S.NO.	Title of paper	Name of the author/s	Department of the teacher	Name of journal	Year of publication	ISSN number
1	Development and validation of RP-HPLC and UV methods for simultaneous estimation of Enalapril maleate and Hydrochlorothiazide in bulk and pharmaceutical dosage form	D.Kumaraswamy	Pharmaceutical Analysis	World Journal of Pharmaceutical Research	2022	ISSN:2277-7105
2	Evaluation of Depression and Quality of Life In Patients With Psoriasis	Sravani S, Shiva D, Venkateshwarlu E, Manasa Sowmya K, and Sharavana Bhava BS	Pharmacy Practice	International Journal of Dermatology and Venereology	2022	ISSN: 2641-8746
3	Colon targeted drug delivery systems: A review on approaches used to target colon	Pembarthi Vikram, Devandla Adukondalu	Pharmaceutics	Clinical and medical research and studies	2022	ISSN:2582-4333
4	Synthesis, Characterization, and Pharmacological Evaluation of Some New Pyrimidine Schiff Bases and Their Amines as Possible Antibacterial Agents	D.Kumaraswamy	Pharmaceutical Analysis	International Journal of pharmacy and pharmaceutical	2022	ISSN:2349-7203
5	Method Development and Validation of Fexofenadine Hydrochloride in Bulk and Solid Dosage Form (Tablets) by UV-Visible Spectrophotometry	D.Kumaraswamy	Pharmaceutical Analysis	International Journal of pharmacy and pharmaceutical	2022	ISSN:2349-7203
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7	Formulation and evaluation of propranolol hydrochloride oral disintegrating tablets	Pavani S, L.Smitha,M.Keerthana	Pharamaceutics	International journal of pharmaceutical sciences and research	2021	ISSN(Online): 0975-8232 ISSN(Print): 2320-5148

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8	Synthesis and anticonsulvant activity of some 1,4 dihydropyridine derivatives	K.Sirisha, Safia begum	Pharmaceutical Analysis	Indian Journal of Chemistry	2021	NIL
9	Fluorescence quantum dots : An insight on synthesis and potential biological application as drug carrier in cancer	S. Pavani, Asish Suttee	Pharamaceutics	Biochemistry and biophysics reports	2021	ISSN: 2405-5808
10	Formulation and evaluation of Fenoverine floating tablets	Pavani S	Pharamaceutics	Asian journal of pharmaceutical and clinical research	2021	ISSN(Online): 0974-2441 ISSN(Print): 2455-3891
11	Formulation and evaluation of valacyclovir hydrochloride effervescent floating tablets	Pavani S	Pharamaceutics	International journal of advances in pharmacy and biotechnology	2021	ISSN:244-8375
12	Safety and Efficacy of Strepyokinase, Tenecteplase, and Reteplase in Patients Diagnosed with St-Elevation Myocardial Infraction: A Comparitive Study	Bhargavi Neela, and Sharavana Bhava BS	Pharmacy Practice	Journal of Indian College of Cardiology	2021	ISSN: 1561-8811
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14	Method development, validation, and stability indicating studies of Olmesartan medoxomil and Hydrochlorthiazide inbulk and pharmaceutical dosage form by UV-Spectroscopy	D.Kumaraswamy	Pharmaceutical Analysis	IJPT	2021	NIL
15	Formulation and evaluation of valacyclovir hydrochloride effervescent floating tablets	Rajani Thoutreddy, Umashankar K, GSN Koteshwar Rao, Alekhya M	Pharmaceutics	International journal of advances in pharmacy and biotechnology	2021	ISSN:244-8375
16	Assessment of psychiatric variables in geriartric patients diagnoised with different types of osteoarthritis: Radiographic- based evidences	Shravani Komuravelly,Venkateshwarlu E, and Sharavana Bhava BS	Pharmacy Practice	Archieves in mental health sciences	2021	ISSN:2589 918X

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20	Design and Evaluation of Ornidazole Sustained release Dental Inserts	Yamsani Shravan Kumar Sunchu Harika	Pharmaceutics	Current Drug Metabolism	2021	ISSN:1875-5433
21	Synthesis, Characterization and Evaluation of New Thiazole Derivatives as Anthelmintic Agents	D.Kumara Swamy, K.Durga Prasad, G.Sai Krishna,	Pharmaceutical Analysis	International Journal of Pharmaceutical Sciences and nanotechnology	2021	ISSN:0974-3278
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23	Safety and Efficacy of Strepyokinase, Tenecteplase, and Reteplase in Patients Diagnosed with St-Elevation Myocardial Infraction: A Comparitive Study	Bhargavi Neela, Venkateshwarlu E	Pharmacy Practice	Journal of Indian College of Cardiology	2021	ISSN: 1561-8811
24	Synthesis, Characterization and Pharmacological evaluation of some metal complexes of quercetin as P-gp inhibitors	Sirisha Kalam	Pharmaceutical Analysis	Future Journal of Pharmaceutical Sciences	2021	ISSN: 2314-7253
25	Synthesis, Characterization and Evaluation of New Thiazole Derivatives as Anthelmintic Agents	D.Kumara Swamy, K.Durga Prasad, G.Sai Krishna,	Pharmaceutical Analysis	International Journal of Pharmaceutical Sciences and nanotechnology	2021	ISSN:0974-3278

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26	Formulation and evaluation of propranolol hydrochloride oral disintegrating tablets	L.Smitha,M.Keerthana	Pharamaceutics	International journal of pharmaceutical sciences and research	2021	ISSN(Online): 0975-8232 ISSN(Print): 2320-5148
27	Design and Evaluation of Ornidazole Sustained release Dental Inserts	Pavani Sriram, Sunchu Harika	Pharmaceutics	Current Drug Metabolism	2021	ISSN:1875-5433
28	Synthesis, Characterization and Evaluation of thiopyrimidine derivatives as possible antimicrobial agents	J. Bharath kumar, Sirisha Kalam	Pharmaceutical chemistry	Indian Journal of Chemistry	2022	nil
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32	Formulation and evaluation of Fenoverine floating tablets	Rashmitha V	Pharmaceutics	Asian journal of pharmaceutical and clinical research	2021	ISSN: 2455-3891

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Evaluation of Depression and Quality of Life in Patients With Psoriasis

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Abstract

Objective: To measure the prevalence of depression in patients with psoriasis and to evaluate the relationship between the severity of psoriasis and depression and its effect on patients' quality of life.

Methods: A total of 154 patients with a confirmed diagnosis of psoriasis were assessed to determine the severity of psoriasis based on the psoriasis area and severity index score, presence, and severity of depression using the patient health questionnaire 9, and quality of life using the dermatology life quality index 10. Pearson correlation coefficient was used to demonstrate the relationship between continuous variables with 95% confidence intervals (CIs); $P < 0.00001$ was taken to indicate statistical significance.

Results: The severity of psoriasis was mild in 36.36% of patients, moderate in 25.97%, severe in 32.47%, and very severe in 5.20%. Of the 154 patients, 139 (90.3%) had depression; the severity of depression was mild in most affected patients (46.7%) and severe in 2.6% of patients. Psoriasis had a moderate effect on the quality of life in 37.01% of patients and a very large effect in 33.77% of patients. The severity of psoriasis was positively correlated with depression (Pearson correlation coefficient, $r = 0.42$, $P < 0.00001$, 95% CI: 0.28–0.54) and quality of life ($r = 0.43$, $P < 0.00001$, 95% CI: 0.29–0.55).

Conclusion: Depression is a common comorbidity in patients with psoriasis. The severity of psoriasis is positively correlated with the severity of depression and is associated with poor quality of life.

Keywords: depression, dermatology life quality index 10, patient health questionnaire 9, psoriasis, psoriasis area and severity index score

Introduction

Psoriasis is a chronic inflammatory dermatological condition characterized by skin lesions covered with white or silver scales,[1-2] with a strong genetic susceptibility, and complex autoimmune pathogenesis.[3] Based on the lesion characteristics, psoriasis is mainly classified into two types; non-pustular psoriasis includes psoriasis vulgaris, guttate psoriasis, erythrodermic psoriasis, inverse psoriasis, and psoriatic arthritis, while pustular psoriasis includes Von Zumbusch psoriasis, impetigo herpetiformis, and acrodermatitis continua of Hallopeau.[4-6] As psoriasis is a disorder with visible skin changes, it results in physical, emotional, and social burdens on the patient.[7] Patients with psoriasis often experience a significant decrease in their emotional wellbeing and social functioning, adversely affecting their quality of life.[8-9] As a result, patients with psoriasis have a high prevalence of psychiatric morbidities, including sleep disorders, anxiety, and most commonly depression.[10] A depressed state of mind has a negative impact on a patient's health by decreasing the adherence to self-care and medication, which consequently leads to a poor disease prognosis.[11-12] In addition, the onset and course of depression in patients with psoriasis shows a strong association with systemic inflammation,[13-14] as there is a negative bidirectional relationship between depression and inflammation in patients with psoriasis.[15-16] The ongoing inflammation causes physiologic and biochemical changes that drive an increase in the levels of inflammatory

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Author contributions: SS, SD, SBBS, and MSK performed the study conception and design; SS, and SD collected data; VE, SBBS and SS performed data analysis and interpretation; SS drafted the manuscript; VE, and SBBS made the critical revision; SS, SD, SBBS, VE, and MSK approved the final version of manuscript to submit.

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Synthesis, Characterization, and Pharmacological Evaluation of Some New Pyrimidine Schiff Bases and Their Amines as Possible Antibacterial Agents

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Keywords: Tetraamino pyrimidine, Benzaldehyde, Schiff base, Antibacterial activity

ABSTRACT

A series of (1Z,1'Z)-N, N'-(5,6-bis{[(E)-benzylidene)amino)pyrimidine-2,4-diyl)bis(1-phenylmethanamine) derivatives were prepared by the reaction of tetraamino pyrimidine using various substituted aldehydes. The synthesized tetraamino pyrimidine-Schiff bases were evaluated for their possible antibacterial activity using the nutrient agar cup-plate method and their minimum inhibitory concentration (MIC)values were calculated using the broth dilution method against four different strains of bacteria i.e., *S. aureus, B. subsites, E. coli,* and *P. aeruginosa.* Compounds III_c &IV_c exhibited the highest antibacterial activity. All the synthesized compounds were characterized by IR,^{1}H NMR, and Mass spectral data.

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Anchoring and Hydrophobic Nature of Coumarin in Newer Coumarin Based Chalcones: Synthesis, In Silico, and In Vitro Cell Viability Studies

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Abstract—Coumarin is active pharmacophore; to enhance the activity of chalcone we inserted coumarin along with other cyclic groups. Fewer pyrazolone aldehydes produced using Wills Maeyer Haack reaction by grinding method. In alcoholic sodium hydroxide, cyclic ketones react with aldehydes to produce title compounds. To treat the ill cell a drug must be with a linker, anchoring group, and hydrophobic group. Herein, the enone group acts as a linker, the rings on both sides are connected, one side ring acts as the anchoring group, and the other side ring acts as the hydrophobic group; anchoring, hydrophobic dual roles played by coumarin ring. In this series, In silico studies results have shown that many compounds of this series potent for anti-cancer activity along with other biological activities, the In vitro cell viability studies of the series shows that, chalcone **(I)**, **(VIII)**, and **(IV)** are having IC_{50} values 2.96, 2.97, and 2.82 μM against call 27 (or) oral cancer cell line.

Keywords: aldehydes, ketones, chalcone, coumarins, MTT assay

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INTRODUCTION

Chalcones serves as the starting material for number of key biological molecules. The biogenetic antecedents of flavonoids and isoflavonoids, which are plentiful in plants, are called chalcones [1]. Polyfunctionalized 3-benzylidenechromone-4 chalcone contained a novel series prepared, among them the majority of compounds have shown a good immune modulatory effect against various cancer cells and compared with the standard drug etoposide [2]. One molecule showed the highest (Tumor specificity) TS and (Potency–Selectivity Expression) PSE values among 15 chalcone derivatives, comparable to doxorubicin and methotrexate, respectively. Chemical modifications to the main molecule could be a viable option for developing novel anticancer medicines [3].

Malaria is a leading cause of death in endemic areas and the rise of drug-resistant parasites is concerning, powerful plant products have been identified. The synthesis of 10 chalcones with different substitutions, and evaluation of their antimalarial activity using chloroquine as a standard, reveals that cytotoxicity, and influence on hemozoin production [4]. Many of tocopherol-based compounds used for gene delivery since they were designed and synthesized by differing in the head group region. Four distinct cell lines were tested for cytotoxity. The data is based on an average of three tests and indicates percentage of viability. The tocopherol-based heterocyclic formulations performed better in all four cell lines evaluated when compared to (Lipofectamine-2000) L2K [5]. A one-pot synthesis of newer 1,4-benzoxazine, 2,4-oxadiazole hybrids prepared from propanenitrile, and different aromatic carboxylic acids. In vitro anti-cancer activity of these compounds tested against four cancer cellines compared with etoposide [6].

Fourteen coumarin-derived compounds prepared and docking, molecular dynamics, and MM/GBSA studies shows that the molecule binds to the active rMAO-B site [7]. For global cancer control, efforts to develop a sustainable infrastructure for the spread of cancer prevention measures and the provision of cancer care in transitioning nations are crucial [8]. On the human hepatoma HepG2 cell line, the cytotoxicity of the decoction and individual plant extracts were assessed. The decoction has a substantial dose-dependent cytotoxic action, according to the results of MTT and SRB experiments [9]. Novel coumarin-pyridazine hybrid compounds with different polarizability and lipophilicity features were produced and evaluated against the two MAO isoforms, MAO-A and MAO-B,

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FORMULATION AND EVALUATION OF PROPRANOLOL HYDROCHLORIDE ORAL DISINTEGRATING TABLETS

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Keywords:

Propranolol hydrochloride, Oral disintegrating tablets, Super disintegrants, *In-vitro* dissolution profile

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ABSTRACT: Background and purpose of the study: Propranolol hydrochloride beta-adrenergic receptor antagonist utilized in the treatment of high blood pressure, atrial fibrillation, myocardial infarction, angina and migraine headaches. The pharmacokinetic parameters make Propranolol hydrochloride an appropriate candidate for oral disintegrating tablets. This work aims to develop orally disintegrating tablets for Propranolol hydrochloride and to evaluate their pre-compression, physicochemical properties and water absorption ratio, disintegrating time, wetting time, *in-vitro* dispersion, time, and *in-vitro* dissolution. **Research rationale:** To attain rapid disintegration, dissolution/absorption, and further improving the bioavailability of the drug. To resolve swallowing issues in geriatric, pediatric patients by rapid disintegration in saliva and to treat high blood pressure, angina, atrial fibrillation, myocardial infarction, migraine. **Methods:** Oral disintegrating tablets prepared by direct compression technique using super disintegrants like Crospovidone, Croscarmellose sodium, Sodium starch glycolate, and Pregelatinised starch in several concentrations. The prepared batches of tablets were evaluated for pre-compression parameters and weight variation, thickness, hardness, friability, drug content, wetting time, disintegrating time, *in-vitro* dispersion time and *in-vitro* dissolution. The physicochemical interaction between drug and excipients were investigated by Fourier transform infrared spectroscopy. **Results:** Among the prepared formulations, F5 (Crospovidone 6%) was optimized and shows the maximum cumulative amount of drug release 97.05% in 14 min and disintegration time is 14.25 sec. Spectroscopic studies showed no evidence of interaction between the drug and excipients. **Conclusion:** Propranolol orally disintegrating tablets were found to possess faster disintegration time and drug release.

INTRODUCTION: Among the various routes of drug delivery system oral route is the most preferred route to the patient because of their convenience in self-administration, pain avoidance, and most significantly the patient compliance.

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However, people experience inconvenience in swallowing conventional forms, such as when water is not available. To overcome this drawback, a new drug delivery system has been developed known as orally disintegrating tablets (ODT) [1].

US Food and Drug administration center for drug evaluation and research (CDER) defines an ODT as " A solid dosage form containing medicinal substances, that disintegrates quickly, typically at usually within a matter of seconds, once placed upon the tongue". ODT is that the most popular route for low bioavailability as a result of the

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Synthesis and anticonvulsant activity of some 1,4-dihydropyridine derivatives

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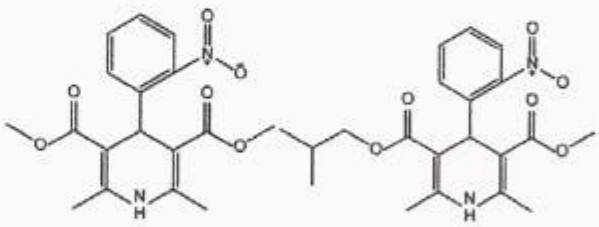
A series of asymmetrical 4-alkyl/aryl-2,6-dimethyl-3-N-(aryl/heteroaryl)-carbamoyl-5-ethoxycarbonyl-1,4-dihydropyridines **3a-d** and symmetrical 4-alkyl/aryl-2,6-dimethyl-3,5-bis-(ethoxycarbonyl)-1,4-dihydropyridines **4a** and **4b** have been prepared by the condensation of various benzaldehydes, ethylacetoacetate, 2-aminopyridine or *p*-toludine in ethanol (Hantzch method). The structures of all the synthesized 1,4-dihydropyridine derivatives have been confirmed by spectral data (IR, ^{1}H NMR) and elemental analysis. Compounds **3a-c**, **4a** and **4b** (10 mg/kg) have been evaluated for their anticonvulsant effect against pentylenetetrazole- induced convulsions with phenytoin (4 mg/kg) as the standard. The anticonvulsant potential of the newly synthesized compounds have been assessed on the basis of increase in latency (onset time) to induce convulsions; decrease in number of convulsions and increase in latency of death compared to control and standard.

Keywords: 1,4-Dihydropyridine, Hantzsch method, pentylenetetrazole, anticonvulsant, synthesis

Convulsion is where the body muscles contract and unwind quickly and over and again, bringing about a wild shaking of the body[1]. In 1950's Bromide was introduced as first true antiepileptic drug (AED). The usage of Bromide has decreased in twentieth century when Phenobarbitone was accidentally discovered to be effective in suppressing seizures. Due to the side effects, toxicity and teratogenic effects of current antiepileptic drugs in the treatment of epilepsy, calcium channel blockers as antiepileptic agents have recently been considered[2]. There are considerable evidences that calcium is an important factor for the induction of epilepsy. Specifically, interesting seizure-instigating administrators or frameworks cause a quick intraneuronal union of calcium particles[3]. In particular, unique seizure-inciting operators or systems cause a fast intraneuronal convergence of calcium particles, which is easily identified with the ensuing epileptiform movement[4]. Conversely, calcium channel inhibitors (1,4-dihydopyridines) are effective against the whole range of convulsive procedures including electro, pentylene tetrazole, sound and pressure-induced seizures. Nifedipine and other dihydropyridine derivatives such as nimodipine, nitradipine, and nisoldipine (Figure 1) are potent blockers of the calcium channels of smooth muscles and also bind with high affinity to the brain membranes, hence can be employed as antiepileptic agents[5-8]. Considering the anticonvulsant potential of 1,4-dihydropyridines and in continuation to our work[9-14] on this scaffold herein we report the synthesis and anticonvulsant activity of 4-alky/aryl-2,6-dimethyl-3-N-(aryl/heteroaryl)-carbomo yl-5-ethoxycarbonyl-1,4-dihydropyridines **3a-d** and 4-alkyl/aryl-2,6-dimethyl-3,5-bis-(ethoxycarbonyl)-1,4-dihydropyridines **4a** and **4b** (Scheme I).

Results and Discussion

N-(aryl/heteroaryl)acetoacetamide **2** was synthesized from the reaction of *p*-toludine/2- aminopyridine and ethylacetoacetate **1** using conventional and microwave irradiation methods. In both the methods there was an increase in yield with increase in concentration of ethylacetoacetate up to 1:1.8 (*p*-toludine/ 2-aminopyridine: ethylacetoacetate), beyond which it decreased. Hence this ratio where highest yield was



Nifedipine Nisoldipine

Figure 1 — Potent calcium channel blockers

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Research Article

FORMULATION AND EVALUATION OF FENOVERINE FLOATING TABLETS

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ABSTRACT

Objective: The purpose of this research was to develop a fenoverine gastroretentive drug delivery system which, following oral administration should have the ability to enhance and prolong the period of gastric residence time (GRD) with the desired *in vitro* release profile.

Methods: In the present study, fenoverine floating tablets were prepared using an effervescent method using sodium bicarbonate and citric acid as a gas-generating agent. The tablets were formulated using direct compression technology using xanthan gum and sodium alginate as polymers. Pre-compression powders were evaluated for angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, and the prepared tablets were evaluated for weight variation, thickness, diameter, hardness, friability, drug content, floating lag time, total floating time, and *in vitro* dissolution studies. The formulations were optimized for the different concentrations of xanthan gum, sodium alginate, and their combinations.

Results: All the prepared formulations showed well *in vitro* buoyancy. The tablets remained buoyant for 6–12 h. The *in vitro* drug-release pattern of fenoverine floating tablets was adapted to different kinetic models with the highest regression to zero-order and Korsmeyer-Peppas, and the mechanism was found to be a Fickian mechanism.

Conclusion: Out of all the formulations prepared, *in vitro* dissolution studies of the F4 formulation were found to be maximum than other batches, which exhibited desired sustained release time followed by acceptable floating properties.

Keywords: Fenoverine, Gastric residence time, Effervescent method, Buoyancy, Floating properties.

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INTRODUCTION

The oral route is the most appropriate and widely used route for the delivery of drugs to the systemic circulation. This route has high acceptability for patients, particularly due to ease of administration. Over the years, oral dosage forms have become increasingly world-wise in the pharmaceutical field, with controlled release drug delivery (CRDDS) systems that release the drug at a predetermined, predictable, and controlled rate playing a major role [1]. The main imperative for the successful action of oral controlled drug delivery systems was to have good drug absorption throughout the gastrointestinal tract (GIT). The most preferable approach of oral controlled drug delivery is gastroretentive drug delivery system, where the dosage form can remain in the stomach for a prolonged period, thereby increasing the gastric residence time (GRT) and targeting site-specific drug release in the upper GIT for producing local or systemic effects. It is obtained by retaining the dosage form in the stomach and by releasing it in a controlled manner [2]. The following two parameters are optimized to develop sustainable orally controlled releasing drug delivery systems that deliver a drug for the required duration for optimal treatment at a therapeutically efficient range to a desirable place [3]. (a) Gastrointestinal transit modulation time: To modulate the transit time for GIT so that dosage form can be taken to or around the target absorption site and thus extend the time limit for maximizing the delivery of drugs. (b) Minimizing the elimination of the first hepatic pass: If the drug to be given undergoes extensive first-pass hepatic removal, preventive measures should be developed to either bypass or minimize the extent of hepatic metabolism. The purpose of the work is to develop drug delivery systems of fenoverine in which after oral administration should have the ability to prolong the gastric residence time with the desired *in vitro* release profile. Fenoverine is an antispasmodic drug used to relieve muscle spasm, cramps associated with the stomach, and abdominal pain associated with irritable bowel syndrome [4,5]. Due to the shorter half-life of Fenoverine (5-7 h) it requires frequent daily dosing and its therapeutic use in chronic conditions necessarily involves its formulation into a sustained release dosage form[6]. It is the most suitable drug to be formulated as a floating drug delivery system as it helps in increasing the gastric residence time and helps to have good control over the fluctuations in plasma drug concentration.

MATERIALS AND METHODS

Materials

Fenoverine was obtained as a gift sample from Euro drugs, sodium bicarbonate, xanthan gum, and sodium alginate obtained from Research-lab fine chem. Industries, citric acid from HiMedia laboratory, Talc from Sd fine-Chem Ltd, magnesium stearate from Qualikems Fine Chemicals Pvt. Ltd, and Lactose from Yarrow Chem products, all the ingredients, and reagents used were of analytical grade.

Methods

Pre-formulation studies

Pre-formulation studies are carried out to know and understand the physical and chemical behavior of a drug and also to know the drug-excipient compatibility using FTIR.

Solubility studies

Solubility was determined by weighing accurately 1 g of the drug and transferring it into 5 different 10 ml volumetric flasks containing different solvents (water, ethanol, methanol, DCM, and 0.1N HCl), respectively [6].

FTIR studies

It is often used to identify organic, inorganic, and polymeric materials present in the dosage form, analyse pure drug formulations, polymer, and drug-loaded polymer formulations, as well as functional group

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Review Article

Formulation and Evaluation of Valacyclovir Hydrochloride Effervescent Floating Tablets

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Keywords:
Valacyclovir hydrochloride, Effervescent, Floating, Tablets, HPMC K100 M, HPMC K 15 M, Sodium alginate, Xanthan gum

ABSTRACT

The purpose of this research was to develop gastro-retentive drug delivery system of Valacyclovir hydrochloride to prolong gastric residence time with desired in vitro release profile. Valacyclovir hydrochloride is an Anti-viral drug with high solubility in gastric pH. In the present study, Valacyclovir hydrochloride floating tablets were prepared by effervescence method using sodium bicarbonate and citric acid as a gas generating agent. The tablets were formulated using direct compression method using polymers like HPMC K15M, HPMC K100M, Xanthan gum and Sodium alginate. Pre-compression parameters such as for angle of repose, bulk density, tapped density and hausner's ratio whereas the prepared tablets were evaluated for weight variation, thickness, hardness, friability, drug content, floating lag time, total floating time, in vitro dissolution study and in vivo radiographic studies. FT-IR and DSC studies elucidated the compatibility of the drug with the polymers and other excipients used in the study. In Vitro release studies of the prepared tablets depicted to follow Zero order kinetics with R2 value of 0.941 and Fickian diffusion where n value is < 0.5 and found to be the main mechanism of drug release. The manufacturing procedure was found to be reproducible and formulations were stable after one month of accelerated stability studies.

1. Introduction

Oral route is considered as the most common route of administration for drug delivery [1]. Effective oral drug delivery may depend upon the factors such as gastric emptying process, gastrointestinal transit time of dosage form, drug release from the dosage form and site of absorption of drugs [2]. Most of the oral dosage forms suffer from several physiological limitations such as variable gastrointestinal transit, variable gastric emptying time, non-uniform absorption profiles, incomplete drug release and shorter residence time of dosage form in stomach [3].

As a result, drugs with absorption window in the upper part of the small intestine undergo incomplete absorption [4]. Hence a beneficial delivery system would be one which possesses the ability to control and prolong the gastric emptying time and can deliver drugs in higher concentrations to the absorption site i.e. upper part of the small intestine [5]. Gastric retention of drugs is one of the approaches used in the prolongation of gastric retention time with suitable therapeutic activity [6].

Valacyclovir Hydrochloride is an anti- viral drug used commonly in the treatment of infections caused by Herpes virus [7]. Valacyclovir HCl converts to acyclovir with L-valine by first-pass metabolism [8]. Plasma concentrations of unconverted valacyclovir are low with transient, generally becoming non-quantifiable by 3 hours after administration. Peak plasma valacyclovir centrations are generally less than 0.5 mcg/mL at all doses [9].

Valacyclovir hydroconchloride is suitable for floating drug delivery system as it undergoes hepatic metabolism which hinders with the oral bioavailability of the drug. It also has multiple dosage activity for a day that maintains stable drug plasma concentration [10].

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Original Article

Safety and Efficacy of Streptokinase, Tenecteplase, and Reteplase in Patients Diagnosed with ST-Elevation Myocardial Infarction: A Comparative Study

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Abstract

Objective: Our primary objective was to compare the efficacy of streptokinase (SK), tenecteplase, and reteplase by studying patients' electrocardiogram (electrocardiogram [ECG]) pre and post thrombolysis. The secondary objectives were to assess chest pain relief using Numerical Pain Rating Scale score and also to compare the side effects (bleeding, hypotension, and anaphylaxis) of three drugs. **Materials and Methods:** This study is a multicentric, prospective, randomized, comparative study. This study was conducted on 150 patients of ST-elevation myocardial infarction admitted in the wards/ICCU- Intensive Coronary Care Unit, Department of Cardiology, Mahatma Gandhi Memorial Hospital and Rohini Superspeciality Hospital. They were selectively divided into three groups. Group A consisted of patients who received SK (50), Group B who received tenecteplase (50), and Group C who received reteplase (50). The study period was 6 months. The follow-up was done in all the patients during their inhospital stay. **Results:** Post thrombolysis, reteplase, tenecteplase, and SK led to mean ST-segment reduction of 64.9 ± 19.77, 52.43 ± 34.57, and 46.97 ± 33.09, respectively. The comparison between the three drugs revealed a significant difference ($P = 0.0103$). **Conclusion:** This study concluded that reteplase is most efficacious in the resolution of ST-elevation and also safer than other thrombolytics used.

Keywords: Reteplase, ST-elevation myocardial infarction, streptokinase, tenecteplase, thrombolytics

Introduction

ST-elevation myocardial infarction (STEMI) is one of the challenging problems among acute coronary syndromes.[1-4] STEMI is a clinical syndrome characterized by typical symptoms of myocardial ischemia associated with persistent electrocardiographic ST-elevation and subsequent release of myocardial necrotic biomarkers. The Universal Definition of Myocardial Infarction defined by the European Society of Cardiology/American College of Cardiology Foundation/American Heart Association (AHA)/World Heart Federation Task Force is defined as new ST-elevation at the point J in at least two contiguous leads of ≥1.5 mm (0.15 mV) in women or ≥2 mm (0.2 mV) in men in leads V2–V3 and/or of ≥1 mm (0.1 mV) in other contiguous chest leads or the limb leads, is characteristic of diagnostic ST-elevation in the absence of left ventricular (LV) hypertrophy or left bundle branch block (LBBB). Coronary artery disease (CAD) is the leading cause of mortality worldwide, and over 7.4 million people died due to CAD in 2015.[5] Nearly three million STEMI cases are estimated to occur in India per year. Cardiovascular diseases are with the highest mortality rate in India accounting for about 21% of the deaths in 2010, with 10% of overall deaths occurring due to CAD.[6]

The ACC/AHA 2013 guidelines for the management of STEMI suggest fibrinolytic therapy when there is an anticipated delay in performing primary PCI within 120 min of first medical contact and lists available fibrinolytic agents (tenecteplase [TNK-tPA], reteplase [rPA], alteplase, and streptokinase [SK]).[4]

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RESEARCH Open Access

Synthesis, characterization, and pharmacological evaluation of some metal complexes of quercetin as P-gp inhibitors

Kirankumar Shastrala[1], Sirisha Kalam[1*], Kumaraswamy Damerakonda[1], Sharvana Bhava Bandaru Sheshagiri[1], Hitesh Kumar[1], Ramu Guda[2], Mamatha Kasula[2*] and Satish Kumar Bedada[3]

Abstract

Background: Six different metal complexes of quercetin (Cu, Zn, Co, Vd, Mo, Ni) were synthesized, purified, and characterized by their physical and spectral (UV, IR) data. They were evaluated for their P-gp (permeability glycoprotein) inhibitory activity by in vitro everted sac method in rats. The apparent permeability of atorvastatin (P-gp substrate) from everted sac of the rat intestine was determined in control, standard (verapamil), and groups treated with quercetin-metal complexes. The drug contents were analyzed by validated RP-HPLC method using a mixture of acetonitrile and water (60:40 v/v) adjusted to pH 2.8 with phosphate buffer as mobile phase.

Results: In vitro studies revealed that the apparent permeability of atorvastatin (P-gp substrate) across the small intestine is much affected by the treatment with Cu/Co/Ni complexes of quercetin. The mean ± SD and apparent permeability of atorvastatin decreased after pre-treatment with these metal complexes.

Conclusions: The quercetin Cu/Co/Ni complexes could inhibit P-gp and increase the atorvastatin absorption. Hence, they could be considered P-gp inhibitors.

Keywords: Quercetin, Metal complexes, Atorvastatin, P-gp, Inhibitors, P-glycoprotein

Background

Cancer is a dreadful disease, killing a large number of the population worldwide. More than 100 different types of cancer are reported to affect humans [1, 2]. Chemotherapy is widely used for cancer treatment but it is hindered mostly due to the resistance of tumor cells to anticancer drugs [3, 4]. Several mechanisms underlying drug resistance were identified. Increased efflux of drugs by cancerous cells, due to over expression of membrane transporter proteins (efflux pumps) is one of the major mechanisms documented. P-glycoprotein (P-gp) is the first discovered multidrug transporter that pumps drugs out of tumor cells, resulting in decreased intracellular drug concentrations and thus reducing the efficacy of drugs [5]. It is present in several normal tissues like intestinal lining epithelium, endothelial cells, and bone marrow.

Quercetin (Q) is a major naturally occurring flavonoid, belonging to the class of flavonols. It is ubiquitously found in a wide variety of plant products like coffee, tea, dyes, vegetables, and fruits [6]. The beneficial effects of quercetin are mostly due to its free radical scavenging or antioxidant property and its ability to chelate metal ions (Fe^{2+} and Fe^{3+}, Cu^{2+}, Ni^{2+}) [7–12]. Quercetin and some of its metal complexes displayed various biological actions such as antimicrobial, antiulcer, antiallergic, anti-Alzheimer's, and anticancer [13–18]. It was reported that quercetin could competitively inhibit the members of MDR family, P-gp, MRP1, and BCRP [19–23]. But, hitherto, there are no reports on the P-gp inhibitory activity of quercetin-metal complexes. In this regard, the present

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METHOD DEVELOPMENT, VALIDATION, AND STABILITY INDICATING STUDIES OF OLMESARTAN MEDOXOMIL AND HYDROCHLORTHIAZIDE IN BULK AND PHARMACEUTICAL DOSAGE FORM BY UV-SPECTROSCOPY

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Abstract:

Development of UV method for simultaneous estimation of Olmesartan Medoxomil development was done by Q-Absorbance ratio method and area under curve method and stability indicating studies using methanol as solvent. Most of the studies are not well validated and not cross validated by other methodology. Here we have made an attempt to develop a simple, specific, accurate, precise and reproducible method for the simultaneous estimation of hydrochlorothiazide and OLM in combined dosage form by UV spectrophotometric method, the method includes area under curve method (Method I) and Q- absorbance Ratio method (Method II). The wavelengths are 243 nm and 272 nm λ_{max} of both the drugs were selected for Method I, and for Q- absorbance Ratio method (Method II) 250 nm an isoabsorptive wavelength and 272 nm were selected for estimation of Olmesartan Medoxomil and Hydrochlorothiazide respectively and The two drugs follow Beer's law over the concentration range of 1-6 µg/ml.

The % recoveries of the both the drugs were found to be nearly 100 % representing the accuracy of the proposed methods. LOD and LOQ values of OLM was found to be 0.400,0.403,0.407,0.400,0.403,0.407 at different wavelengths 272nm, 250nm, 242nm and LOD LOQ values of HTZ were found to be 0.135, 0.133, 0.182, 0.410, 0.405, 0.550 at 272nm, 250nm, 242nm.

Validation of the proposed methods was carried out for its accuracy, precision, specificity and ruggedness according to ICH guidelines. The proposed methods successfully applied in routine work for determination of Olmesartan medoxomil and hydrochlorothiazide in combined dosage form.

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Review Article

Formulation and Evaluation of Valacyclovir Hydrochloride Effervescent Floating Tablets

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ABSTRACT

The purpose of this research was to develop gastro-retentive drug delivery system of Valacyclovir hydrochloride to prolong gastric residence time with desired in vitro release profile. Valacyclovir hydrochloride is an Anti-viral drug with high solubility in gastric pH. In the present study, Valacyclovir hydrochloride floating tablets were prepared by effervescence method using sodium bicarbonate and citric acid as a gas generating agent. The tablets were formulated using direct compression method using polymers like HPMC K15M, HPMC K100M, Xanthan gum and Sodium alginate. Pre-compression parameters such as for angle of repose, bulk density, tapped density and hausner's ratio whereas the prepared tablets were evaluated for weight variation, thickness, hardness, friability, drug content, floating lag time, total floating time, in vitro dissolution study and in vivo radiographic studies. FT-IR and DSC studies elucidated the compatibility of the drug with the polymers and other excipients used in the study. In Vitro release studies of the prepared tablets depicted to follow Zero order kinetics with R2 value of 0.941 and Fickian diffusion where n value is < 0.5 and found to be the main mechanism of drug release. The manufacturing procedure was found to be reproducible and formulations were stable after one month of accelerated stability studies.

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As a result, drugs with absorption window in the upper part of the small intestine undergo incomplete absorption [4]. Hence a beneficial delivery system would be one which possesses the ability to control and prolong the gastric emptying time and can deliver drugs in higher concentrations to the absorption site i.e. upper part of the small intestine [5]. Gastric retention of drugs is one of the approaches used in the prolongation of gastric retention time with suitable therapeutic activity [6].

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Valacyclovir hydroconchloride is suitable for floating drug delivery system as it undergoes hepatic metabolism which hinders with the oral bioavailability of the drug. It also has multiple dosage activity for a day that maintains stable drug plasma concentration [10].

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Original Article

Assessment of psychiatric variables in geriatric patients diagnosed with different types of osteoarthritis: Radiographic based evidences

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Context: Osteoarthritis (OA) is the most prevalent musculoskeletal condition in the world and is the most common cause of joint disability in approximately 15% of the total world population. The severity of the disease increases with age. It can have adverse effects on mental stability and is associated with poor clinical prognosis.

Aim: The aim of the study is to assess psychiatric variables (depression, anxiety, and perceived stress) in geriatric patients diagnosed with OA based on radiographic evidence and the item(s)/question(s) from questionnaires influencing their emotional instability.

Settings and Design: The prospective observational study was conducted in a tertiary care Mahatma Gandhi Memorial Hospital, Warangal.

Subjects and Methods: The study conducted for a period of 6 months and encompasses 158 elders with different types of OA. Standardized questionnaires were used to assess psychiatric variables.

Statistical Analysis Used: Statistical analysis was conducted using Microsoft Excel 2019 and IBM SPSS Statistics for Windows, Version 22.0. (IBM Corp, Armonk, NY, USA).

Results: The results of Pillai's trace revealed the scores of depression and anxiety as severe and perceived stress as moderate. Linear logistic regression stepwise disclosed the order of included variables affecting depression, anxiety, and perceived stress based on their level of significance ($P < 0.05$).

Conclusion: The findings in our study exemplify a strong correlation between psychiatric variables and OA.

Keywords: Anxiety, depression, geriatric patients, osteoarthritis, perceived stress

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FORMULATION AND EVALUATION OF PROPRANOLOL HYDROCHLORIDE ORAL DISINTEGRATING TABLETS

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Keywords:

Propranolol hydrochloride, Oral disintegrating tablets, Super disintegrants, *In-vitro* dissolution profile

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ABSTRACT: Background and purpose of the study: Propranolol hydrochloride beta-adrenergic receptor antagonist utilized in the treatment of high blood pressure, atrial fibrillation, myocardial infarction, angina and migraine headaches. The pharmacokinetic parameters make Propranolol hydrochloride an appropriate candidate for oral disintegrating tablets. This work aims to develop orally disintegrating tablets for Propranolol hydrochloride and to evaluate their pre-compression, physicochemical properties and water absorption ratio, disintegrating time, wetting time, *in-vitro* dispersion, time, and *in-vitro* dissolution. **Research rationale:** To attain rapid disintegration, dissolution/absorption, and further improving the bioavailability of the drug. To resolve swallowing issues in geriatric, pediatric patients by rapid disintegration in saliva and to treat high blood pressure, angina, atrial fibrillation, myocardial infarction, migraine. **Methods:** Oral disintegrating tablets prepared by direct compression technique using super disintegrants like Crospovidone, Croscarmellose sodium, Sodium starch glycolate, and Pregelatinised starch in several concentrations. The prepared batches of tablets were evaluated for pre-compression parameters and weight variation, thickness, hardness, friability, drug content, wetting time, disintegrating time, *in-vitro* dispersion time and *in-vitro* dissolution. The physicochemical interaction between drug and excipients were investigated by Fourier transform infrared spectroscopy. **Results:** Among the prepared formulations, F5 (Crospovidone 6%) was optimized and shows the maximum cumulative amount of drug release 97.05% in 14 min and disintegration time is 14.25 sec. Spectroscopic studies showed no evidence of interaction between the drug and excipients. **Conclusion:** Propranolol orally disintegrating tablets were found to possess faster disintegration time and drug release.

INTRODUCTION: Among the various routes of drug delivery system oral route is the most preferred route to the patient because of their convenience in self-administration, pain avoidance, and most significantly the patient compliance. However, people experience inconvenience in swallowing conventional forms, such as when water is not available. To overcome this drawback, a new drug delivery system has been developed known as orally disintegrating tablets (ODT) [1].

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US Food and Drug administration center for drug evaluation and research (CDER) defines an ODT as " A solid dosage form containing medicinal substances, that disintegrates quickly, typically at usually within a matter of seconds, once placed upon the tongue". ODT is that the most popular route for low bioavailability as a result of the

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Research Article

FORMULATION AND EVALUATION OF FENOVERINE FLOATING TABLETS

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ABSTRACT

Objective: The purpose of this research was to develop a fenoverine gastroretentive drug delivery system which, following oral administration should have the ability to enhance and prolong the period of gastric residence time (GRD) with the desired *in vitro* release profile.

Methods: In the present study, fenoverine floating tablets were prepared using an effervescent method using sodium bicarbonate and citric acid as a gas-generating agent. The tablets were formulated using direct compression technology using xanthan gum and sodium alginate as polymers. Pre-compression powders were evaluated for angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, and the prepared tablets were evaluated for weight variation, thickness, diameter, hardness, friability, drug content, floating lag time, total floating time, and *in vitro* dissolution studies. The formulations were optimized for the different concentrations of xanthan gum, sodium alginate, and their combinations.

Results: All the prepared formulations showed well *in vitro* buoyancy. The tablets remained buoyant for 6–12 h. The *in vitro* drug-release pattern of fenoverine floating tablets was adapted to different kinetic models with the highest regression to zero-order and Korsmeyer-Peppas, and the mechanism was found to be a Fickian mechanism.

Conclusion: Out of all the formulations prepared, *in vitro* dissolution studies of the F4 formulation were found to be maximum than other batches, which exhibited desired sustained release time followed by acceptable floating properties.

Keywords: Fenoverine, Gastric residence time, Effervescent method, Buoyancy, Floating properties.

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INTRODUCTION

The oral route is the most appropriate and widely used route for the delivery of drugs to the systemic circulation. This route has high acceptability for patients, particularly due to ease of administration. Over the years, oral dosage forms have become increasingly world-wise in the pharmaceutical field, with controlled release drug delivery (CRDDS) systems that release the drug at a predetermined, predictable, and controlled rate playing a major role [1]. The main imperative for the successful action of oral controlled drug delivery systems was to have good drug absorption throughout the gastrointestinal tract (GIT). The most preferable approach of oral controlled drug delivery is gastroretentive drug delivery system, where the dosage form can remain in the stomach for a prolonged period, thereby increasing the gastric residence time (GRT) and targeting site-specific drug release in the upper GIT for producing local or systemic effects. It is obtained by retaining the dosage form in the stomach and by releasing it in a controlled manner [2]. The following two parameters are optimized to develop sustainable orally controlled releasing drug delivery systems that deliver a drug for the required duration for optimal treatment at a therapeutically efficient range to a desirable place [3]. (a) Gastrointestinal transit modulation time: To modulate the transit time for GIT so that dosage form can be taken to or around the target absorption site and thus extend the time limit for maximizing the delivery of drugs. (b) Minimizing the elimination of the first hepatic pass: If the drug to be given undergoes extensive first-pass hepatic removal, preventive measures should be developed to either bypass or minimize the extent of hepatic metabolism. The purpose of the work is to develop drug delivery systems of fenoverine in which after oral administration should have the ability to prolong the gastric residence time with the desired *in vitro* release profile. Fenoverine is an antispasmodic drug used to relieve muscle spasm, cramps associated with the stomach, and abdominal pain associated with irritable bowel syndrome [4,5].

Due to the shorter half-life of Fenoverine (5-7 h) it requires frequent daily dosing and its therapeutic use in chronic conditions necessarily involves its formulation into a sustained release dosage form[6]. It is the most suitable drug to be formulated as a floating drug delivery system as it helps in increasing the gastric residence time and helps to have good control over the fluctuations in plasma drug concentration.

MATERIALS AND METHODS

Materials

Fenoverine was obtained as a gift sample from Euro drugs, sodium bicarbonate, xanthan gum, and sodium alginate obtained from Research-lab fine chem. Industries, citric acid from HiMedia laboratory, Talc from Sd fine-Chem Ltd, magnesium stearate from Qualikems Fine Chemicals Pvt. Ltd, and Lactose from Yarrow Chem products, all the ingredients, and reagents used were of analytical grade.

Methods

Pre-formulation studies

Pre-formulation studies are carried out to know and understand the physical and chemical behavior of a drug and also to know the drug-excipient compatibility using FTIR.

Solubility studies

Solubility was determined by weighing accurately 1 g of the drug and transferring it into 5 different 10 ml volumetric flasks containing different solvents (water, ethanol, methanol, DCM, and 0.1N HCl), respectively [6].

FTIR studies

It is often used to identify organic, inorganic, and polymeric materials present in the dosage form, analyse pure drug formulations, polymer, and drug-loaded polymer formulations, as well as functional group

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Design and Evaluation of Ornidazole Sustained release Dental Inserts

Sunchu Harika [1], Y Shravan Kumar [2], Y Madhusudhan Rao [3], Pavani Sriram [4], Uma Shankar [5]

Affiliations

PMID: 33618642 DOI: 10.2174/1389200222666210222152940

Abstract

Aim & Background: Ornidazole an antimicrobial drug used to treat certain types of vaginal, urinary tract, and interstitial infections. The objective of this study is to formulate and evaluate the dental inserts by using drug candidate to sustained release of drug to improve patient compliance, reduce dosing frequency, better therapeutic efficacy and fewer side effects, reduce the risk of dose dumping as well as also to avoid the first-pass metabolism.

Materials & method: The dental inserts were prepared using various polymers and in combination with the different ratios of polymers. The evaluation parameters like thickness, drug content, content uniformity, moisture reuptake, weight variation, swelling studies, and erosion studies of the optimized inserts were studied. The in-vivo studies were conducted for determining the reduction of pocket depth in human volunteers.

Results: The system containing ethylcellulose and hydroxyl methyl propyl cellulose K100M (4:1) formulation F6 was optimized because drug release was sustained up to 120 hrs with respect to other formulations. Optimized formulation follows first-order kinetics and Peppas release kinetics via fickian diffusion. There was no swelling, itching, irritation and the reduction of pocket depth was absorbed in in-vivo studies.

Conclusion: The study concluded that dental inserts can extend the release of Ornidazole for many hours also enhanced bioavailability, further it also helps in avoiding the first-pass effect. The observations of in vivo studies were, there was no itching, irritation, swelling, and reduction in pocket depth was observed.

Keywords: Anaerobic bacteria; Enhanced bioavailability; Ethylcellulose; Intra pocket drug delivery; Minimum inhibitory concentration; Periodontal Disease; Pocket depth; Sustained-release.

LinkOut - more resources

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Synthesis, characterization and evaluation of new thiazole derivatives as anthelmintic agents

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A series of 2-amino substituted 4-phenyl thiazole derivatives has been synthesized by the conventional method. The thiazole derivatives have been synthesized by three steps. The obtained five derivatives have been purified by recrystallization process by using methanol as solvent and column chromatography [IVd Compound] and have been characterized by melting point, TLC, FTIR, ^{1}H NMR and mass spectral data. All the five derivatives have been evaluated using *in silico* studies by using different softwares (Lipinski's Rule of 5, OSIRIS molecular property explorer, Molsoft molecular property explorer, PASS and docking studies). These compounds have then been evaluated for anthelmintic activity against Indian adult earth worms (*Pheretima postuma*). All the compounds show significant anthelmintic activity. The compound IVc and IVe are shown to be potent compounds when compared with the standard drug (Mebendazole). Molecular docking studies have guided and prove the biological activity of the sythesised compounds against beta tubulin protein (1OJ0).

Keywords: Anthelmintic activity, *Pheretima postuma*, molecular docking, thiazole derivatives, β-tubulin protein

Helminthic infections are one of the World's long standing health problems in humans and domestic animals. We can recognize many of the characteristic clinical features of helminthes infections from the ancient writings of Hippocrates, Egyptian medical papyri, and the Bible. In recent past, several reports of failures in the treatment of human helminthes have been published and suspected for anthelmintic resistance (AR). AR is the most important disease problem faced by sheep-farming industry in Australia, South Africa. Even multiple-drug resistance is not uncommon in helminthes of veterinary importance. Helminthes are resistant to all available broad spectrum anthelmintics[1-5]. Considering the fact of AR, its potential threat and potential anthelmintic activity of thiazole derivatives, it was planned to synthesize new thiazole derivatives as anthelmintic drugs.

Thiazole is a five-membered heterocyclic ring with nitrogen and sulfur atom. Thiazole and related compounds are called 1,3-azoles (nitrogen and one other heteroatom in a five- membered ring). They are isomeric with the 1,2-azoles, containing nitrogen and sulfur atoms called isothiazole. Thiazole itself is a clear to pale yellow liquid with a boiling point of 116-118°C. Its specific gravity is 1.2 and it is sparingly soluble in water. It is soluble in alcohol and ether[6]. Thiazole is an aromatic ring on the basis of delocalization of a lone pair of electrons from the sulfur atom. The resonance forms of thiazole are shown in Scheme I. The thiazoles synthesized by using different techniques are from haloketones using halogen and thiourea[7], using NBS and thiourea[8], using oxidizing agent[9], using formamide disulfide dihydrobromide[10], from α-haloketones[11] (Scheme I).

Experimental Section

Chemicals used for the synthetic work were 4-methyl acetophenone, Bromine (Br_2), hydrobromic acid (HBr), glacial acetic acid, thiourea, thionyl chloride ($SOCl_2$), acetonitrile, acetyl chloride, chloro acetic acid, ethyl chloro formate, 4-chloro aniline, benzoyl chloride.

All the reactions were performed in the dried Borosil glass beakers, round bottomed flasks, conical flasks. Precoated silica gel plates (Merck) were used for TLC to monitor progress of the reaction. Compounds melting points were determined by capillary method and are uncorrected. JASCO UV chamber was used for detection of spots in TLC. IR spectra were recorded on Bruker FTIR spectrometer. ^{1}H NMR spectra were recorded on Bruker-400MHz spectrometer using DMSO-d_6 as solvent. The chemical shift data were expressed as values relative to TMS in δ (ppm).

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Cefotaxime Induced Staphylococcal Scalded Skin Syndrome: A Case Report

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ABSTRACT

Staphylococcal scalded skin syndrome (SSSS) is as well called as Ritter von Ritterschein disease, Lyell disease, Ritter disease and staphylococcal necrolysis of the epidermis. More common in neonates and children of age less than five years and are at a greater risk of SSSS. To fight against SSSS, children should attain lifetime immunity in the form of antibodies against exotoxins of staphylococcal strains. Symptoms include fever and redness on the overall surface of skin. Within 24-48h, fluid-filled blisters appear on the body. We report a case of 2 years old male child developed SSSS after intravenous administration of Cefotaxime.

Key words: Staphylococcal scalded skin syndrome, Immunity, Exotoxins, Cefotaxime, Exfoliative, Cephalosporins.

INTRODUCTION

Staphylococcal scalded skin syndrome is one of the major exfoliating skin infections. Mainly caused by Staphylococcus and the skin looks as if it has been burnt by a hot liquid.[1] Due to the lack of immunity and underdeveloped renal clearance, there is a greater chance of SSSS in children.[2]

Two exfoliating toxins A and B which are released from *Staphylococcus aureus*, but the mechanism for exfoliation is unclear until today. Beneath the granular cell layer, separation of the epidermis and red rash occurs when these toxins act at a remote layer.[3] Two types of SSSS exist localized form superficial involvement of skin and a generalized form involvement of significant areas. Localized infection of *Staphylococcus aureus* in the skin, nose, mouth, throat, umbilicus and gastro intestinal tract (GIT). General malaise, irritability, fever, skin tenderness may be prominent. Other signs include facial edema, conjunctivitis and perioral crusting.[4]

Cephalosporin's are used as a prophylactic treatment in many patients because of their β- lactamase stability, lack of toxicity and broad-spectrum.[5] Cefotaxime is a third-generation cephalosporin antibiotic.[6] Here we discuss a case of SSSS due to Intravenous Cefotaxime administration.

CASE REPORT

A two years old male child who was hospitalized in the Pediatric Department for fever since 3 days, facial puffiness, 2 episodes of vomiting containing food for 1 day, Swelling of legs and feet for 2 days. Then the patient was given Cefotaxime 280mg IV, Paracetamol 5ml syrup, Cetirizine 5ml syrup.

After two days, the patient developed pedal edema and rashes on legs. The physician stopped the medication and the patient was referred to dermatology. On general examination child was conscious, febrile. His pulse rate was 146/min and blood pressure was 90/50mmHg. Physical examination revealed multiple fluid -filled vesicles and bullae noted on the lower limbs and hyperpigmented lesions noted on the

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Original Article

Safety and Efficacy of Streptokinase, Tenecteplase, and Reteplase in Patients Diagnosed with ST-Elevation Myocardial Infarction: A Comparative Study

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Abstract

Objective: Our primary objective was to compare the efficacy of streptokinase (SK), tenecteplase, and reteplase by studying patients' electrocardiogram Electrocardiogram(ECG) pre and post thrombolysis. The secondary objectives were to assess chest pain relief using Numerical Pain Rating Scale score and also to compare the side effects (bleeding, hypotension, and anaphylaxis) of three drugs. **Materials and Methods:** This study is a multicentric, prospective, randomized, comparative study. This study was conducted on 150 patients of ST-elevation myocardial infarction admitted in the wards/ICCU- Intensive Coronary Care Unit, Department of Cardiology, Mahatma Gandhi Memorial Hospital and Rohini Superspeciality Hospital. They were selectively divided into three groups. Group A consisted of patients who received SK (50), Group B who received tenecteplase (50), and Group C who received reteplase (50). The study period was 6 months. The follow-up was done in all the patients during their inhospital stay. **Results:** Post thrombolysis, reteplase, tenecteplase, and SK led to mean ST-Segment reduction of 64.9 ± 19.77, 52.43 ± 34.57, and 46.97 ± 33.09, respectively. The comparison between the three drugs revealed a significant difference ($P = 0.0103$). **Conclusion:** This study concluded that reteplase is most efficacious in the resolution of ST-elevation and also safer than other thrombolytics used.

Keywords: Reteplase, ST-elevation myocardial infarction, streptokinase, tenecteplase, thrombolytics

Introduction

ST-elevation myocardial infarction (STEMI) is one of the challenging problems among acute coronary syndromes.[1] STEMI is a clinical syndrome characterized by typical symptoms of myocardial ischemia associated with persistent electrocardiographic ST-elevation and subsequent release of myocardial necrotic biomarkers. The Universal Definition of Myocardial Infarction defined by the European Society of Cardiology/American College of Cardiology Foundation/American Heart Association (AHA)/World Heart Federation Task Force is defined as new ST-elevation at the point J in at least two contiguous leads of ≥1.5 mm (0.15 mV) in women or ≥2 mm (0.2 mV) in men in leads V2–V3 and/or of ≥1 mm (0.1 mV) in other contiguous chest leads or the limb leads, is characteristic of diagnostic ST-elevation in the absence of left ventricular (LV) hypertrophy or left bundle branch block (LBBB). Coronary artery disease (CAD) is the leading cause of mortality worldwide, and over 7.4 million people died due to CAD in 2015.[2] Nearly three million STEMI cases are estimated to occur in India per year. Cardiovascular diseases are with the highest mortality rate in India accounting for about 21% of the deaths in 2010, with 10% of overall deaths occurring due to CAD.[1]

The ACC/AHA 2013 guidelines for the management of STEMI suggest fibrinolytic therapy when there is an anticipated delay in performing primary PCI within 120 min of first medical contact and lists available fibrinolytic agents (tenecteplase [TNK-tPA], reteplase [rPA], alteplase, and streptokinase [SK]).[3]

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Synthesis, characterization and evaluation of thiopyrimidine derivatives as possible antimicrobial agents

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A series of new thiopyrimidine derivatives have been synthesized *via* the reaction of Chalcones **3a-c** with thiourea to give the corresponding pyrimidine thiones **4a-c**. S-alkylation of pyrimidine thiones have resulted in novel 4,6-diaryl-2-alkyl thiopyrimidine **5a-i** derivatives. Molecular properties like number of hydrogen bond acceptors, number of hydrogen bond donors, volume, polar surface area, molar refractivity, number of rotatable bonds and drug likeness for synthesized compounds have been predicted by using different softwares such as Molinspiration, Molsoft and Chemsketch. The newly synthesized 4,6-diaryl-2-alkyl thiopyrimidine derivatives **5a-i** have been evaluated for their possible anti-microbial activity. Compounds **5b**, **5d** and **5e** have revealed significant activity against *E. coli*, *P. aerugenosa* (Gram +ve) and *B. subtilis*, *S. aureus* (Gram −ve) species while compounds **5a**, **5c**, **5f-i** are moderately active as compared to the standard drug Ciprofloxacin. Compounds **5c** and **5g** show potent anti-fungal activity against *Penicillium* species amongst the series in comparison to the standard Fluconazole.

Keywords: Chalcone, thiopyrimidine, S-alkylation, molecular properties, anti-microbial

Pyrimidine is one of the most important heterocycles exhibiting remarkable pharmacological activities. It contains two nitrogen atoms at positions 1 and 3 of the six-membered ring exhibiting a wide range of biological activities. Numerous methods for the synthesis of pyrimidine offer enormous scope in the field of medicinal chemistry[1,2]. Condensed pyrimidine derivatives have been reported as anti-microbial, analgesic, anti-viral, anti -inflammatory, anti- HIV, anti-tubercular, anti-tumor, anti-neoplastic, anti-malarial, diuretic, cardiovascular agents and hypnotic drugs for the nervous system, calcium-sensing receptor antagonists, adenosine receptor antagonists, *etc*.[3] Thiopyrimidines (Figure 1) are broadly found in bioorganic and medicinal chemistry with applications in drug discovery and developments[4]. They are reported to possess broad spectrum of biological activities such as antibacterial, fungicidal, insecticidal, antihypertensive, tranquilizing, analgesic, antidiabetic, anticancer, *etc*.[5,6] Recent reports revealed thiopyrimidine derivatives as platelet aggregation inhibitors and as selective inhibitors of CDK2 transferase[7].

Thus, in view of their biological potential and to produce new molecules to combat the problem of drug resistance in microbial infections, some new thiopyrimidine derivatives have been designed in the present work based on our earlier studies on thiopyrimidines[8]. Herein, we report the synthesis and antimicrobial activity of some 4,6-diaryl-2-alkyl thiopyrimidines **5a-i**.

Results and Discussion

Chemistry

α,β-Unsaturated ketones (chalcones) **3a-c** have been prepared according to crossed aldol condensation by condensing aromatic/heteroaromatic methyl ketone **1** with different aromatic/heteroaromatic aldehydes **2** in dilute ethanolic sodium hydroxide solution at RT. Reaction of appropriate chalcones **3a-c** with thiourea and sodium hydroxide in ethanol produced thiopyrimidines **4a-c**. S-alkylation of thiopyrimidines **4a-c** using appropriate alkyl halides in presence of ethanolic sodium hydroxide solution *via* nucleophilic substitution reaction afforded 4,6-diaryl-2-alkyl thiopyrimidines **5a-i** (Scheme I).

Molecular Properties Prediction

Various molecular properties for synthesized compounds were predicted by using different softwares such as Molinspiration, Molsoft and Chemsketch[9].

Original Article

Evaluation of Corticosteroid Use Pattern and Their Adverse Effects in Patients Visiting the Dermatology Department of a Tertiary Care Teaching Hospital in Warangal, India

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Abstract

Introduction: Corticosteroids have become a mainstay of pharmacotherapy in dermatology because of their anti-inflammatory and immunosuppressive properties. However, misuse and sudden cessation of these drugs may render a patient to develop numerous adverse effects (AEs). Adverse drug reactions (ADRs) are important causes of mortality in both hospitalized and ambulatory patients. Early detection, evaluation, and monitoring of ADRs are essential to reduce harm to patients. Therefore, to achieve optimum benefit with the least AEs, safe and effective use of these agents is very crucial.

Objective: To examine the corticosteroid use pattern, to assess the frequency of misuse and the associated AEs that are encountered in dermatological practice.

Materials and Methods: A prospective observational study was conducted in the dermatology department of a tertiary care teaching hospital, Warangal for a period of six months. All patients using at least one corticosteroid either topically or systemically were included in the study. Informed consent was taken from patients.

Results: A total of 151 participants were included in the study. Among them, 56% of females developed ADRs compared with males (44%). Among patients using topical corticosteroids (TCs), the most frequently reported ADRs include facial erythema (7.31%), acne (17.07%), and hyperpigmentation of the face (2.43%). The AEs associated with oral corticosteroids include weight gain (19.51%) and taenia corporis (19.5%).

Conclusion: Corticosteroids have extreme importance in dermatological practice. However, inappropriate and prolonged users render a patient to develop several AEs. Precise drug regimens and proper patient counseling can help in minimizing and managing the AEs associated with inappropriate use.

Keywords: Acne, corticosteroids, erythema, hyperpigmentation, taenia corporis

Key Message: To prevent or manage steroid-induced AEs.

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AUCTORES
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Journal of Pharmaceutics and Pharmacology Research
D. Adukondalu *

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Review Article

Regulatory Guidelines for New Drug Development

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Abstract

Aim: The aim of present project work is to understand the guidelines and regulatory requirements for investigational new drug and development of new drug

Objectives: The objective of current project include

1. Need of a new drug to investigate
2. New drug development targets
3. Understanding the properties of new dug
4. Required protocols for submission of new drug to regulatory authority
5. Regulatory requirements to get approval of new drug.

Keywords: drug development, regulatory authority, IND regulation, pharmacokinetic

Introduction

Definition of an Investigational Product

ICH GCP defines an investigational product as, "A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial" (ICH GCP 1.33). This may include a marketed product that is being used in a different form than the one it was approved for, or a marketed product being used for an unapproved or new indication.

Definition of an Investigational New Drug

The Code of Federal Regulations (CFR) defines an investigational new drug as: "...a new drug or biological drug that is used in a clinical investigation." In the U.S. Food and Drug Administration (FDA) regulations, an investigational new drug is any substance (such as a drug, vaccine or other biological product) for which FDA approval is being sought. A drug may be considered "new" even if it has been in use for years if a change is proposed in its use, formulation, route of administration, use in patient population where risk would be increased, or packaging. For example, years ago the FDA approved a drug to treat high blood pressure.

Drug discovery is a process, which aims at identifying a compound therapeutically useful in treating and curing a disease. Typically a drug discovery effort addresses a biological target that has been shown to play a role in the development of the disease or starts from a molecule with interesting biological activities. The process of drug discovery involves the identification of candidates, synthesis, characterization, screening, and assays for therapeutic efficacy. Once a compound has shown its value in these tests, it will begin the process of drug development prior to clinical trials. Drug discovery and development is an expensive process due to the high costs of R&D and human clinical tests. The average total cost per drug development varies from US$ 897 million to US$ 1.9 billion. The typical development time is 10-15 years.

Figure1: *Drug Discovery Pipeline.*

The developing world suffers the major burden of infectious disease, yet the range of drugs available for the treatment of many infectious diseases is limited. In the past most drugs have been discovered either by identifying the active ingredient from traditional remedies or by serendipitous discovery [1]. At present a new approach is being tried to understand how disease and infection are controlled at the molecular and physiological level and to target specific entities based on this knowledge.

Steps in Modern Drug Discovery

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Research Article

Formulation and *In-vivo* Studies of Clopidogrel by Self-nanoemulsifying Drug Delivery System

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ABSTRACT

A self-nano emulsifying drug delivery system (SNEDDS) has been explored to improve poorly water-soluble drug clopidogrel's solubility and dissolution rate. Different formulations were prepared using oil, surfactant, and co-surfactant in varying ratios. From the ternary phase diagram resultant formulations were investigated for clarity, phase separation, drug content, % transmittance, globule size, freeze-thaw, in vitro dissolution studies, particle size analysis, and zeta potential. Based on particle size, zeta potential and dissolution profile, and other studies, F6 was the best formulation of clopidogrel SNEDDS. The particle size of the optimized SNEDDS formulation was found to be 5.2 nm, and zeta potential was found to be -29 mV which complies with the requirement of the zeta potential for stability. The % release from optimized SNEDDS formulation F6 was highest (98.93%) and faster than other SNEDDS formulations and pure drug substance (32%), indicating the influence of droplet size on the drug dissolution rate. FTIR data revealed no physicochemical interaction between drug and excipients. In vivo bioavailability studies were carried out on the optimized formulation (F6), mean time to attain peak drug concentration (T_{max}) was 0.5 ± 0.53 and 1.5 ± 0.72 minutes for the optimized and pure drug, respectively, while means maximum drug concentration (C_{max}) was 6.77 ± 1.73 ng/mL and 2.10 ± 0.39 ng/mL respectively. $AUC_{0-\infty}$ and AUC_{0-t} for the optimized formulation were significantly higher ($p<0.05$) 20.5 ± 2.48 ng.h/mL than the pure drug 6.34 ± 1.73 ng h/mL, respectively. Thus, the results indicate clopidogrel with SNEDDS formulation may be used to improve solubility and dissolution rate for the effective management of heart disease.

Introduction

Drugs with poor solubility are difficult to formulate by applying conventional approaches as they pose problems such as the slow onset of action, poor oral bioavailability, lack of dose proportionality, failure to achieve steady-state plasma concentration, and undesirable side effects, thus resulting in over or under medication and poor patient compliance.[1] These challenges can be overcome by applying self-nano emulsifying systems that offer benefits like reduction in dose frequency, lowering of dose size, site-specific targeting, enhanced permeability, and improvement in oral bioavailability.[2] Nanotechnology is a promising strategy in drug delivery systems, especially for those potent drugs whose clinical development failed due to poor solubility, low permeability, inadequate bioavailability, and other poor biopharmaceutical properties. SNEDDS formulations for poorly water-soluble drugs have shown a considerable increase in solubility and bioavailability. Clopidogrel, sold as the brand name Plavix among others, is used to reduce the risk of heart disease and stroke in those at high risk.[3-5] The study's main aim is to formulate and evaluate the SNEDDS clopidogrel formulation to improve its solubility and dissolution rate.

Materials and Methods

Clopidogrel was obtained as a gift sample from Aurobindo Pharma Limited, Hyderabad. Caproic acid, gelucire 44/14, transcutol p and labrasol, sunflower oil and

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