflammatory properties of the plant in the present investigation.

Keywords: *Sarcostigma kleinii* Wight & Arn., Free radical scavenging, COX inhibition, Carrageenan induced rat paw edema model.

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DETERMINATION OF *IN-VITRO* ANTI-UROLITHIATIC ACTIVITY OF *SPIRULINA PLATENSIS* AND *TRACHYSPERMUM AMMI*

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ABSTRACT

Background: Kidney stones are also known as renal calculi which are formed in the kidneys due to crystal aggregation which are formed from the dietary minerals which are present in the urine. Renal calculus or crystal aggregation is a complex process which involves super-saturation, nucleation, growth, aggregation and retention of crystals within the kidney. Various in-vitro and in-vivo studies reveled that some of the phytochemical elements which are present in various plant species are useful in the management of urolithiasis or kidney stones or renal calculi. In the present study *Spirulina platensis* and *Trachyspermum ammi* were selected for screening their in-vitro anti-urolithiatic activity. **Objectives:** To isolate the active constituents from *spirulina platensis* and fruits of *trachyspermum ammi* through various extraction procedures, and to perform the anti-urolithiatic activity studies by titrimetric method of analysis, aggregation and nucleation and compare the percentage of inhibition and percent dissolution between the two herbal drug extracts. **Results and Discussion:** Both the *Spirulina* and *Ajowan (trachyspermum ammi)* extracts has shown significant level of percentage of inhibition in both the nucleation and aggregation assay, it has been observed that as the concentration (100, 200, 300, 400, 500µg/ml) of both the herbal drugs extract was increased there was significant level of decrease in the growth of the CaOx crystals *spirulina* showed more inhibition of the crystal growth than *ajowan* when compared to the standard drug cystone. In titrimetric method the percent dissolution of the *spirulina* was more than *ajowan,* and *spirulina* showed almost equal percent dissolution to standard drug cystone. **Conclusion:** From the above study *Spirulina platensis* and *Trachyspermum ammi (Ajowan)* has shown anti-urolithiatic activity by inhibiting the crystal growth, *Spirulina platensis* has shown more inhibition of crystal growth compared to *Trachyspermum ammi.*

KEYWORDS: Anti-urolithiatic Activity, Nucleation, Aggregation, Percentage Inhibition.

INTRODUCTION

Urolithiasis is the third most common disorder of the urinary tract.[1] The worldwide incidence of urolithiasis is quite high and inspite of tremendous advances in the field of medicine, there is no truly satisfactory drug for the treatment of renal calculi. Most patients still have to undergo surgery to be rid of this painful disease.[2]

Kidney stones typically form in the kidney and leave the body through the urine stream, a small stone may pass without causing any symptoms, if a stone grows more than 5millimeters (0.2 inches) it can cause blockage of the ureter, resulting in sharp and severe pain in the lower back or abdomen. A stone may also result in blood in the urine, vomiting, or painful urination.[3]

Most stones form by the combination of genetics and environmental factors. Risk factors include high urine calcium levels, obesity, certain foods, some medications, calcium supplement hyperparathyroidism, gout and not drinking enough fluids.[4]

Between 1% and 15% of people all around the globe are affected by kidney stones at some point of time in their lives. In 2015, 22.1 million cases of renal calculi occurred, resulting in about 16,100 deaths. They have become more common in the Western world since the 1970s. Generally, more men are affected with kidney stones than women.[5]

Globally, kidney stone disease prevalence and recurrence rates are increasing day by day, with limited options of effective drugs. Urolithiasis affects 12% of the world population at some stage in their life time. It affects all ages, sexes, and races but occurs more frequently in men than in women within the age of 20-49 years.[6] The relapsing rate of secondary stone formations if patients do not apply metaphylaxis is estimated to be 10-23% per

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Ensemble Pharmacophore Meets Molecular Docking: A Novel Screening Approach for the Identification of B-Raf Kinase Inhibitors

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Abstract

In US about 106110 diagnosed as melanomas, 7,180 people expected to die due to melanoma. B-RAF is a cytoplasmic serine - threonine kinase that is found in a mutated form in melanoma and colorectal cancer. Sorafenib was initially introduced as a B-RAF inhibitor in melanoma. Hence it is taken as a pivot molecule in our study. Four potent B-Raf kinase inhibitors (Sorafenib, Regorafenib, N-desmethyl sorafenib & Donafenib) are used to build a pharmacophore model with 'PharmaGist webserver' which generated a 5-point hypothesis. The best model with score of 27.780, was used to screen the Zinc database of ZINCPharmer web server to obtain similar pharmacophore hits. By applying filters like Lipinski rule, RMSD criteria in ZINCPharmer top ten hits were identified. Subsequently, molecular docking was performed on wild (1UWH) and mutated (3IDP) B-Raf kinase protein targets by using GLIDE 5.6 (Schrödinger), to prioritize top lead molecules. Further these molecules are subjected to ADME Properties Prediction by Qik Prop module. Among ten, nine molecules have glide scores in the range nearer to the standard molecule i.e., Sorafenib. Finally, we conclude that ZINC02853810 may act as a powerful inhibitor against both wild and mutant type B-Raf kinase as it has highest glide scores than the Standard.

Keywords: B-Raf kinase inhibitors, Pharmacophore modeling, PharmaGist, ZINCPharmer, ADME, Binding energy

Introduction

Cancer can be targeted by using agent's peculiar for regulating signaling pathways of cancer cells [1]. Melanoma is one among the most aggressive forms of skin cancer and a serious health issue worldwide because of its increasing incidence and the lack of satisfactory chemotherapy for the advanced stages of the disease [2,3]. It has a high ability of metastasis and rapid invasion of other organs, e.g., lymph node, lung, liver, brain, etc. [4]. In US about 106,110 diagnosed as melanomas, 7,180 people expected to die due to melanoma.

The Ras/Raf/MEK/Erk (MAPK) signaling pathway converts extracellular signals from cell membrane receptors to nuclear protein synthesis factors, thereby modulating fundamental cell processes like cellular amplification, differentiation, migration, growth, survival [5,6]. Ras is one of the specific proteins to be concentrated on. Ras (a membrane associated guanine nucleotide binding protein) will be triggered when it binds to an extracellular ligand. Ras proteins belong to a superfamily of low molecular weight GTP binding proteins [7]. A Protein, i.e., serine/threonine kinase Raf is the 1st mammalian direct effector of RAS. GTP-bound activated Ras binds and leads to activation of 3 intimately related RAF proteins named C-Raf, B-Raf, and A-Raf. This causes Raf to relocate to the plasma membrane, a prerequisite for its activity [8]. Raf (Rapidly accelerated fibrosarcoma) activation that can promote cell-cycle progression is identified as a downstream effector kinase of Ras [9]. The oncogene BRAF, as discovered in 1988 was thought to be responsible for 66 % of melanomas.

B-Raf is a mitochondrial protein having a molecular weight of 94kDa acts as a mutational target in various human cancers. Ras-Raf pathway is depicted in (**Figure 1**). The mutations in BRAF are present in approximately 2 % of human cancers, including particularly high frequencies 50 - 70 % of malignant melanomas and a lower frequency in a variety of other types of human cancers, such as thyroid (30 %), colorectal (10 %), and ovarian (35 %) cancers [10]. Melanomas show a high incidence of BRAF mutations and the most common mutation is a valine for glutamic acid substitution at position 600, termed

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Research Article

In-vitro Pancreatic Lipase, Alpha-amylase and Alpha-glucosidase Inhibitory Activities of the Phytochemical Barbaloin

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ABSTRACT

The phytochemical barbaloin was studied for *in-vitro* pancreatic lipase, alpha (α)-amylase and alpha (α)-glucosidase inhibitory activities in the present study. The aim of this work is to evaluate the inhibitory activities of the phytochemical barbaloin at different concentrations. Pancreatic lipase is an enzyme that hydrolyzes the lipids obtained from the diet which acts as an important target to treat obesity. The natural medicines that can inhibit pancreatic lipase enzyme and thus decrease absorption of dietary fat in the body gained much attention for treating and preventing obesity. Diabetes mellitus is a metabolic disorder marked by an elevated level of glucose that circulates in the blood plasma. Alpha amylase and alpha glucosidase inhibitors are used to attain control over hyperglycemia in type 2 diabetes mellitus. The present study was designed to screen the novel pancreatic lipase, alpha-amylase and alpha-glucosidase inhibitors using a phytochemical, barbaloin, to minimize the toxicity and side effects of the inhibitors used at present to treat the disorders like obesity and hyperglycemia. The phytochemical, barbaloin exhibited significant pancreatic lipase, α-amylase and α-glucosidase inhibitory activities with an IC_{50} value 5.52, 8.22 and 5.81 µg/mL, respectively and well compared with standard orlistat for pancreatic lipase and acarbose for alpha (α)-amylase and alpha (α)-glucosidase inhibitory activities, respectively.

INTRODUCTION

Obesity and diabetes are two main disorders prevalent in the world and are interlinked to each other. Obesity causes diabetes to worsen faster. Obesity is also a major risk factor for many chronic diseases such as diabetes mellitus, coronary heart diseases, cancer (endometrial, breast, and colon) and respiratory disorders.[1] Barbaloin is reported to produce pharmacological activities such as histamine release inhibitory activity, anti-inflammatory, antiviral, antimicrobial, anticancer, cathartic, and antioxidant activities and used widely in cosmetic applications.[2] Obesity has nearly tripled worldwide since 1975, with about 13% of adults being obese and about 39% of adults being overweight. Common treatments for overweight and obesity include weight loss through healthy eating, weight-loss medicines, devices, bariatric surgery, etc.[3] Orlistat is lipase inhibitor used in treating obesity by decreasing the absorption of fats by the body. Due to its side effects like flatulence with fecal discharge, fecal incontinence, back pain, difficulty in moving, diarrhea etc., use of orlistat and other similar synthetic drugs are restricted.[4] Thus there is a need to explore new and newer natural drugs with less or no side effects for treating obesity. Diabetes mellitus is a metabolic disorder marked by an elevated level of glucose that circulates in the blood plasma. Over time leads to serious damage to the body's vital organs of the body *viz.*, heart, kidneys, eyes, blood vessels, and nerves.[5] The most common is type 2 diabetes, which occurs in adults when the body becomes resistant to insulin or doesn't make insulin sufficient to the body's needs.[6] The number of people with diabetes rose from 108 million in 1980 to 422 million in 2014 and is estimated to reach 643 million by 2030.[7] Among 7.7 billion of total population in 2019, around 463 million adult people have diabetes with

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ORIGINAL ARTICLE **OPEN ACCESS**

Design and *In Vitro* Characterization of Domperidone Effervescent Floating Tablets

Haarika Balusu*, Navya Mudapelly, Nabeela Sadaf, Aishwarya Mukkamala, Lakshmi Koumudi Devaraju, Divya Chamakuri, Srinivas Nimmagadda
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ABSTRACT

The objective of the present research is to develop an ideal floating drug delivery system using domperidone to increase the gastric residence time in the stomach and evaluate the in vitro quality control tests of prepared tablet formulation. Materials and Methods: In this study Domperidone effervescent floating tablets were prepared using xanthan gum, HPMC K_4M as polymers, gas releasing agent sodium bicarbonate, acidifying agent's citric acid, stearic acid, talc and magnesium stearate was used as flow promoters. Wet granulation technique was employed and compressed by using a tablet rotary compression machine. Before compression, the granular material was evaluated for angle of repose, bulk density, tapped density, carr's index and hausner's ratio. After punching the tablets are subjected to weight variation, hardness, friability, drug content, floating lag time, duration of buoyancy and cumulative percent drug release. The formulations were optimised for different concentrations of HPMC K4M, Xanthan gum and their formulations. The Optimised formulation was subjected to stability studies and characterised by FTIR. Results and Discussions: All the prepared tablets showed good in vitro buoyancy for >9 to>24 hr. the optimized formulation showed cumulative percent drug release 99.8±0.14, buoyancy lag time of 43±0.09 and duration of buoyancy >24±0.3. The release kinetics of optimized formulation showed zero order with non-fickian diffusion. Conclusion: Out of nine formulations, F6 has 80mg of xanthan gum was considered as the best formulation based on buoyancy, swelling studies and the drug release mechanism corresponds to zero order and non-fickian diffusion.

Keywords: *Domperidone, Effervescent floating tablets, HPMC K_4M, Xanthan gum, In vitro evaluation.*

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INTRODUCTION

Domperidone is a benzimidazole derivative and is a specific dopamine-2 receptor Antagonist, is mainly used as anti-sickness medicine [1]. Floating systems are low density systems that have sufficient buoyancy to float through the gastric contents and remain buoyant in the stomach for a longer period of time. FDDS has a bulk densityless than gastric fluids [2]. Remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time[3]. In an effervescent drug delivery system, CO_2 is evolved once dose type comes up-to-date with viscous fluid, hydrogen carbonate, acid or hydroxy acid is employed for gas generation during this approach. In this process carbonic acid gas is sometimes entrapped by gel forming or swellable material like hydroxypropyl methylcellulose (HPMC) [4]. Domperidone belongs to class II drug as per biopharmaceutical classification system which is having poor solubility and high permeability. Domperidone is absorbed orally about 15 percent [6]. Domperidone shows first pass effect in liver and gastro-intestinal metabolism. It helps to stop feeling or being sick, nausea or vomiting. Domperidone increases the level of prolactin hormone which is involved in breast milk production.It helps to improve milk supply. Antiemetics are a group of drugs that are used to control nausea and vomiting. Nausea and vomiting are common symptomswith multiple causes including cancer, pregnancy[8].

Multiple-dose treatment leads to the build of parent drugs and active metabolites, which results in extreme muscle fatigue, respiratory depression, and sedation [2]. Domperidone conventional dosage form has increased dosing frequency, which leads to plasma peak fluctuation. Therefore, this is given through the gastro retentive system in a controlled release manner, decreasing the accumulation of a drug by maintaining plasma blood concentration within the therapeutic window[3]. This floating drug delivery system remains in the stomach for several hours, which results in prolonged gastric-retention and reduces fluctuation of doses· Floating drug delivery systems can also be given as local delivery to

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Pharmacophore-based virtual screening & molecular docking studies on selected plant constituents of *Plantago major*

Muni Sireesha Sunkara[1*], Vinutha Kuchana[1], Jahnavi Pragna Sree[1], Rachana Prabugari[1], Ashwini Pilli[1], Farhani Irum[1], Saritha Jyostna Tangeda[1], Dipankar Bhowmik[2]

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Autodock vina, molecular docking, pharmacophore modeling, pharmaGist, pharmit, virtual screening.

ABSTRACT

Phytochemicals are a striking source to discover new leads for the expansion of novel compounds for several diseases. In this study, various *in silico* techniques are used to showcase the multitarget inhibitors of selected plant constituents of *Plantago major*. Five plant components having an anti-inflammatory activity are used to build a pharmacophore model with "PharmaGist webserver" which generated a four-point hypothesis. The best model with a score of 12.402, was used to screen the National Cancer Institute database of the Pharmit web server to obtain similar pharmacophore hits. Subsequently, molecular docking was performed on the Cyclooxygenase-2 (PDB ID: 4COX) protein by using Autodock Vina, to prioritize top lead molecules. Among all the hits, four compounds have the best dock scores than the standard Celecoxib (−9 kcal/mol). From our result, compound NSC86473 has the highest potential as an anti-inflammatory agent with binding energy (−10 kcal/mol) and may act as a powerful inhibitor against Cyclooxygenase 2 as it has the lowest binding energy than the standard with specified pharmacophoric features according to developed pharmacophore model 1 model. In accordance with earlier findings, it can provide a few insights to research scholars in the future to identify and design new lead molecules with effective anti-inflammatory activity.

INTRODUCTION

Natural products can serve as budding resources for the development of anti-inflammatory drugs due to better pharmacological activities and lower toxicity (Deng *et al*., 2010). Presently, almost all drugs are derived from plant origins. Plant constituents are attractive agents with low cost, effectiveness, and biocompatibility, which makes phytochemicals a prominent cause for the development and identification of the lead compounds that provide support to the pharmacological activity of existing drugs (Samuelsen, 2000). Plant extracts have been reported with enormous biological activities like anti-inflammatory, antioxidant, wound healing activity, weak antibiotic, analgesic, immunomodulating, and antiulcerogenic activity (Mozaffarian, 2012).

Plantago major is a perennial plant that belongs to the family Plantaginaceae. It consists of biologically potent compounds like alkaloids, polysaccharides, flavonoids, iridoid glycosides, lipids, caffeic acid derivatives, terpenoids, and organic acids (Samuelsen, 2000) (Fig. 1). These compounds can be found in almost all parts of the plant such as the seeds, leaves, flower, and roots (Adom *et al*., 2017; Wang *et al*., 2015). Earlier studies reported that *P. major* is used in different parts of the world for the treatment of numerous conditions like skin diseases, infectious diseases, digestive problems, respiratory abnormalities, glitches related to reproduction, circulation, tumors, and inflammation (Azab *et al*., 2016). Owing to the tradition of employing *P. major* for wound healing, it is worth exploring this plant further for anti-inflammatory activity (Mozaffarian, 2012; Samuelsen, 2000).

In recent years, great advancement has been made in the expansion and resolution mechanisms of chronic inflammatory diseases, and the use of phytoconstituents to lighten inflammatory

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DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR ESTIMATION OF MITAPIVAT IN BULK AND PHARMACEUTICAL DOSAGE FORM

Siva Jyothi Buggana[1], Nerendla Ramya[1], Bhooma Shirisha[1], R. Prasanthi[1], Mamatha Tirunagari [1*]

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Abstract:

A simple, rapid, precise, sensitive and reproducible reverse phase high performance liquid chromatography (RP-HPLC) method has been developed for the quantitative analysis of Mitapivat in pharmaceutical dosage form. Chromatographic separation of Mitapivat was achieved on Waters Alliance-e2695, by using Zorbax SB C18 (250x4.6mm, 5µ) column and the mobile phase containing ACN and Water in the ratio of 80:20% v/v. The flow rate was 1.0 ml/min; detection was carried out by absorption at 278nm using a photodiode array detector at ambient temperature. The number of theoretical plates and tailing factor for Mitapivat were NLT 2000 and should not more than 2 respectively. %Relative standard deviation of peak areas of all measurements always less than 2.0. The proposed method was validated according to ICH guidelines. The method was found to be simple, economical, suitable, precise, accurate & robust method for quantitative analysis of Mitapivat.

Key words: *HPLC Method, Mitapivat, ICH guidelines, Validation, Degradation studies.*

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SUBJECT: Letter of Acceptance MS/ IJBPAS/2024/8167

Dear Mr./ Ms./ Dr. BALUSU HAARIKA

We are very pleased to inform that your manuscripts No. **MS/IJBPAS/2024/8167:** Titled: **"FORMULATION AND EVALUATION OF ATORVASTSTIN CALCIUM ORO DISPERSIBLE TABLETS USING DESIGN EXPERT"** under consideration with **IJBPAS** have been approved by our editorial team for publication in the forthcoming issue **Volume 13(7) (Releasing in July 2024)** of **"International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)"**.

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Dear Mr./ Ms./ Dr. BALUSU HAARIKA

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Review Article

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SOLID DISPERSIONS: A TECHNIQUE OF SOLUBILITY ENHANCEMENT METHOD COMPREHENSIVE REVIEW

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ABSTRACT

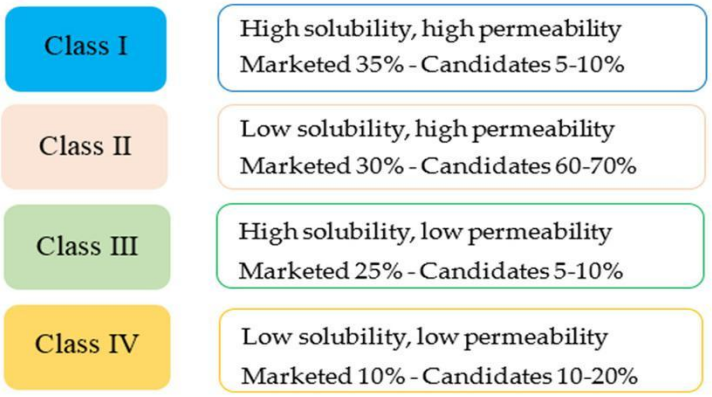
During preparation of every pharmaceutical formulation the main goal is to deliver the product with good bioavailability, because it is the main parameter that contributes to the therapeutic activity of the drug molecule. The major drawback in most of the formulations existing today is solubility which directly effects dissolution, poor dissolution effects bioavailability at end. To address the solubility problem of a drug molecule, we have many solubility enhancement methods for poorly water-soluble drugs such as Micronization, nanoparticles, use of salt forms and use of surfactant spray freezing etc. Every method has its own limitations, like in micronization of the drugs often leads to agglomeration and decreases the wettability.so, solid dispersions methods like hot melt extrusion, solvent evaporation, spray drying, supercritical fluid methods etc. are the promising methods to address all the problems of solubility and bioavailability. This article gives an overall view of solid dispersions and its role in improving solubility and bioavailability of poorly water-soluble drugs.

KEYWORDS: Solid dispersion, Bioavailability, supercritical fluid extraction, solvent evaporation, cellulose polymers, stability, solubility.

INTRODUCTION

Solid dispersions are dispersions of hydrophilic carrier and hydrophobic drug molecules dissolved in volatile-solvents such as methanol in which liquid solvent is removed by evaporation by applying reduced pressure which results in formation of amorphous precipitate of the drug [1]. Basically, they are two component systems, generally they are two component systems. First time solid dispersions are prepared by Sekiguchi and obi on drug sulfathiazole by using water soluble inert carrier. [2] As we know that amorphous form of drug is more soluble than its crystalline form so solid dispersions are the best approach for solubility enhancement. [3] In case of particle size reduction the agglomeration occurs, but in solid dispersions particles no need to exist in a micronized state. [4] The relation between solubility and permeability is clearly understood by

Biopharmaceutical system of classification



SOLUBILITY

Solid dispersions will enhance the solubility and permeability of class – 4 drugs.

Methods include:

1) Physical methods

Used for compounds which are non-molecular

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Research Article

FORMULATION AND *INVITRO* EVALUATION OF GLIMEPIRIDE MUCOADHESIVE MICROSPHERES

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ABSTRACT

Microspheres are free-flowing spherical particles made up of either proteins or synthetic polymers that are having sizes between 1 and 1000 µm. Microspheres are manufactured to obtain extended or controlled drug delivery to increase bioavailability and activity at the targeted site to a predetermined rate. By encouraging the production of insulin granules from the pancreatic islet beta cells, Glimepiride decreases blood sugar levels. Mucoadhesive drug delivery systems retain in the stomach for a longer period and avoid the first-pass effect. The current study's objectives are to increase gastrointestinal resident time and provide controlled oral release of Glimepiride. To achieve these goals, Glimepiride mucoadhesive microspheres were created using the ionic gelation process. The formulation of microspheres includes Glimepiride, Carbopol 934, Tragacanth, Sodium alginate, and Calcium chloride. Preformulation studies were conducted to evaluate drug excipient compatibility studies by FTIR. Formulated microspheres were evaluated for particle size, percentage yield, entrapment efficiency, swelling index, and % drug release. Among all GP3 formulation has shown the best % drug release, so selected as optimized formula. These *invitro* drug release results are subjected to kinetic studies of different models. It followed Peppas model indicates the mechanism of drug release i.e., release of drug from the formulation is by diffusion, erosion, swelling and may by the combination of diffusion and swelling.

INTRODUCTION

Microspheres are solid sphere-shaped particles with a diameter ranging from 1-1000 micrometers. They are freely moving spherical particles made up of proteins or artificial biodegradable polymers. (Sarlesh Rajput *et al*., 2015 and T. Virmani *et al*., 2017).

These drug delivery systems make use of the bioadhesion properties of particular polymers, where they become adhesive upon hydration and may thus be used for targeting specific area. The Adhesion that takes place between a biological substrate and an artificial membrane, for example adhesion between a polymer & a biological membrane. The "mucoadhesion" word is used to explain the attachment of a polymer to that of the mucosal tissue containing the mucin layer. Various approaches can be used to deliver mucoadhesive drug delivery systems such as buccal, oral, rectal, ocular, vaginal, nasal drug delivery systems. (B. SreeGiri Prasad, *et al* 2014, and D. Srinivasa Rao, *et al*., 2014).

METHODS AND MATERIALS

Glimepiride was obtained as a Gift sample from Hetero labs, Hyderabad. Carbopol 934, Tragacanth, Sodium alginate, and Calcium chloride were procured from SD Fine Chemicals Ltd.

Preformulation studies

Identification of drug and excipient compatibility study

The Spectral analysis of pure drugs and physical mixtures of drugs and various excipients used to create microspheres was investigated by FTIR (BRUKER).The sample was placed on aappropriate holder in an IR spectrometer and the spectrum was measured from 4000- 400 cm^{-1}. FTIR study was carried on the Glimepiride, polymers, physical mixture of Glimepiride and polymers individually. It was compared to look for any spectral alterations in the final spectrum.They were noticed when the corresponding functional groups in the test compounds had the expected peaks (S. Sivaprasad *et al*., 2022 and R. Saisree *et al*., 2019)

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Estimation Method for Dapagliflozin in Bulk and Marketed Dosage Form: Development and Validation by UV-Spectroscopy

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ABSTRACT

To develop a novel, sensitive method of spectrophotometric estimation in the UV region for the assay of Dapagliflozin in its tablet formulation and to validate all the parameters of the analysis as per ICH guidelines. Dapagliflozin was found to show its λ max at 220 nm using a UV-Vis spectrophotometer with a 1 cm quartz cell and methanol: water in the ratio of (15:85) for the preparation of stock solution (1000 µg/ml) and distilled water was used for further dilutions, for the preparation of working solutions. The technique used followed Beer's Lambert's law in the concentration range of 5–30 µg/ml, with a correlation value of 0.999. The limits of detection (LOD) and quantification (LOQ) were 0.623 µg/ml and 1.889 g/ml, respectively. The estimated percentage of the drug was nearly 103%, in good agreement with the marketed dosage form label **(Udapa*10).** Recovery experiments were carried out at three distinct levels, and the results were determined to be good. Furthermore, the findings of the methodologies devised for robustness and roughness are within their limitations. The suggested method is inexpensive, simple to use, and appropriate for regular analysis of dapagliflozin in bulk and commercial dose forms.

Key Words: *Dapagliflozin, UV-Spectrophotometer, Bulk and marketed dosage form, Validation*

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INTRODUCTION

Dapagliflozin is a Category III antidiabetic drug under the Biologics Classification System (BCS) of the European Medicines Agency (EMA). These inhibitors are a new class of antidiabetic drugs called flozins, which are more soluble and nearly impermeable [1]. It is a sodium-glucose co transporter 2 (SGLT2) inhibitor that works largely by inhibiting glucose reabsorption from the liver, resulting in higher urine glucose excretion and, as a result, decreased blood sugar levels in type 2 diabetes patients. The medication has demonstrated an enhanced mode of action that is independent of insulin and only depends on plasma glucose and renal function. Dapagliflozin is a pill that is taken orally. It is particularly effective in the treatment of type 2 diabetes mellitus (DM) patients, both as a single agent and in combination with other anti-diabetic medications. Recent studies have shown that the fast action of Dapagliflozin decreased the fasting plasma glucose levels within one week of treatment [2].

This is a crystalline white powder that is readily soluble [3] in methanol, ethanol, dimethylformamide, and dimethylsulfoxide. Chemically, it is (1S)-1, 5-Anhydro-1-[4-chloro-3-(4-ethoxybenzyl) phenyl]-D-glucitol with a molecular weight of 408.98 and a molecular formula of $C_24H_{33}ClO_8$. **Figure 1** depicts the chemical structure of Dapagliflozin.

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Acceptance Letter

To,

Targeting ER- α & ER- β Receptors: In Silico Predictions of Pregnane Glycosides from *Caralluma fimbriata*

Anuradha Bai Sandala[1], Neelima Kudumula[1], Muni Sireesha Sunkara[1], Saritha Jyotsna Tangeda[1], Vinutha Kuchana[*1]

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Dear Sir/Madam,

I have immense pleasure to inform you that your paper has been accepted and the editorial board agrees to publish your paper in the forthcoming issue of the journal ADVANCES IN BIORESEARCH Volume 14.

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DEVELOPMENT AND VALIDATION OF A DERIVATIVE SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF IMEGLIMIN IN BULK AND PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

Objective: To develop a novel, simple and economical derivative spectrophotometric method as the literature survey indicated that no method had been reported till date for the estimation of Imeglimin a new tetrahydrotriazine-containing class of oral antidiabetic agents, the "glimins" and also there is a need for a validated UV spectrophotometric method to estimate the drug in bulk and pharmaceutical dosage forms. **Materials and Methods:** A UV spectrophotometric method was developed on Shimadzu UV-1800 double beam spectrophotometer using water as solvent for all measurements. The maximum absorption of Imeglimin was found to be at 237 nm for zero order and the absorbance's at its first and second derivatives were measured at 236 nm and 240 nm, respectively. **Results:** The developed derivative method proved to be linear in the concentration range of 2-12 µg/ml for Imeglimin and shows a good correlation coefficient. The precision of the developed method was less than the maximum permissible limit (% RSD < 2) set by the ICH guidelines. The limit of detection (LOD) and limit of quantification (LOQ) were 0.306 µg/ml and 0.9299 µg/ml, respectively. Excellent % recovery (98% - 101%) with less than 2% RSD indicates that the method was accurate, also found to be robust and rugged for the intended use. **Conclusion:** The developed UV method was simple, eco-friendly, precise and accurate as per ICH guidelines.

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A REVIEW ON ANALYTICAL METHODS FOR ESTIMATION OF DAPAGLIFLOZIN AND VILDAGLIPTIN IN BULK AND IN PHARMACEUTICAL COMBINED DOSAGE FORMS

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ABSTRACT

Dapagliflozin and Vildagliptin both are anti-diabetic medications used to treat people with type-2 diabetes mellitus. Dapagliflozin lowers blood glucose levels and enhances urine glucose excretion. Vildagliptin causes extended enzyme inhibition by forming a covalent bond with the DPP-4 catalytic site. When a single medication is ineffective for treating high blood sugar, Vildagliptin and Dapagliflozin are both administered in combination. Numerous analytical techniques, including UV, HPLC, LC-MS, and HPTLC approaches, have been developed for the determination of Dapagliflozin and Vildagliptin in pharmaceutical dosage form and bulk form. The study that follows shows a review of analytical techniques that covers estimating type-2 diabetic medication.

Keywords: Dapagliflozin, Vildagliptin, UV-spectroscopy, RP-HPLC.

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New Validated UV-Spectrophotometric Method for the Determination of a New Pregabalin Derivative in Capsule Dosage Form

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Abstract
Pregabalin, an anti-epileptic drug has very low UV absorptivity and hence normally it is difficult to analyze this drug by UV Spectroscopy. Benzene sulfonyl chloride, a derivatizing agent, was used to introduce a chromogen for the purpose of detecting pregabalin in bulk and capsules. A wavelength of 205nm was used to find the pregabalin after derivatization by UV-spectroscopy. The spectrophotometric validation parameters such as linearity, precision, accuracy, robustness, and ruggedness were studied and verified using the ICH guidelines. With a correlation coefficient of 0.999, the linearity between 20µg/ml and 100µg/ml was observed. The intermediate and intraday precision's respective RSDs were found to be 1.27% and 1.40%. The accuracy concentration range was spiked at 50%, 100%, and 150%, and the %recovery values were found to be in the range of 95.7% to 99.4%. The method was found to be rugged and robust. Without any interference from typical excipients, the devised approach was effectively verified and applied to the detection of pregabalin in bulk and pharmaceutical formulation.

Keywords
Absorbance, Derivative, Methanol, Pregabalin, UV

*****

INTRODUCTION
Pregabalin is chemically known as (S)-3-(aminomethyl)-5-methyl hexanoic acid, commonly used to control seizures & convulsions. Although pregabalin is a derivative of GABA (γ-aminobutyric acid), it has no impact on GABA receptors. The two primary manifestations of neuropathic pain, allodynia, and hyperalgesia are lessened by pregabalin. Additionally, it acts as an analgesic, anxiolytic, and in the management of opioid withdrawal.[1]

Pregabalin is a saturated carboxylic acid that lacks π electron density. It has very low UV absorptivity and hence it is difficult to accurately estimate it by UV spectroscopy. Chemical derivatization of this molecule increases its UV absorptivity. Earlier workers have analyzed pregabalin by UV-Visible spectrometry after carrying out its derivatization with reagents like xanthone, ninhydrin, ascorbic acid etc.[2,3] For UV-spectroscopic studies of pregabalin, mostly methanol was used as solvent.[4,5] Apart from UV-spectrophotometry,[6-10] HPLC[11-17] and hyphenated techniques like LC-MS-MS,[18,19] SPE-LC-MS/MS using PFP HPLC column[20] were used to estimate pregabalin. All of the strategies that have been described so far involve intricacy in derivatization and evaluation. Hence the present work was aimed to prepare a simple, stable,

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REVIEW ON TRANSDERMAL DRUG DELIVERY SYSTEMS

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Abstract

The transdermal drug delivery system (TDDS) is generally accepted mode of drugdelivery, & transdermalpatchesare used to treat various diseases. (1) They lead to over-injectable &oral routes by increasing patient compliance &avoiding the first-passmetabolism. They can prevent drug-related gastrointestinal problems & low absorption (2). These healing benefits reflect the higher marketing potential of TDDS (3). More & more research being carried out in this field & increasing interest ofresearchers in the form of drug delivery, number of transdermal devices reaching the market place are expected to increase sharply. The aim of review is to present latest explorations carried out in recent years utilizing possible drug candidates. New polymer along with novel penetration enhancers have been presented. Most of the researchers have been utilizing HPMC as the preferred film forming polymer but recently use of Eudragit grades also has gained interest amongst scientists.

Keywords: Transdermal patches,methods, evaluation, polymers,

Introduction

Oral route of drug delivery has excessed the route of choice for drug delivery to systemic circulation from centuries back for therapeutic effectiveness due to well-known advantages of patient compliance & ease of self-administration (4,5).

Transdermal route of drug delivery, hence appears to be a good alternative approach of oral route as it eliminates chances of drug loss by hepatic metabolism & provides heal their patient compliance as opposed to other routes like parenteral route. (6,7)

Transdermal patches is a self-contained dosage that is applied to intact skin &provides drug in a controlled manner. (8) Due to continuous success, currently, 35 TDDS patches are in the market for various diseases like hypertension, angina pectoris, motion sickness, female menopause, & male hypogonadism (9).

The market share for transdermal delivery $12.7 billion in the year 2005, which rose to $21.5 billion in the year 2010, $31.5 billion in the year 2015, & increasing every year.

Advantages

- First pass metabolism of drug gets avoided.
- They can be improved bioavailability.
- They can inter and intra patient variation to be avoid & they can enhance therapeutic efficacy.
- They can be maintained drug plasma concentration.
- Gastrointestinal incompatibilities get avoided.

Disadvantages

- They have chances of allergic reactions at the site of application like itching, rashes, local edema etc.
- They are not suitable for high drug doses.
- They may occur skin irritation & hyper sensitivity reactions.
- They can be delivered only small, lipophilic drugs currently through the skin.

Structure of skin

Skin is the largest organ of the body. These are having three main layers, epidermis, dermis, & subcutaneous layer.

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A REVIEW ON MUCOADHESIVE BUCCAL TABLETS

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ABSTRACT: Mucoadhesive drug delivery systems interact with the mucus layer covering the mucosal epithelial surface, and mucin molecules and increase the residence time of the dosage form at the site of absorption. Bioadhesion may be defined as the state in which two substances, at least one of which is of a biological nature, are held together for extend periods of time by interfacial forces Mucosal layer represents potential sites for the attachment of any bioadhesive systems because mucosal layer lines number of the body including the gastrointestinal tract, the urogenital tract, vaginal tract, eye, ear, and nose. The drugs which have local action or those which have maximum absorption in gastrointestinal tract (GIT) require increased duration of stay in GIT. Thus, mucoadhesive dosage forms are preferable in increasing the drug plasma concentrations and also therapeutic activity. In this regard, this review covers the areas of structure and function of oral mucosa, mechanisms and theories of Mucoadhesion, factors affecting oral absorption and also various mucoadhesive dosage forms. Buccal tablets were characterized for number of parameters like Hardness, weight uniformity, thickness, % friability, swelling index, mucoadhesive strength, surface pH, drug–excipient interaction study, drug content uniformity and In vitro drug release study.

Index Terms: **Mucoadhesive drug delivery, Mucoadhesion/Bioadhesion, Theories, Polymers, Mucoadhesive dosage forms.**

INTRODUCTION:

The mucosa of the mouth is very different from the rest of the gastrointestinal tract and morphologically is more similar to skin. Although the permeability of skin is widely regarded as poor, it is not generally appreciated that the oral mucosa lacks the good permeability demonstrated by the intestine. These differences within the gastrointestinal tract can largely be attributed to the organization of the epithelia, which serve very different functions. A simple, single-layered epithelium lines the colon, stomach, and small intestine, which provides for a minimal transport distance for absorbents. In contrast, a stratified or multi-layered epithelium covers the oral cavity and oesophagus and, in common with skin, is composed of layers with varying states of differentiation or maturation evident on progression from the basal cell layer to the surface. Drugs have been applied to the oral mucosa for topical applications for many years. Although, recently there has been interest in utilizing the oral cavity as a portal for delivering drugs to the systemic circulation. Notwithstanding the relatively poor permeability characteristics of the epithelium, a number of advantages are offered by this route of administration. Major among these are the avoidance of first-pass metabolism, ease of access to the delivery site, and the opportunity of sustained drug delivery principally via the buccal tissues [(1)].

Various advantages and aspects of this buccal route are elucidated of the following:

Advantages of mucoadhesive buccal drug delivery:

Drug administration via the oral mucosa offers several advantages

1. Easy of administration and termination of therapy in emergency.
2. Permits localization of the drug for a prolonged period of time.
3. Can be administered to unconscious and trauma patients.
4. Offers an excellent route for the systemic delivery of drug which by passes first pass metabolism, there by offering a greater bioavailability.
5. Significant reduction in dose can be achieved, thereby reducing dose, dose dependent side effects, and eliminates peak-valley profile.
6. Drugs which are unstable in acidic environment of stomach or are destroyed by the enzymatic or alkaline environment of the intestine can be administered.
7. It offers a passive system for drug absorption.

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A REVIEW ARTICLE ON DELAYED RELEASE TABLETS

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Abstract:

A delayed release dosage form is designed/intended to release the drug from the dosage form at a time other than promptly after administration or after the tablet pass GI tract. A common example for the delayed release tablets is Enteric coated tablet such that all the enteric coated tablets are Delayed release tablet's but not all delayed release tablets are enteric coated. Delayed release dosage form is best formulations which are used for drugs that are destroyed in the gastric fluids, or cause gastric irritation, or are absorbed preferentially in the intestine. Such preparations contain an alkaline core material comprising the active substance, a separating layer and enteric coating layer. This review focus on the types of ER tablets, Method of preparation of tablets, defects in tablets, mechanisms involved for release of drug in extended release tablets and advantages of DR tablets over conventional tablet.

Key word: Extended release, Tablet, Concentration, Defects, Granules, Coating etc.,

INTRODUCTION:

1. ORAL DRUG DELIVERY:

Oral route is the most preferred route of drug administration among all routes that have been explored for the systemic delivery of drug via various pharmaceutical products of different dosage form as they being user friendly route of administration. Powders, pills, cachets, capsules or tablets administered orally as Solid medicaments. These dosage forms contain a quantity of drug which is given as a single unit and they are known collectively as solid unit dosage forms. The stringent formulation requirements of modern medicaments, the many advantages of tablet and capsule medication and currently they account for well over two third of the total number and cost of medicines produced all over the world.

2. TABLETS

Tablets are solid dosage forms usually obtained by single or multiple compression of powders or granules. They are uncoated or coated. Tablets are normally right circular solid cylinders, the end surfaces of which are flat or convex and the edges of which may be bevelled. Tablets containing active ingredients having a narrow therapeutic window should generally not be presented with break-marks for subdivision. Tablets containing active ingredients having a narrow therapeutic window should generally not be presented with break-marks for subdivision.

Advantages:

1. The unit dosage form having greatest capabilities amongst all the oral dosage form.
2. Low cost, Lighter and compact.
4. Easiest and cheapest to package and strip.
5. Easy to swallowing with least tendency for hang- up.
6. Sustained release product is possible by enteric coating.
7. Objectionable odour and bitter taste can be masked by coating technique.

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A REVIEW OF FLOATING DRUG DELIVERY SYSTEM

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ABSTRACT: The principal objective behind the writing of this article on the floating drug delivery system (FDDS) was to systematize the recent literature with the core process of floatation in acquiring gastric retention. Oral administration is the most convenient and preferred means of any drug delivery to the systematic circulation. The different strategies used in the development of FDDS by constructing the effervescent and non-effervescent type of floating tablets basis of which is buoyancy mechanism. FDDS is a method to deliver the drugs that are active locally with a narrow absorption window in the upper gastrointestinal tract, unstable in the lower intestinal environment, and possess low solubility with higher pH values. Floating dosage forms can be delivered in conventional forms like tablets, capsules with the addition of suitable ingredients along with the gas generating agent.

Index Terms: **Gastro retentive system, Floating drug delivery system, Single unit, Multiple units.**

INTRODUCTION:

Oral administration is the most convenient and preferred means of any drug delivery to the systematic circulation. Oral controlled release drug delivery has recently been of increasing interest in pharmaceutical field to achieve improved therapeutic advantages, such as ease of dosing administration, patient compliance and flexibility in formulation. The solid oral dosage forms such as capsule, tablets give specific drug concentration in systemic blood circulation without getting any control over drug delivery system and also cause major fluctuations in plasma drug concentrations. Floating drug delivery systems (FDDS) are invented to retain the drug in the stomach and applicable for drugs with poor solubility and low stability in intestinal fluids. The basis behind FDDS is making the dosage form less dense than the gastric fluids to make it float on them. FDDS are hydro-dynamically controlled low-density systems with sufficient buoyancy to float over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. The residual system is emptied from the stomach with the release of the drug. This results in enhanced gastric residence time and good control over plasma drug concentration fluctuations. The principle of buoyant preparation offers a simple and practical approach to achieve increased gastric residence time for the dosage form and sustained drug release [1]. Prolonging the gastric retention of a delivery system is desirable for achieving the greater therapeutic efficacy of the drug substance under certain circumstances. For example, drugs which show better absorption at the proximal part of the gastrointestinal tract and drugs with low solubility and get degraded in alkaline pH found efficient in prolonging gastric retention. In addition, for sustained drug delivery to the stomach and proximal small intestine in treating certain ulcerative conditions, prolong gastric retention of the therapeutic moiety and hence offer numerous advantages including improved bioavailability and therapeutic efficacy with reduction of dosing frequency [2].

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REVIEW ON BILAYER TABLETS

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ABSTRACT: Bilayer tablets can be a primary option to avoid chemical incompatibilities between API by physical separation, and to enable the development of different drug release profiles like the immediate release with extended release. Bilayer tablet is a very different aspect of anti-inflammatory and analgesic. In the last decade interest in developing a combination of two or more API's in a single dosage form has increased in the pharmaceutical industry, promoting patient convenience and compliance. Bi-layer tablet is suitable for sequential release of two drugs in combination, separate two incompatible substances and also for sustained release tablet in which one layer is immediate release as initial dose and second layer is maintenance dose. There are various applications of the bi-layer tablet consists of monolithic partially coated or multilayered matrices. Several pharmaceutical companies are presently developing bi-layer tablets, for a variety of reasons patent extension, therapeutic, marketing to name a few. Several pharmaceutical companies are presently developing bi-layer tablets, for a variety of reasons patent extension, therapeutic, marketing to name a few.

Keywords– *bilayer tablets, synergistic effect, combination therapy, challenges, compliance.*

I. Introduction

Now a days various developed and developing countries move towards a combination therapy for treatment of various diseases and disorders requiring long term therapy such as hypertension, Diabetes and Cardiovascular diseases 1. Over 90% of the formulations manufactured today are ingested orally. It shows that this class of the formulation is the most popular world wide and the major attention of the researcher is towards this direction. The major aim of controlled drug delivery is to reduce the frequency of dosing 2. The design of modified release drug product is to optimize a therapeutic regimen by providing slow and continuous delivery of drug over the entire dosing interval providing greater patient compliance and convenience. Bilayer tablet is the newer a for the successful development of controlled release formulation and better than the traditionally used dosage forms. Bilayer tablet is suitable for sequential release of two drugs in combination it is also capable of separating the two types of incompatible substances and also for sustained release tablet in which one layer is immediate release as initial dose and the second player is maintenance dose. In certain cases bilayered tablets have 2 sustain release layers of of different drugs 3. Bilayer tablet is an improved technology to overcome the short coming of the single layered tablet. Player tablets contain immediate, sustained release layers, and the immediate release layer delivers the initial dose, it contains superdisintegrates, which promotes the drug release rate and attains the onset of action quickly (loading dose) where as sustained release(maintenance dose) layer releases the drug in a sustained manner for a prolonged time period4- 5. The biphasic system isused mostly when maximum relief needs to be achieved quickly and it is followed by a sustained release phase. It also avoids repeated administration of a drug. Coronary vasodilators, antihypertensive, antihistamines, analgesics, antipyretics and antiallergenic agents are mainly suitable for this type of drug delivery6. Some bilayer tablets have both the layers as the sustain release layers examples are a certain antidiabetic agents7-8.

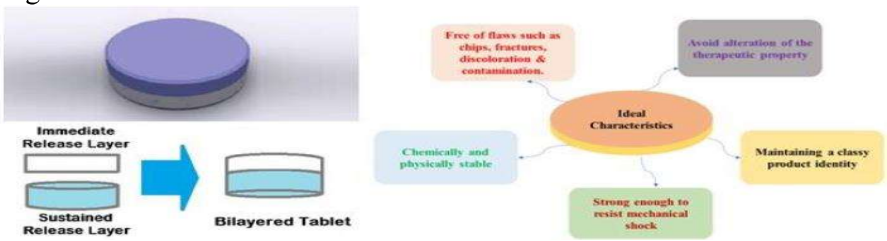

Figure 1: Bi layer tablet and characteristics

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REVIEW ON FLOATING BEADS

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ABSTRACT:

The recent scientific and patented literature concluded that an increased attractiveness in novel dosage forms which retained in the stomach for predictable and prolong period of time has been shown. Floating beads are often having gastro retentive property without affecting the gastric emptying rate they are used for controlled drug release. Floating beads drug delivery systems are mainly based on non-effervescent system. Floating beads is useful for various categories of drugs which act locally in stomach, poorly soluble in alkaline pH, having narrow absorption window, unstable in intestine or colonic environment and primarily absorbed in stomach. Floating dosage forms can be prepared by using different method of preparation such as tablets, capsules by adding suitable ingredients as well as by adding gas generating agent. It is expected that pharmacotherapy of drugs may enhance by floating beads. Several approaches are currently utilized in the prolongation of the GRT, including floating drug livery system, swelling and expanding systems, polymeric Bio adhesive systems, high-density systems, modified-shape systems and other delayed gastric emptying devices. Floating dosage forms are emerging as a promising dosage forms. Gastro retentive delivery systems can be retained in the stomach and assist in enhancing absorption and the bioavailability of drug which has a narrow absorption window in a particular region of gastrointestinal tract. Floating beads are formulated for various drugs those which are available for treatment of diseases like gastric ulcers, duodenal ulcers, zollinger-ellison syndrome, hypertension and gastro oesophageal reflux disease etc. In this review types, method of preparations, evaluation techniques, advantages, limitation and applications of floating beads are discussed.

Index Terms-Floating beads, Gastro retentive, Gastric time, Gastric emptying.

1.INTRODUCTION:

The Oral route is most convenient and extensively used dosages form. Primarily due to ease of administration this route has high patient acceptability [1-4]. The goal of any drug delivery system is to maintain the desired drug concentration by releasing a therapeutic amount of drug to the specific site in the body [5]. Gastric emptying is a complex process that is highly variable and makes the in vivo performance of drug delivery systems. All these physiological problems are overcome by drug delivery systems with prolonged gastric retention time. Gastro retentive drug delivery is an approach to enhance gastric residence time, thereby targeting to a specific site and shows local or systemic effects. Floating systems or hydro dynamically controlled systems are low density systems which have sufficient buoyancy to float over the gastric contents and remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. [6] While the particulate is floating in the gastric content; the drug is released slowly from the particulate at a desired rate. Carbon dioxide gas forming agents such as carbonates or bicarbonates are commonly used as material in FDDS.

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A REVIEW ON MICROBALLOONS

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ABSTRACT

Microballoons also known as hollow sphere drug delivery systems. These are typically spherical in size from 200 microns and do not have a core. They have a gastric retention drug delivery system (GRDDS), which can improve drug bioavailability and reduce stomach irritation. These floating microballoons have the convenience that they stay buoyant and circulate uniformly over the gastric ingredients to withhold the variations of gastric emptying and release the drug for extended period of time. It's floating containing synthetic polymers that improves the processing of solid dosage forms such as tablets, capsules and powders. Due to the presence of hollow space inside the microballoons, these improve gastric drug therapy and gastric mucosal concentration which helps reduce drug residence time in the stomach. It is less soluble at higher pH. The formulation of these Microballoons depends on temperature, preparation and surface smoothness to increase the buoyancy of a good propellant as it uses a multiple unit system. It helps to treat peptic ulcers, chronic stomach problems and Rheumatoid arthritis.

KEYWORDS: Microballoons, Hollowspheres, Gastric Retention Drug Delivery Systems, Buoyant agent, Floatability, Bioavailability.

INTRODUCTION

Microballoons are drug delivery systems and these microballoons show promise as a specific approach for the treatment of gastric retention. Microballoons are based on a non effervescent system consisting of spherical hollow particles without a core, ideally these are 200 microns in size. These microballoons are free flowing powders composed of proteins and synthetic polymers. In general, microballoons are a low density system with sufficient buoyancy to float on gastric fluid for long periods of time without irritating the gastrointestinal tract.[1] these are prepared by different techniques such as single solvent evaporation method, double emulsification method, spray drying method, polymerization method, coagulation method by spraying and the hot melt encapsulation method.[2] The drug is slowly released at the desired rate, resulting in increased gastric retention and reduced fluctuations in plasma drug concentration. By reducing the frequency of administration, the microballoons can improve patient compliance and provide better efficacy of drug therapy and a short halflife can be achieved. Absorption of drugs dissolved only in the stomach is increased, so gastric residence time is increased due to buoyancy.[3] Polymers such as Eudragit RS-100,Eudragit RL-100, Eudragit S, ethyl cellulose, Dichloromethane (DCM), ethanol, water and HCL have been used in

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Review Article

TRANSDERMAL DELIVERY OF DRUGS USING TRANSFEROSOMES: A COMPREHENSIVE REVIEW

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ABSTRACT

Transdermal delivery systems have gained popularity as a non-invasive method of drug administration that offers several advantages over other routes of drug delivery. They are noninvasive and self-administered delivery system which improves patient compliance and provide a controlled release of the drug. The greatest challenge of transdermal delivery systems is that in which the outermost layer of skin acts as a barrier function for transfer of therapeutic agent into the body. Molecules with high molecular weights do not pass through the skin. Therefore, only a limited number of drugs are administered by this route. So encapsulating the drugs in transfersomes is one of the best approaches to overcome this problem. Transferosomes are lipid based vesicular drug delivery systems which have a unique composition that allows them to overcome the limitation of conventional drug delivery system. They are composed of phospholipids and surfactants, which provide them with the ability to encapsulate both hydrophilic and hydrophobic drugs. They penetrate through stratum corneum by either intracellular route or the transcellular route by the generation of natural osmotic gradient. Compared to conventional drug delivery systems, transferosomes offer several advantages like avoidance of first pass metabolism, increasing bioavailability of drugs. Due to its high deformability it enhances the penetration of intact vesicles. Transferosomes vary from other conventional vesicles due to their softer, better adjustable and ultra deformable artificial membranes. This review summarizes the concept of transfersomes, including their structure, formation mechanism of action, different methods of preparation, advantages, limitations along with applications.

Keywords: Osmatic gradient, Stratum corneum,Transfersomes, Transdermal delivery system

1. INTRODUCTION

Drug delivery systems are crucial in the development and administration of pharmaceutical, with the aim of achieving a safe and effective therapeutic response. The design and development of drug delivery systems have been an area of reducing toxicity, and increasing patient compliance [1]. Therefore many drug delivery systems have been developed and studied over the past decades to overcome these problems. One of the promising approaches is the use of transdermal delivery systems, as they are less invasive methods without first-pass metabolism. Transdermal drug delivery system delivers medicine through the skin to systemic circulation at a predetermined rate and maintain effective concentrations over a prolonged period of time, they are noninvasive and self administered delivery system [2]. Delivery of drug through the transdermal route is convenient and safe this offers several advantages over conventional systems. The major drawback of TDDS is the permeability of the skin, it is permeable to small molecules, lipophilic drugs and impermeable to macromolecules and hydrophilic drugs. The major disadvantage of transdermal drug delivery is the poor penetration of compounds across the skin. The major barrier and rate limiting step for diffusion of drug across is provided by the skin, stratuem corneum. Many investigations are done to develop systems that are capable of carrying drugs and macromolecules into the deeper tissues. These approaches have resulted in developing of novel vesicular carriers like ethosomes and ultra flexible lipid based elastics vesicles transferosomes [3].

2. TRANSFEROSOMES [4-5]

The name means carrying body, and is derive from the Latin word *Transferred* meaning across, and Greek word

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RESEARCH ARTICLE

TRANSFERSOMES AS NOVEL DRUG DELIVERY SYSTEM

Mounika K., Praneetha P. and Srinivas N.
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Key words:-
Transferosomes, Transdermal drug delivery system, Transcellular route, Vesicular drug delivery system

Abstract

Transdermal drug delivery appears to be most vital drug delivery system because of its merit over conventional systems. Transferosomes & the fundamental concept of transfersomes were launched by Gregor Cevc in the year 1991. The name means "carrying body" and is derived from the Latin word 'transferre', meaning 'to carry across' and the Greek word 'soma', meaning 'a body'. Novel drug delivery system aims to deliver the drug at a rate directed by need of body during the period of treatment and channel the active entity to the site of action. Transferosome is one of the novel vesicular drug delivery system which consists of phospholipids, surfactant and water for enhanced transdermal delivery. Transferosomes are able to reach intact deeper regions of the skin after topical drug administration while delivering higher concentrations of active substances making them a successful carrier for transdermal applications. These vesicular systems can deliver low as well as high molecular weight compounds. Targeted and controlled release formulations can also be prepared by transferosomes as it can accommodate drug molecules with wide range of solubility. Various strategies can be used to augment the transdermal delivery which includes iontophoresis, electrophoresis, sonophoresis, chemical permeation enhancers, microneedles, & vesicular system (liposomes, niosomes, elastic liposomes such as ethosomes & transfersomes). It exists as an ultra-deformable complex having a hydrated core surrounded by a complex layer of lipid. It penetrates the stratum corneum by either intracellular route or the transcellular route by the generation of "osmotic gradient". Advantages of Transferosomes are wide range of solubilities, better penetration, biocompatible and biodegradable etc. Disadvantages of Transferosomes are oxidative degradation, expensive, etc. The transfersomes were formulated by the conventional rotary evaporation sonication method. Transferosomes can be applied in controlled release, transportation of large molecular weight compounds, target delivery to peripheral subcutaneous tissues, transdermal immunization etc.

Introduction:-

Transfersomes is a promising vesicular carrier for improved drug permeation through skin [1,2]. Transfersomes means "carrying body" that is derived from the Latin word "transferred" for carrying and "soma" for a body. These

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Transdermal patch: An effective transdermal drug delivery system

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Abstract
Transdermal drug delivery systems (TDDS) are topically administered medicaments. Transdermal drug delivery is defined as a self contained discrete dosage form, which when applied to the intact skin, will deliver the drug at a controlled rate to the systemic circulation. Transdermal patches are pharmaceutical preparation of varying sizes, containing, one or more active ingredient, intended to be applied to the unbroken skin in order to deliver the active ingredient to the systemic circulation after passing through the skin barriers. Compared to oral or systemic dosage systems, TDDS can offer a controlled release of the drugs through the skin into the patients, which could reduce the first-pass metabolism effects, lessen systemic side effects, improve the dosage efficacy by enabling steadier blood drug profiles throughout the treatment, and enhance patient compliance. Through a diffusion process, the drug enters the bloodstream directly though the skin. Since there is high concentration on the patch and low concentration in the blood, the drug will keep diffusing into the blood, the drug will keep diffusing into the blood for a long period of time, maintaining the constant concentration of drug in the blood flow. Characterization of transdermal patch is used to check it's quality, size, time of onset & duration, adhesive property, thickness, weight of patch, moisture content, uniformity & cutaneous toxicological studies. The present poster discusses the methods of preparation, characterization and applications of transdermal patches.

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Keywords: Controlled release, charaterization, first-pass metabolism, transdermal patch

Introduction

In recent years, vesicular systems have gained prominence as a method for achieving sustained or controlled drug release. The term ‘’Transferosome’’ and its associated concept were first introduced in 1991 by Gregor Cevc. The name “Transferosome” originates from the latin word ‘Transfer’ meaning “to carry across” and the Greek word “soma” referring to a body [1].

In many instances, achieving an effective therapeutic treatment is challenging due to various factors, including hepatic first-pass metabolism, unwanted side effects, resistance to invasive treatments, and patient non-compliance. As a result, researchers have focused on developing drug delivery systems in recent decades to address these issues. Among these approaches, transdermal delivery systems stand out as a promising solution, offering minimally invasive administration without first-pass effects [2].

Vesicles are employed in transdermal drug delivery due to their dual role: they serve as carriers for delivering encapsulated drugs through the skin and also function as penetration enhancers due to their specific composition [3].

Numerous chemical and physical methods have been employed to enhance the effectiveness of material transfer through intact skin. These approaches include penetration enhancers, iontophoresis, sonophoresis, and the utilization of colloidal carriers like lipid vesicles such as liposomes and proliposomes as well as non ionic surfactant vesicles like niosomes and proniosomes [4].

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Estimation of a New Gabapentin Derivative in Capsule Dosage Form by New Validated UV Spectrophotometric Method

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Abstract

A new simple, sensitive, and economic spectrophotometric method has been developed and validated for the determination of a new gabapentin derivative in pure form and pharmaceutical preparations. The method is based on the reaction between the amino group of gabapentin with benzene sulphonyl chloride to form the gabapentin derivative (sulphonamide) via addition-elimination mechanism. The new gabapentin derivative was prepared by two different methods using sodium carbonate (method 1) and sodium hydroxide (method 2). The colourless product obtained was analysed by TLC. In UV-spectrophotometry, its absorption maximum was found to be 275nm in ethanol. The linearity range for the new gabapentin derivative was found to be 2-10 µg/ml. Accuracy was performed at three concentration levels of 50%, 100% and 150% and the respective percentage recoveries were found to be 1.34,1.06 and 0.68. Precision results were found to be within the limits of acceptance criteria and the method was found to be robust with % RSD less than 2.0. The LOD and LOQ values were found to be 0.28µg/mL and 0.86µg/mL respectively.

Keywords

Derivative, Gabapentin, Spectrophotometry

*****

INTRODUCTION

A cyclic analogue of GABA [gamma-amino butyric acid] is Gabapentin [1-(amino methyl)-cyclohexane acetic acid] **(Fig. 1)**. It is frequently utilized to treat pain, particularly neuropathic pain, and nystagmus **[1-3].** Most patients tolerate it well, it has a modest side effect profile, and it is not metabolized as it leaves the body. It is believed to bind to the voltage-dependent calcium channel's subunit 2 in the central nervous system.

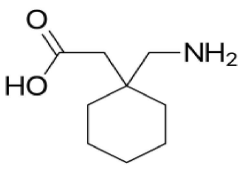

Fig. 1: Chemical structure of Gabapentin

Gabapentin has been estimated by various spectrophotometric and spectrofluorimetric methods **[4-9],** thin-layer chromatography (TLC), high-performance liquid chromatography (HPLC) **[10-14],** high performance thin layer chromatography (HPTLC) **[15, 16],** Gas chromatography (GC) **[17],** capillary electrophoresis **[18]** and potentiometric methods **[19]**.

Gabapentin has very low UV absorptivity and hence it is difficult to accurately estimate it by UV spectroscopy. Chemical derivatization is adopted by few of them to convert the non-UV absorbing gabapentin into its derivatives which can be easily detected with high sensitivity **[20]**. However, the number of such reports are very few and they suffer with some disadvantages associated with stability,

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Analytical Method Development and Validation for Esomeprazole by Using UV Spectrophotometric Method

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ABSTRACT

A simple, sensitive UV-spectrophotometric technique was developed and validated to measure esomeprazole in bulk and various dose forms. Esomeprazole has the highest absorbance at 299nm by using methanol as a solvent. Many analytical performance criteria, such as linearity, precision, accuracy, and robustness, were also determined using ICH recommendations. LOD and LOQ were determined from the regression equation. The linearity range was found to be 2-10µg/ml, the %RSD for repeatability was found to be less than 2, and the correlation coefficient (r2) was 0.999. The % mean recovery was found to be for the different concentrations for 98-99.23% for esomeprazole. %Assay was found to be between 98.1-98.3.The findings of the analysis were statistically confirmed and supported by recovery studies.

Keywords: Esomeprazole, methanol, UV-Visible spectrophotometry, Validation

INTRODUCTION

Esomeprazole is used to treat the disease known as excessive stomach acid production. Gastro-oesophageal reflux disease (GORD), a condition that causes persistent acid reflux, indigestion, heartburn, and acid reflux, is usually treated with it. Brands include Nexium and Vimovo. Molecular Weight: [345.41g.mol-1] and Molecular Formula: [C17H19N3O3S]. The bioavailability ranges from 50 to 90%, while the elimination half-life is between 1.1 and 1.5 hours.

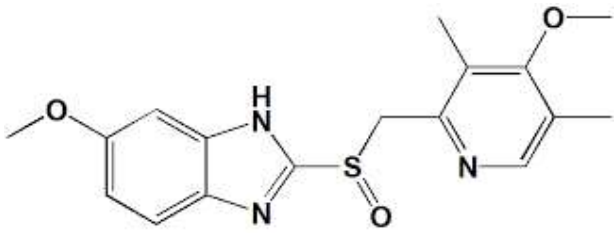

Figure 1: Esomeprazole Structure

Iupac name: (S)-(-)-5-Methoxy-2-[(4-methoxy-3,5-dimethylpyridin-2-yl)methylsulfinyl]-3H-benzoimidazole.

The experimental data underwent statistical validation in order to confirm the suggested method's precision, accuracy, and reproducibility.

Mechanism: Esomeprazole works by specifically inhibiting H+/K+-ATPase in the gastric parietal cell to reduce stomach acid production.

MATERIAL AND METHODS

Equipment's utilized

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Cleaning Method Development and its Validation for Quantification of Cinacalcet API Using UV Spectroscopy

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ABSTRACT

Simple, precise and cost effective cleaning method and validation by UV spectrophotometry has been developed for the estimation of Cinacalcet shows λmax at 279nm . The drug follows Beer-Lambert law in the concentration range of 2-10 µg/ml with correlation coefficient of 0.999. The method was validated by following analytical performance parameters suggested by the international conference on harmonization. All validation parameters were within the acceptable range. The developed method was successfully applied to estimate the amount of cinacalcet.

Keywords: cleaning method , Cinacalcet, UV spectrophotometry.

INTRODUCTION

Cinacalcet hydrochloride is an oral calcimimetic that is used to treat patients with parathyroid cancer and dialysis-dependent patients with end-stage renal disease (ESRD) in order to lower hypercalcaemia and treat secondary hyperparathyroidism (HPT)[1]. The first of a new class of medications known as calcimimetics, which function by making the parathyroid gland's calcium detecting receptors more sensitive,[2] is cinacalcet hydrochloride1, 2, 3. Cinacalcet hydrochloride is chemically represented as N-((1R)-1-(1-Naphthyl) ethyl)-3-(3-(trifluoromethyl) phenyl) propan-1-amine hydrochloride (Fig. 1).

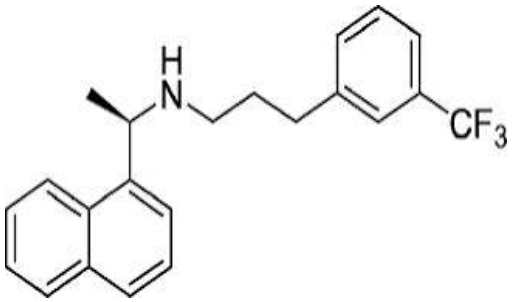

Figure 1: Cinacalcet hydrochloride's structure is displayed[3].

According to a review of the literature, many analytical techniques have been described for the measurement and identification of each drug separately in human plasma using tandem mass spectrometry and liquid chromatography[4-6]. There hasn't been a spectrophotometric approach for estimating cinacalcet hydrochloride using the two straightforward methods published in the literature. As a result, a straightforward, quick, accurate, and exact approach is created and verified for the estimation of cinacalcet hydrochloride in bulk and pharmaceutical formulation[7-10].

MATERIAL AND METHODS

Dr Reddy's provided samples of cinacalcet hydrochloride . 30 mg commercial PTH pills (Intas Pharma) were bought from a nearby market and utilised before the end of their shelf life. The other compounds that were employed were all analytical or pharmaceutical grade. Instruments For the purpose of measuring absorbance and spectrum, a LABINDIA double beam UV-visible spectrophotometer (Model: UV-3200) with a fixed bandwidth (1.5 nm) and a 1 cm quartz cell was employed. Furthermore, this study made use of an electronic balance, a micropipette, and a sonicator.

A CRITICAL REVIEW ON CINACALCET; ANALYTICAL PROFILE AND RECENT ADVANCEMENTS

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ABSTRACT

A medication called cinacalcet hydrochloride (CNA) is used to treat both hypercalcemia and hyperthyroidism. Thyroid hormones are overproduced, which results in hyperthyroidism. Similar to hypercalcemia, hypercalcemia is a condition in which the blood's calcium level is elevated. This review article discusses the reported analytical methodologies for the measurement of CNA in API (Active Pharmaceutical Ingredient) and pharmaceutical dosage forms using a thorough computer assisted literature survey. The current write-up also includes numerous study publications that have been published, such as those that use spectroscopic techniques, , HPTLC, and HPLC procedures. Along with this, hyphenated strategies related to CNA estimate were also covered. Although many techniques were mentioned in the literature, HPLC stands out as the most effective for measuring CNA.

Keywords: Analytical methods, HPLC, Cinacalcet hydrochloride, Hypercalcemia, Hyperthyrodism,

INTRODUCTION

Cinacalcet Hydrochloride (CNA), a calcimimetic that has been approved to treat secondary hyperparathyroidism in individuals receiving chronic dialysis, Hypercalcemia and kidney disease (CKD) in people with parathyroid carcinoma.[1].N-[(1R)-1-naphthalen-1-ylethyl] cinnacalcet hydrochloride-3-[3-(trifluoromethyl) phenyl] propan-1-amine;hydrochloride[2]. CNA has the chemical formula C22H22F3N.HCl and a molecular weight of 357.41 g/mol as a freebase and 393.87 g/mol as a salt of HCl.It is a white to off-white, crystalline solid that is somewhat soluble in water, methanol, and 59% ethanol. CNA has a pKa value of 8.72 (Strongest Base: 10.3) and a melting point between 175 and 177 °C

Uncontrolled hyperparathyroidism (HPT), especially HPT brought on by chronic kidney disease (CKD), is linked to high cardiovascular mortality and morbidity. The management of HPT and associated vascular and skeletal consequences has not been well addressed by conventional medical therapy (e.g., vitamin D sterols, calcium, phosphate binders). CNA, a first-in-class calcimimetic that has received regulatory approval in both the US and the EU, offers a novel therapeutic strategy for the treatment of Secondary hyperparathyroidism (SHPT). CNA is a hydrochloride made from cinacalcet and hydrogen chloride in equimolar proportions. It functions as a P450 inhibitor and calcimimetic. It is descended from the cinacalcet. Commercially, CNA is offered in basic and hydrochloride salt forms. The readers are provided with extensive information on the numerous analytical techniques in this review article. the most effective analytical technique was found to be HPLC.followed by hyphenated systems, spectrophotometric and developed and validated method for the estimation of CNA various techniques (Figure 2).Given the quick advancements in CNA research and development, as

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HPLC BASED *IN VIVO* PHARMACOKINETIC STUDIES OF SELEGILINE HYDROCHLORIDE MICROSPHERES FOR PARKINSON'S DISEASE

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ABSTRACT

Selegiline hydrochloride functions as an irreversible mono amino oxidase inhibitor and is typically prescribed to treat the symptoms of idiopathic Parkinson's disease. The microspheres were created for prolonged drug retention in the gastrointestinal tract, leading to improved oral bioavailability and superior absorption. Mucoadhessive microspheres were developed using the ionotropic gelation technique using different concentrations of sodium alginate, calcium chloride, carbopol 940p, and karaya gum with different levels of stirring speed. The optimization process was carried out using Design Export 13 software. Followed by investigating and comparing the pharmacokinetic profiles of selegiline hydrochloride pure drug and its microsphere optimized formulation in rat plasma by RP-HPLC using tetradeuteroselegiline as internal standard with a single oral administration of 0.129 mg. When compared with pharmacokinetic parameters of selegiline hydrochloride, the $AUC_{0\text{-}t}$, $AUC_{0\text{–}\infty}$, T_{max} and $t_{1/2}$ of selegiline hydrochloride microspheres were increased, while the C_{max} was decreased. These results suggested that formulation modification of selegiline hydrochloride into microspheres enhanced bioavailability.

Keywords: Selegiline hydrochloride, Parkinson's disease, Mucoadhesive microspheres, Pharmacokinetics, HPLC

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HPLC based *in vivo* pharmacokinetic studies of rasagiline mesylate microspheres for Parkinson's disease

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Abstract

Rasagiline mesylate functions as an irreversible mono amino oxidase inhibitor and is typically prescribed to treat the symptoms of idiopathic Parkinson's disease. The microspheres were created for prolonged drug retention in the gastrointestinal tract, leading to improved oral bioavailability and superior absorption. Mucoadhessive microspheres were developed using the ionotropic gelation technique using different concentrations of sodium alginate, calcium chloride, carbopol 934, and xanthan gum. The optimization process was carried out using Design Export 13 software. Followed by investigating and comparing the pharmacokinetic profiles of rasagiline mesylate pure drug and its microsphere optimized formulation in rat plasma by RP-HPLC using pseudoephedrine as internal standard with a single oral administration of 0.0258 mg. When compared with pharmacokinetic parameters of rasagiline mesylate, the AUC0-t, AUC0–8, Tmax and $t_{1/2}$ of rasagiline mesylate microspheres were increased, while the C_{max} was decreased. These results suggested that formulation modification of rasagiline mesylate into microspheres enhanced bioavailability.

1. Introduction

A microsphere can have a diameter of between 1 and 1000 µm. The sphere-shaped, free-flowing particles are made of proteins or polymers. In addition to the first two, they are made with waxes, disintegrating synthetic polymers, and natural polymers. A second-generation monoamine oxidase type B inhibitor called rasagiline mesylate permanently and specifically blocks dopamine in the central nervous system. Parkinson's disease-related motor problems have been treated with rasagiline mesylate. On the other hand, rasagiline mesylate undergoes first-pass metabolism, having a low bioavailability (36%) and a short half-life between 1.5 to 3.5 h. Due to the drug's short half-life, poor bioavailability, and need to maintain therapeutic levels, a gastro retentive formulation must be created (Sharma *et al.,* 2015; Ali *et al.,* 2020). For initial monotherapy with rasagiline mesylate, a dosage of 1 mg once daily is advised, whereas an initial dose of 0.5 mg per day is advised for adjunctive therapy with levodopa. Literature review on analytical methods of rasagiline mesylate reveals that there are methods such as reverse phase high-performance liquid chromatography (RP-HPLC) (Sundaramurthy *et al.,* 2011), high performance thin layer chromatography and UV-visible spectrophotometry for estimation of pharmacokinetic parameters (Singaram *et al.*, 2012).

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2. Materials and Methods

2.1 Materials

Methanol of the HPLC grade was purchased from E. Merck Ltd. in Mumbai. Sun Pharma, Mumbai, India, provided the reference standard rasagiline mesylate. Pseudoephedrine (internal standard) received from Beryl Drugs Limited. In Mumbai, India, Merck sold HPLC acetonitrile, and S.D. Fine sold potassium dihydrogen orthophosphate and ammonia solution. Methocel purchased from Sakshi Private Limited, Nagpur. The reagents were all HPLC grade. Wherever necessary, solutions were prepared using milli-Q grade (Millipore, France) water that had been filtered *via* a 0.45 µm membrane filter before to use. Waters HPLC system and a C-18 cosmosil packed column used for analysis (Omar *et al.,* 2020; Parasuraman *et al.,* 2010).

2.2 Preparation and evaluation of rasagiline mesylate mucoadhessive microspheres

Using the ionic gelation method, mucoadhesive microspheres containing rasagiline mesylate have been created. In the purified water, sodium alginate was mixed with mucoadhesive polymers such carbopol 934P and xanthan gum. Rasagiline mesylate added to polymer dispersion on a magnetic stirrer. The gelation medium, which facilitates in the creation of stable microspheres, was produced by dissolving 10% calcium chloride in a 2% solution of glacial acetic acid. The homogenous alginate solution extruded into the gelation medium while stirring with a 21G syringe needle. Particle size, cumulative percent drug release, compatibility studies (FTIR and DSC), and scanning electron microscopy were all evaluated (Prasanthi *et al.,* 2023; Ravi Kumar *et al.,* 2018; Anusree *et al.,* 2018; Dewi Melani *et al.,* 2020; Veerendra *et al.,* 2021).

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Research Article

GASTRORETENTIVE DRUG DELIVERY SYSTEMS- A NOVEL APPROACH TO ENHANCE THE BIOAVAILABILITY OF POORLY SOLUBLE DRUGS

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ABSTRACT

A gastro-retentive drug delivery system (GRDDS) can be defined as a system that remains in the stomach for a sufficient time interval against all the physiological barriers, releasing the active moiety in a controlled manner. GRDDSs can improve the controlled delivery of drugs that have an absorption window by continuously releasing the drug for a prolonged period of time before it reaches its absorption site. Oral route is most preferable route of administration but it has certain limitations for those drugs which absorb from specific region of gastrointestinal tract. It has to improve the solubility and prolongation of the retention time of those drugs having low solubility at high intestinal pH in stomach. The bioavailability of drugs can be improved by increasing their retention time in the stomach. This novel approach has proved to be efficient in systemic actions as well as in local actions to treat gastric or duodenal ulcers. Local activity in the upper part of the small intestine can be obtained by improving the residence time of delivery system in the stomach. This system is useful for drugs which are unstable or low solubility in the small intestine. A variety of GRDDS approaches comprise high density (sinking) systems, low-density (floating systems), mucoadhesive, expandable, unfoldable, superporous hydrogel systems, and magnetic systems.

INTRODUCTION

The development of effective drug delivery systems is crucial for enhancing the therapeutic efficacy of poorly soluble drugs. Gastroretentive drug delivery systems have gained prominence in recent years as an innovative approach to tackle this issue. They aim to prolong the residence time of drugs in the stomach[(1)], which can lead to improved drug absorption and bioavailability.

Gastroretentive Approaches

GRDDS employ various approaches to achieve gastric retention, including: Gastric retention approaches are diverse and aim to prolong the residence time of drugs or dosage forms in the stomach for various therapeutic purposes. Here are some different approaches to achieving gastric retention[(2,3)]

a. Floating Systems

Floating Tablets or Capsules: These dosage forms contain low-density materials or gas-generating agents that enable them to float on the gastric fluid. The buoyancy keeps the drug in the stomach for an extended period, allowing for slow and controlled drug release[(4).]

Hollow Floating Systems: Hollow structures like balloons or reservoirs can be filled with drug formulations. They remain buoyant and release the drug over time as they float on the gastric contents[(5)].

b. Mucoadhesive Systems

Mucoadhesive Tablets or Patches: These systems use polymers (e.g., chitosan, sodium alginate) that adhere to the gastric mucosa, prolonging contact with the absorption sites and ensuring retention in the stomach.

Bioadhesive Hydrogels: Hydrogel-based formulations can adhere to the gastric mucosa upon hydration,[(6)] leading to sustained drug release and gastric retention.

Swelling and Expandable Systems: Swelling Tablets or Hydrocolloid-Based Systems: These formulations swell upon contact with gastric fluid, increasing in size and reducing gastric emptying rates. Superporous hydrogels are also employed for this purpose.

Shape Memory Polymers: Materials with shape-memory properties can change shape in response to environmental stimuli such as temperature or pH, allowing them to adapt and fit into the stomach's shape.

c. High-Density Systems

High-Density Tablets or Beads: These dosage forms have densities greater than gastric fluids, preventing their passage

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Original Article

Design Formulation and *in vitro* Evaluation of Gastroretentive Microspheres of Selegiline Hydrochloride for Parkinson's Disease by Design Expert

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ABSTRACT

Introduction: Selegiline hydrochloride is primarily used to treat Parkinson's disease. Selegiline hydrochloride mucoadhesive microspheres were prepared to improve the bioavailability of the drug and its appropriate therapeutic performance. **Materials and Methods:** The ionic gelation process was used to formulate the gastroretentive mucoadhesive microspheres using different polymers such as gum kondagogu (150 to 450 mg), karaya gum (10 to 70 mg), and carbopol 940P (150 to 450 mg) of different concentrations in preliminary trial formulations (SM1-SM14) after performing preformulation studies. Optimisation of selegiline hydrochloride mucoadhesive microspheres (SHM1 to SHM11) was done by optimizing. The study employed independent variables-Karaya gum concentration (10, 40, and 70 mg) and stirring speed (500, 1000, and 1500 rpm)-alongside dependent variables: percentage entrapment efficiency, particle size, and cumulative drug release. Design Expert 13 software employing Central Composite Design facilitated optimization. ANOVA elucidated the influence of these variables on the dependent ones, providing insights into the interplay between polymer concentration, stirring speed, and the measured outcomes. For optimised formulation, SEM was done to determine structural features. **Results:** Initial investigations revealed that, aside from gum kondagugu, formulations containing carbopol 934P demonstrated superior mucoadhesion and drug release characteristics. The optimised formulation SHM12 (given by Design Expert 13 software in Overlay Plot) having 64.31 mg of Karaya Gum at stirring speed 1500 rpm showed 84.84% entrapment efficiency, 450 µm particle size, and 96.53 cumulative percent drug release. Results were confirmed experimentally. **Conclusion:** The study concluded that the developed mucoadhesive microspheres for selegiline hydrochloride exhibited enhanced cumulative drug release, ultimately enhancing bioavailability.

Keywords: Selegiline hydrochloride, Parkinson's disease, Mucoadhesion, Microspheres, Ionic gelation method, Design Expert 13, Response Surface Methodology.

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INTRODUCTION

Oral drug administration is the most desirable and feasible drug delivery method, but this route of administration is limited due to poor bioavailability. Microspheres are one of the multiparticulate drug delivery systems that are used for controlled drug delivery. This dispenses the medications more uniformly in the gut. Gastroretentive dosage forms in the form of mucoadhesive microspheres help to retain the drug in the stomach for a longer period, improving bioavailability.[1]

Gastroretentive microspheres are widely used to delay and modify the characteristics of drug release. The ionic gelation method that was used for this preparation has reproducibility in results and also avoids local irritation as the formulation is free from organic solvents.[2,3]

Parkinson's disease causes trembling, stiffness, and difficulty walking. Most widely used medication is carbidopa, levodopa, dopamine agonists such as pramipexole and apomorphine, monoamino oxidase inhibitors such as selegiline and rasagiline, anticholinergics such as benztropine. Selegiline hydrochloride is an invariable MAOB inhibitor and is used for Parkinson's disease, dementia, and depression. Selegiline hydrochloride has a low biological half-life (1.5 to 3.5 hr). The release can be extended by developing micro particulate drug delivery systems that can deliver a drug over extended periods compared with conventional delivery systems. That minimises drug-related side effects and

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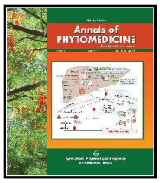

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Formulation design and evaluation of aceclofenac transdermal patches

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Abstract

Transdermal drug delivery systems are a widely utilized method of drug delivery, and transdermal patches are used to treat a variety of disorders. They can help to avoid drug-related gastrointestinal issues and poor absorption. More and more research is being conducted on this subject, and with researchers growing interest in drug delivery; the number of transdermal devices entering the market is predicted to grow. Compatibility testing revealed no reaction between the drug and polymers. The drugs and polymers physicochemical compatibility, determined by differential scanning calorimetry and infrared spectroscopy, indicated the absence of any incompatibility. After one dose, the drug concentration rises to high levels throughout the system, at least immediately. The use of drugs to treat sickness has entered a period of tremendous expansion. Therapy with such formulations entails achieving and maintaining therapeutically effective drug concentrations in the body by introducing set dosages of a drug into the body at regular intervals. New polymers and penetration enhancers have been introduced, formulated by using HPMC, PVPK30 and by selecting solvents as chloroform and methanol plasticizer as dibutylphthalate penetration enhancers as propylene glycol and formulated F1 to F8 with various evaluation results such as folding endurance, drug content determination, tensile strength, thickness, and wt. variation. The highest-releasing formulation is found to be F4. The majority of researchers have been using HPMC as their preferred film-forming polymer.

1. Introduction

Transdermal route of drug delivery hence appears to be a good alternative approach to the oral route as it eliminates chances of drug loss by hepatic metabolism and provides healing patient compliance as opposed to other routes like the parentral route (Dunn and Legrand, 2004). Transdermal drug delivery offers an attractive alternative to oral administration and injection. Today about 74% of drugs are taken orally and are found not to be as effective as desired.

Drug delivery through the skin (for systemic effect) is commonly known as TDD and differs from traditional topical drug delivery, also known popularly as 'patches' (Pareek and Chandurkar, 2013). Transdermal patches are dosage forms designed to deliver a therapeutically effective amount of drug from the outside of the skin through its layers into the bloodstream.

Transdermal drug delivery systems (patches) are dosage forms designed to deliver a therapeutically effective amount of drug across a patient's skin also defined as a medicated adhesive patch that is placed on the skin to deliver a specific dose of medication through the skin and into the blood stream (Pareek *et al*., 2011).

Macromolecules such as hormones, interferons and bioactive peptides can be divided by transdermal delivery system. Devices based on ethylene vinyl acetate copolymers. Devices based on silicone elastomer. This device is used as an implant. The matrix must have a channel to facilitate the release of macromolecules. Recent approaches iontophoresis built-in battery layer. Comparable in size to a normal transdermal patch (Dooley *et al*., 2011).

Asymmetric TPX membrane method was discovered by Berner and John (1994). In this prototype patch method can be prepared by using heat-sealable polyester film with a concave 1cm diameter as the backing membrane. Drug dispersed on the concave membrane, covered by a TPX (poly [4-methyl-1-pentene]) asymmetric membrane and sealed by an adhesive (Gonzalez -Alvaro *et al*., 2016).

Circular teflon mould method was discovered by Baker and Heller (1989). Polymeric solution in various portions is used as an organic solvent and the solution is divided into two parts. In one part, deliberate amount of the drug is dissolved and in another part, enhancers in different concentrations are dissolved and then two parts are mixed. Plasticizer (Di-N-butyl phthalate) is added into the drug polymer solution and the total contents are to be stirred for 12 h and then poured into a circular teflon mould. Moulds are to be placed on a level surface and covered with an inverted funnel to control solvent vaporization in a laminar flow with an air speed of 0.5 m/s solvent is allowed to evaporate for 24 h. After the dried film is formed, it is to be stored for another 24 h at 25 ± 0.5°C in a desiccators containing silica gel before evaluation to eliminate ageing effects (Brogden and Wiseman, 2019).

Mercury substrate method

They are prepared drug and plasticizer dissolved in polymeric solution. It is stirred for 10-15 min to produce homogenous dispersion, then it is poured into a level mercury surface and covered with an inverted funnel to control solvent evaporation (Dooley *et al*., 2011).

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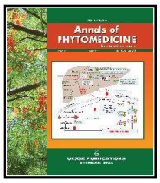

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Formulation and evaluation of esomeprazole magnesium trihydrate controlled release floating tablets

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Esomeprazole magnesium trihydrate

Abstract

The creation and evaluation of floating tablets for esomeprazole magnesium trihydrate, with a specific focus on investigating the influence of polymer types and concentrations. These tablets, designed for a floating drug delivery system, were manufactured by using the direct compression method. The key components employed in the formulation included polymers such as Carbopol 940P and hydroxyl propyl methyl cellulose, along with calcium carbonate serving as a gas-generating agent. The prepared tablets were assessed using FTIR spectroscopy, SEM, angle of repose, pre-formulation parameter, floating lag time, and floating duration time and release behavior. Pre-formulation and post-formulation evaluations are conducted for all the formulations F1-F7. Importantly, the post-formulation parameters of all formulations met the established criteria for quality. All formulations underwent pre-formulation studies, and all formulations were under the limits for each parameter discovered to be met successfully about angle of repose for all formulations F1-F7 in the range of 24.27 ± 0.25 to 26.78 ± 0.34, bulk density for all formulations F1-F7 0.320 ± 0.02 to 0.510 ± 0.01, for all formulations F1-F7 Carr's index values are 5.60 ± 0.01 to 10.65 ± 0.01 and tapped density for all formulations F1-F7 in the range of 0.370 ± 0.02 to 0.529 ± 0.01. One formulation, labeled as F7, stood out due to its remarkable extended floating duration of more than 24 h and drug release profile. The lag time for formulation F7 was found to be 3 sec, floating duration time was more than 24 h. The analysis indicated that the drug release mechanism from these formulations (F7) adhered to a nonfickian pattern, specifically following first-order release kinetics.

1. Introduction

Gastro retentive drug delivery systems are designed to be retained in the stomach for more time and release their active ingredients and thereby enable sustained and prolonged input of the drug to the upper part of the gastrointestinal tract (Chien,1992). A modified release drug delivery system with prolonged residence time in the stomach is of particular interest for drugs acting locally in the stomach; having an absorption window in the stomach or in the upper part of the small intestine; those unstable in the intestinal or colonic environments, or those having low solubility at high pH values (Caldwell *et al.*,1988).

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2. Materials and Methods

Esomeprazole magnesium trihydrate, an active pharmaceutical ingredient was procured from a local vendor. Carbopol 940P (Loba Chemie Pvt. Ltd., Mumbai, India), and HPMC (Qualigens Fine Chemicals, Mumbai, India), were procured and used in this investigation. The entire chemicals of analytical grade and double distilled water were used throughout the experiment.

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2.1 Development of standard calibration curve

2.1.1 Determination of λmax of esomeprazole magnesium trihydrate solution

Using a UV spectrophotometer, a drug solution of 10 µg/ml was produced and scanned against 0.1N HCl as a reference solution over the wavelength range of 200 - 400 nm. A graph was created by taking X axis and Y axis for concentration and absorbance. The graph's tallest peak was designated as "max"(Chen and Park, 2000).

2.1.2 Preparation of standard stock solution of drug

Esomeprazole magnesium trihydrate should be carefully weighed and dissolved in 100 ml of ethanol. This results in a standard stock solution concentration of 1000 µg/ml.

2.1.3 Preparation of working stock solution

10 ml of esomeprazole standard stock solution was taken and diluted up to 100 ml with 0.1N HCl. It will give a 100 µg/ml concentration of working esomeprazole standard stock solution (Subramanyam, 2000).

2.1.4 Preparation of working dilutions

1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5 and 5 ml are taken from the working standard stock solution and 10 ml of 0.1N HCl was added to make up the solution to produce 10, 15, 20, 25, 30, 35, 40, 45, and 50 µg/ml concentrations, respectively, to produce 10, 15, 20, 25, 30, 35, 40, 45 and 50 µg/ml concentrations, respectively (Choi *et al.*, 2002).