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An Investigation on Leprosy Treatment Patterns, including Disease Prevalence, Adverse Event Monitoring, and Medication Adherence Assessment

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ABSTRACT

A prospective observational study was carried out for six months among the leprosy patients in two districts in Telanagana (Ranga Reddy and Hyderabad). The study was carried out to determine the prevalence, treatment pattern and drug related problems among the leprosy patients. During our study period 40 cases were reported from Hyderabad district and 64 from Ranga Reddy. So the prevalence of leprosy in Hyderabad and Ranga Reddy district was found to be 0.001 and 0.002 respectively. In the current study among among a total of 104 patients included, 49 (47%) were in the age group of 31-50 years. The mean age was 42.13 ± 18.61 years. Nearly 6% of the patients were aged less than 15 showing the transmission is still going on the community. This high prevalence in younger age group calls for more vigorous means of case detection like active search for cases especially in communities known to be leprosy endemic. 104 patients were enrolled in the study, of them 74(71%) were males and 30(29%) were females, demonstrating male predominance over female population. There are three important principles for leprosy work in the future. It includes; Sustainability (new cases of leprosy are continuing and many of the consequences are lifelong so our approaches need to be sustainable), the leprosy workers cannot do everything themselves (they need to work in alliances at all levels with other agencies, other health care workers, social services, communities, patients themselves and their families), Anti-leprosy services need to be integrated with general health and social services (this includes training, primary health care, hospital care, and community based rehabilitation) Finally we would like to emphasize the importance of a proper health education, daily ulcer care and skin adjustments as systemic therapy and also to prevent the development of new ulcers.

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Keywords: Leprosy, Prevalence Drug Therapy





Study of Prevalence of Stroke and Prescribing Pattern of medication for Stroke Patients

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Abstract

Aim and Objectives: To study the prevalence of stroke and prescribing pattern of medications for stroke patients.

Methodology: This prospective observational study conducted at Aware Global Hospital inHyderabad aimed to investigate stroke prevalence and prescribing patterns for stroke patients.Over a 6-month period, data was collected from 100 neurology department.

Results: The research findings reveal a higher stroke incidence in males (54%) than females(46%), predominantly ischemic stroke (48%). The 41 to 50 age group faces a higher risk (25%),often linked to hypertension and diabetes. Treatmentinvolves use of Proton pump inhibitors (90%), Antiplatelets (86%), Statins(85%), Anti-hypertensives (64%), Antipyretics/Analgesics (48%), and Anti-emetics(30%). Multivitamins(92%) and Anti-diabetic medication(48%) were also frequently administered. Commonly prescribed Antiplatelet therapy often combines Aspirin and clopidogrel (86%).

Conclusion: The study, focused on stroke demographics, found a peak in the 41-50 age group,with a higherincidencein males when compared tofemales. Smoking and alcohol use weremore prevalent. Ischemic strokes were predominant, often linked with hypertension and diabetes.Prescribing patterns included proton pump inhibitors, antiplatelets, statins, and multivitamins.Drug combinations for diabetes and antiplatelet therapy were identified, offering insights into stroke management.

Keywords: Ischemic stroke, hemorrhagic stroke, diabetes, hypertension, aspirin





International Journal of Medical and All Body Health Research

RP-HPLC Method Development and Validation for the Quantitative Determination of Ruxolitinib in Pure Form and Marketed Pharmaceutical Dosage Form

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Abstract

A novel, simple, accurate, precise, sensitive and specific analytical RP-HPLC method was developed and validated for the quantitative estimation of Ruxolitinib in bulk drugs and pharmaceutical dosage form. Chromatographic separation was achieved on an Symmetry ODS C18 (4.6×250mm, 5µm) analytical column using mobile phase composition of methanol and Phosphate Buffer in ratio of (35: 65 v/v) that was set at a flow rate of 1.0µl/min with detection of 235 nm. The retention time of Ruxolitinib was found to be 3.006min. The drug was analyzed by following the guidelines of International conference on Harmonization (ICH). This drug showing linearity in the concentration range of 6-14µg/ml and the correlation coefficient showing R² = 0.9996. The % Recoveries showing within the limits. The presentation of the method was validated according to the present ICH guidelines for accuracy, precision and robustness, Linearity, limit of quantification, limit of detection linearity.

Keywords: Ruxolitinib, RP-HPLC, Method Development, Accuracy, Precision

Introduction

Ruxolitinib ^[1] is a pyrazole substituted at position 1 by a 2-cyano-1-cyclopentylethyl group and at position 3 by a pyrrolo [2, 3-d] pyrimidin-4-yl group. Used as the phosphate salt for the treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia Vera myelofibrosis and post-essential thrombocythemia myelofibrosis. It has a role as an antineoplastic agent and an EC 2.7.10.2 (non-specific protein-tyrosine kinase) inhibitor. It is a nitrile, a pyrrolopyrimidine and a member of pyrazoles. Ruxolitinib ^[2] is a Kinase Inhibitor and Janus Kinase Inhibitor. The mechanism of action of Ruxolitinib is as a Janus Kinase Inhibitor. Ruxolitinib, formerly known as INCB018424 or INC424, is an anticancer drug and a Janus kinase (JAK) inhibitor. It is a potent and selective inhibitor of JAK1 and JAK2, which are tyrosine kinases involved in cytokine signalling and hematopoiesis. Myeloproliferative neoplasms, such as myelofibrosis and polycythemia Vera, are often characterized by aberrant activation of the JAK-STAT pathway, leading to abnormal blood cell counts and thrombotic complications. By inhibiting JAK1 and JAK2, Ruxolitinib ^[3] works to block the dysregulated cell signalling pathways and prevents abnormal blood cell proliferation. Due to a large number of patients with myeloproliferative neoplasms who have JAK2 mutations, Ruxolitinib was the first ATP-competitive inhibitor of JAK1 and JAK2 developed. Ruxolitinib is an antineoplastic agent that inhibits cell proliferation, induces apoptosis of malignant cells and reduces pro-inflammatory cytokine plasma levels by inhibiting JAK-induced phosphorylation of signal transducer and activator of transcription (STAT). Inhibition of STAT3 phosphorylation, which is used as a marker of JAK activity, by Ruxolitinib is achieved at two hours after dosing which returned to near baseline by 10 hours in patients with myelofibrosis and polycythemia Vera. In clinical trials, Ruxolitinib reduced splenomegaly and improved symptoms of myelofibrosis. In a phase III trial of myeloproliferative neoplasms, administration of Ruxolitinib was associated with prolonged survival. Ruxolitinib inhibits both mutant and wild-type JAK2; however, JAK2V617F mutation, which is often seen in approximately 50% of patients with myelofibrosis, was shown to reduce



International Journal of Medical and All Body Health Research

Formulation and evaluation of metoprolol tartrate transdermal drug patches

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Abstract

The objective of present study was to develop matrix type transdermal therapeutic systems of Metoprolol tartrate using various such as Sodium alginate and HPMC polymers as matrix formers. Results revealed that prepared patches showed good physical characteristics and no drug-polymer interaction was observed. The in vitro release study revealed that F3 formulation showed maximum release in 8 hrs. Formulation F3 was subjected for accelerated stability studies. The F3 formulation was found to be stable as there was no drastic change in the Physico-chemical properties of the patches, which was also confirmed by FTIR. Thus, conclusion can be made that stable transdermal patch of Metoprolol tartrate has been developed. F3 formulation showed highest cumulative percentage drug release of 93.97 % were obtained during in vitro drug release studies after 8 hrs. The predominant release mechanism of drug through the fabricated matrices was believed to be by diffusion mechanism. Based upon the in vitro dissolution data the F3 formulation was concluded as optimized formulation.

Keywords: Metoprolol tartrate, Sodium alginate and HPMC, solvent casting technique, in vitro drug release studies

Introduction

Transdermal drug delivery system (TDDS) is a widely accepted means of drug delivery, and transdermal patches are devised to treat various diseases ^[1]. TDDS are extended release dosage forms that can offer a stable systemic drug concentration and avoid first pass metabolism. They can even avoid gastrointestinal problems associated with drugs and low absorption ^[2]. These therapeutic advantages reflect the higher marketing potential of TDDS ^[3]. Transdermal drug delivery system is a self-contained delivery use for topical application in the form of multilaminated adhesive patch which gives a specific dose of drug at a predetermined rate and controlled the rate of drug release through skin ^[4] Metoprolol tartrate, a beta adrenoreceptor-blocking agent used in the treatment of cardiovascular disorders. The drug has a short half-life due to extensive first pass metabolism ^[5]. The Transdermal drug delivery system designed by various methods such as transdermal patches includes matrix, micro reservoir, reservoir, adhesive, and membrane matrix hybrid. Matrix type transdermal patches are most popular as they are easy to construct ^[6]. The Metoprolol tartrate transdermal patch in this paper also developed by using the Matrix type of transdermal drug delivery system ^[7].

Materials

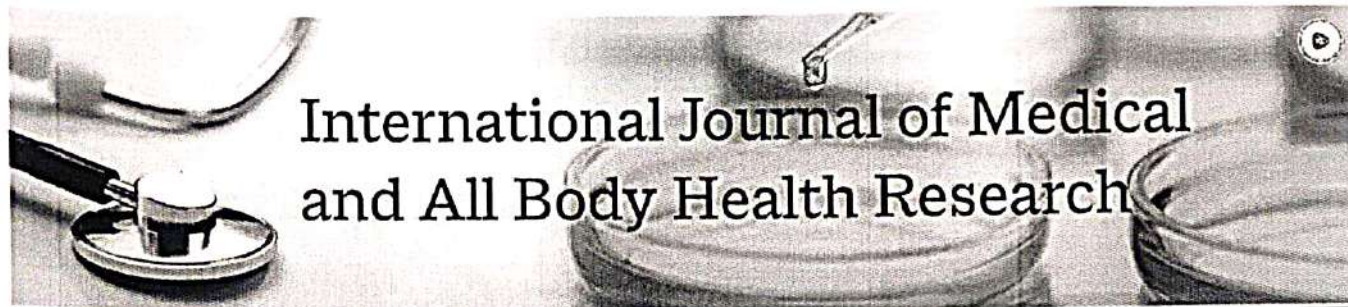
Metoprolol tartrate was obtained from Hetero Labs, HYD. HPMC and Eudragit were procured from Synpharma Research Labs, Hyderabad, and other chemicals the reagents used were of analytical grade.

Methodology

Compatibility studies of drug and polymers ^[8]

In the formulation of Metoprolol tartrate patch formation, API and Excipient may interact as they are in close communication





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A new analytical novel RP-HPLC method development and validation for the quantitative determination of Dasatinib in pure form and marketed pharmaceutical dosage form

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Abstract

The present work includes a simple, economic, rapid, accurate and precise isocratic RP-HPLC method development for estimation of Dasatinib in bulk form and its marketed formulation. Estimation was done at 286nm which was found to be λ_{max} of Dasatinib. The simple, selective, isocratic RP-HPLC method for Dasatinib was developed on Phenomenex Luna (C₁₈) RP Column; 250 mm x 4.6 mm, 5 μ m with a mobile phase of Phosphate Buffer (pH-4.6) and Methanol were taken in the ratio of 65:35% v/v at a flow rate of 1.0 ml/min and detection wavelength 286nm. The developed method was validated successfully according to ICH Q2 (R1) guidelines. The chromatographic methods showed a good linear response with r^2 values of 0.9995. The percentage relative standard deviation for method was found to be less than two, indicating that the methods were precise. The mean percentage recovery was for RP-HPLC method was 100.437%. From the results it could be concluded that both the developed method was specific, selective and robust. The method could be successfully applied for analysis of Bulk form and Marketed formulation of Dasatinib.

Keywords: Dasatinib, RP-HPLC, Method Development, Validation, ICH Guidelines

Introduction

Dasatinib Anhydrous is an orally bioavailable synthetic small molecule-inhibitor of SRC-family protein-tyrosine kinases. Dasatinib¹ binds to and inhibits the growth-promoting activities of these kinases. Apparently because of its less stringent binding affinity for the BCR-ABL kinase, Dasatinib has been shown to overcome the resistance to imatinib of chronic myeloid leukemia (CML) cells harboring BCR-ABL kinase domain point mutations. SRC-family protein-tyrosine kinases interact with variety of cell-surface receptors and participate in intracellular signal transduction pathways; tumorigenic forms can occur through altered regulation or expression of the endogenous protein and by way of virally-encoded kinase genes. Dasatinib^[2] is indicated for the treatment of newly diagnosed adults with Philadelphia chromosome-positive (Ph⁺) chronic myeloid leukemia (CML) in chronic phase, as well as adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph⁺ CML with resistance or intolerance to prior therapy including imatinib, and adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph⁺ ALL) with resistance or intolerance to prior therapy. Dasatinib is also indicated for the treatment of paediatric patients 1 year of age and older with Ph⁺ CML in chronic phase or newly diagnosed Ph⁺ ALL in combination with chemotherapy. Dasatinib is an orally available small-molecule multikinase inhibitor. During clinical trials, less than 1% of patients treated with Dasatinib^[3] had QTc prolongation as an adverse reaction, and 1% experienced a QTcF higher than 500 ms. The use of Dasatinib is also associated with myelosuppression, bleeding-related events, fluid retention and pulmonary toxicity, pulmonary arterial hypertension, severe dermatologic reactions, tumor lysis syndrome and hepatotoxicity. It may also cause embryo-fetal toxicity and lead to adverse reactions associated with bone growth and development in pediatric patients.

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Formulation and evaluation of naproxen mouth dissolving tablets

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Abstract

The objective of the study was to formulate and evaluate Mouth Dissolving Tablets Of Naproxen Direct compression method was used to formulate orally disintegrating tablet of Naproxen by employing different super disintegrants, polymers, and magnesium stearate (lubricant), Talc. These prepared formulations were then evaluated. Dissolution and drug content tests were performed using USP apparatus II and ultraviolet spectrophotometry, respectively. All formulations showed compliance with pharmacopeia standards. The effect of super disintegrants concentration and direct compression method on drug release profile was studied. Release profile of F3 were found to be satisfactory comparing to other formulations. F3 Formulation as processed excipient was found to be the best super disintegrants for the preparation of Naproxen mouth dissolving tablets formulations. Due to it has exhibited faster disintegration time and best dissolution profile when compared to other formulations.

Keywords: Naproxen, super disintegrants, direct compression technique, in-vitro drug release studies

Introduction

Mouthdissolving tablet (MDT) are also called as orodispersible tablets, quick-dissolve, fast-melt, and rapid disintegrating tablets and freeze-dried wafers, porous tablets and rapimelts ^[1]. The conventional dosage forms, which include tablets and capsules, are widely used. But, unlike the conventional dosage forms, the mouth dissolving tablets has some unique features like: Rapid disintegration of tablet results in quick dissolution and rapid absorption which provide rapid onset of action ^[2]. Medication as "bitter pill" has changed by excellent mouth feel property produced by use of flavors and sweeteners in ODTs. Bioavailability of drugs that are absorbed from mouth, pharynx, and oesophagus is increased. Pre-gastric absorption of drugs avoids hepatic metabolism, which reduces the dose and increase the bioavailability ^[3]. Difficulty to swallow is particularly experienced by pediatric and geriatric patients. Technique that are frequently employed in the preparation of mouth dissolving tablets include, freeze drying, sublimation, spray drying, moulding, mass extrusion and direct compression ^[4].

Naproxen is a propionic acid derivative related to the aryl acetic acid group of nonsteroidal anti-inflammatory drugs (NSAID), cyclooxygenase inhibitor, used to treat the inflammation and pain of arthritis ^[5]. The purpose of the present study was to formulate and evaluate mouth dissolving tablets to avert the problem of swallowing and to provide rapid onset of action.

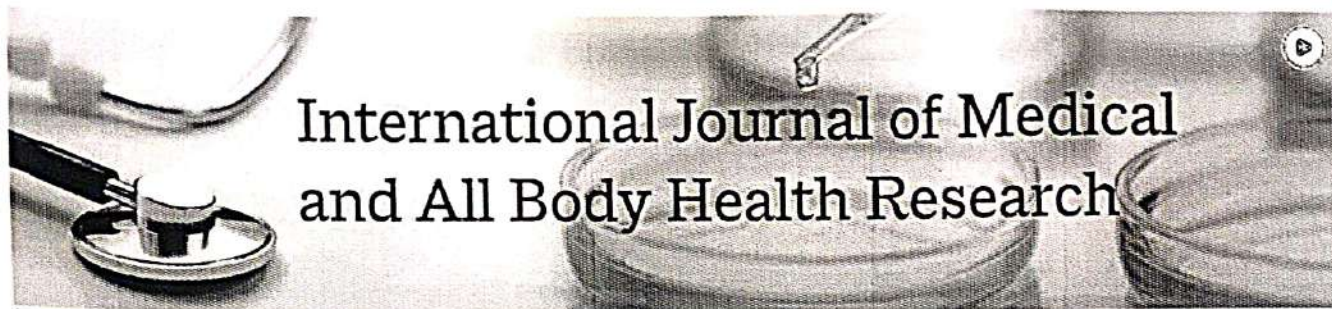
Materials

Naproxen was obtained from Hetero Labs, HYD. Crospovidone, Sodium starch glycolate were procured from Synpharma Research Labs, Hyderabad, and other chemicals the reagents used were of analytical grade.

Methodology

Drug excipient compatibility ^[6]

Compatibility studies of Naproxen and the disintegrates were carried out by using Fourier Transform Infrared Spectroscopy (FTIR). Fourier transform infrared spectra of the samples were obtained in the range of 4000 to 450-cm⁻¹ using a FTIR by the KBr disc method.



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Analytical method development and validation for the quantitative analysis of Ibrutinib in API form and marketed pharmaceutical dosage form by using RP-HPLC

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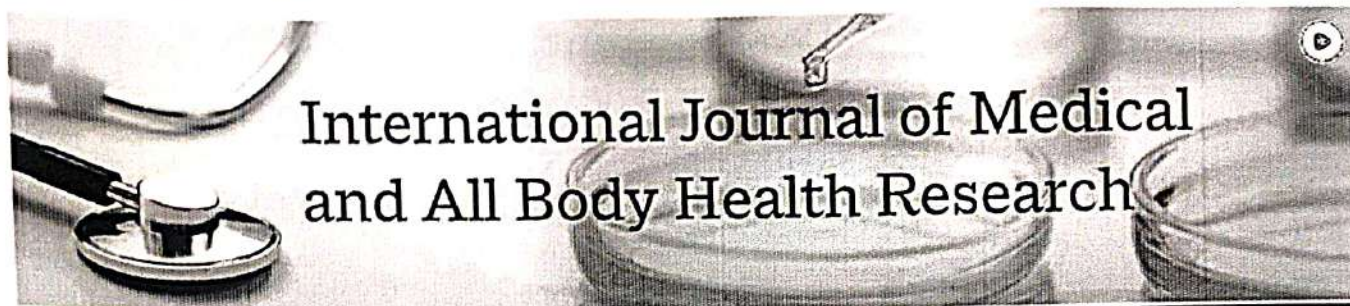
Abstract

A simple, rapid, specific and accurate reverse phase high performance liquid chromatographic method has been developed for the validated of Ibrutinib in bulk as well as in marketed pharmaceutical dosage form. This separation was performed on a Symmetry ODS C18 (4.6×250mm, 5µm) column with Methanol: Phosphate Buffer (35:65) v/v as mobile phase at a flow rate of 1.0 mL min⁻¹ with UV detection at 235 nm; the constant column temperature was Ambient. The runtime under these chromatographic conditions was less than 8 min. The retention time of Ibrutinib was found to be 2.276min. The calibration plot was linear over the concentration range of 6–14 µg mL⁻¹ with limits of detection and quantification values of 1.2 and 3.6 ng mL⁻¹ respectively. The mean % assay of marketed formulation was found to be 99.86%, and % recovery was observed in the range of 98-102%. Relative standard deviation for the precision study was found <2%. The developed method is simple, precise, specific, accurate and rapid, making it suitable for estimation of Ibrutinib in bulk and marketed pharmaceutical dosage form dosage form.

Keywords: Ibrutinib, RP-HPLC, Validation, Accuracy, Precision, ICH Guidelines

Introduction

Ibrutinib is a member of the class of acrylamides that is (3R)-3-[4-amino-3-(4-phenoxyphenyl) pyrazolo [3, 4-d] pyrimidin-1-yl]piperidine in which the piperidine nitrogen is replaced by an acryloyl group. A selective and covalent inhibitor of the enzyme Bruton's tyrosine kinase, it is used for treatment of B-cell malignancies. It has a role as an EC 2.7.10.2 (non-specific protein-tyrosine kinase) inhibitor and an antineoplastic agent. It is a pyrazolopyrimidine, an aromatic amine, aromatic ether, a member of acrylamides, an N-acylpiperidine and a tertiary carboxamide. Ibrutinib¹ is a small molecule that acts as an irreversible potent inhibitor of Bruton's tyrosine kinase. It is designated as a targeted covalent drug and it presents a very promising activity in B cell malignancies. Ibrutinib was developed by Pharmacyclics Inc and in November 2013 was FDA-approved for the treatment of mantle cell lymphoma. Later, in February 2014, Ibrutinib was approved for the treatment of chronic lymphocytic leukemia and it is also indicated for the treatment of patients with Waldenström's Macroglobulinemia. Ibrutinib² has also been approved by the EMA for the treatment of chronic lymphocytic leukemia and mantle cell lymphoma. Ibrutinib was approved for use in chronic graft versus host disease (cGVHD) in August 2017 which was later approved to be used in children, making it the first FDA-approved cGVHD treatment for kids 1 year and older after failure of one or more lines of systemic therapy. Ibrutinib³ is a Kinase Inhibitor. The mechanism of action of Ibrutinib is as a Protein Kinase Inhibitor. The IUPAC Name of Ibrutinib is 1-[(3R)-3-[4-amino-3-(4-phenoxyphenyl) pyrazolo [3, 4-d] pyrimidin-1-yl] piperidin-1-yl] prop-2-en-1-one. The Chemical Structure of Ibrutinib is as follows



International Journal of Medical and All Body Health Research

Formulation and evaluation of gastroretentive floating microspheres of nimodipine

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Abstract

The objective of the present work was to formulate floating hollow microspheres of Nimodipine which is soluble and shows better absorption in gastric pH. Microspheres were prepared by emulsion solvent diffusion technique. Using various such as ethyl cellulose, carbopol 934, eudragit and sodium alginate polymers. The formulations were evaluated for micromeritic properties, buoyancy, % yield, entrapment efficiency and *in vitro* studies. They were characterized by FT-IR. FT-IR and studies indicated that there was no interaction between the drug and polymers. SEM photographs showed the outer surface of microspheres was smooth and dense where as internal surface was porous which helped to prolong floating to increase residence time in stomach. The results showed that floating microspheres could be successfully prepared with better yield. Results showed larger the particle size, longer was the floating time. *In vitro* drug release studies showed controlled release of Nimodipine for over 8 h. From the results it can be concluded that gastric floating hollow microspheres can be successfully used for the delivery of Nimodipine to control the blood pressure.

Keywords: Nimodipine, Polymers, emulsion solvent diffusion technique, FTIR Studies, floating time, *in vitro* drug release studies

Introduction

Majority of drugs are preferentially absorbed in the upper part of the small intestine. So, Gastro retentive drug delivery systems are preferred. The retention of oral dosage forms in the upper GIT causes prolonged contact time of drug with GI mucosa leading to higher bioavailability and hence therapeutic efficacy, reduced time intervals for drug administration, potentially reduced dose size and thus improved patient compliance ^[1]. FDDS are preferred as they are economic and has improved patient compliance and they are advantageous for drugs absorbed from the stomach EG: ferrous salts and for drugs meant for local action in the stomach ^[2]. The floating systems are low-density systems that have sufficient buoyancy to float over the gastric content and remain buoyant the stomach without affecting the gastric emptying rate for a prolonged period of time which causes the inadequate release of drug at the absorption site ^[3]. Here we are developing lower density system that's floating microsphere, is prepared by solvent evaporation method incorporating Nimodipine as a model drug ^[4]. Nimodipine is a dihydropyridine calcium channel blocker developed for the treatment of high blood pressure. Nimodipine has a half-life of 8-9 h the bioavailability of 13% and it has narrow absorption window in upper part of the gastrointestinal tract (GIT), hence floating drug delivery system (FDDS) is preferred ^[5]

Materials

Nimodipine was obtained from Micro lab, HYD. Eudragit and ethyl cellulose were procured from Synpharma Research Labs, Hyderabad, and other chemicals the reagents used were of analytical grade.



International Journal of Medical and All Body Health Research

Formulation and *in vitro* evaluation of Diltiazem controlled release tablets

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Abstract

The aim of the present work is to Formulate and Evaluate controlled release of Diltiazem matrix tablets used for treat high blood pressure and control angina. Development of CR Diltiazem is proposed considering the adverse event profile and high fluctuation index of Diltiazem observed with IR dosage forms. In the present work, attempts were made to formulate and evaluate controlled release of matrix tablets of Diltiazem. Diltiazem was subjected to preformulation studies, based on the results obtained Diltiazem controlled release tablets were successfully formulated. Formulations prepared by wet granulation using HPMC and carbopol 934 as control release polymers and 5% W/W of povidone in isopropyl alcohol as binder solution have showed desired *in vitro* release. Set of trials were formulated for which Diltiazem evaluated parameters (bulk density, tapped density, compressibility index, hausner's ratio, weight, thickness, hardness) were found to lie within the specifications. Dissolution study was performed in USP type II apparatus at 100 RPM in pH 6.8 phosphate phosphate buffer.

Keywords: Diltiazem, polymers, wet granulation technique, *in vitro* drug release studies, FTIR studies

Introduction

Controlled release DDS release drug at rates, which are significantly different from conventional dosage forms. The controlled release dosage forms are designed to control the rate of drug delivery, target the delivery of the drug to a tissue and/or maintain the duration of therapeutic efficacy ^[1]. Oral drug delivery is the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage form. Oral route is considered most natural, convenient and safe due to its ease of administration, patient acceptance, and cost effective manufacturing process ^[2]. Pharmaceutical products designed for oral delivery are mainly immediate release type or conventional drug delivery systems, which are designed for immediate release of drug for rapid absorption ^[3]. Diltiazem hydrochloride is a Calcium channel and broadly utilized in the treatment of specific kinds of cardiovascular issues ^[4]. The therapeutic impacts of Diltiazem hydrochloride are identified with its capacity to hinder the flood of calcium particles in cardiovascular and vascular smooth muscle during membrane depolarization ^[5]. A basic dosing plan with more than once every day administration of the antihypertensive agent is known to expand patient compliance ^[6].

Materials

Diltiazem was obtained from Hetero labs, HYD. HPMC, Carbopol 934 were procured from Synpharma Research Labs, Hyderabad, and other chemicals the reagents used were of analytical grade.

Methodology

FT-IR study ^[7]

Compatibility of the drug with excipients was determined by FT-IR spectral analysis, this study was carried out to detect any



International Journal of Medical and All Body Health Research

Formulation and evaluation of Pregabalin microspheres

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Abstract

Microspheres play a very important role as particulate drug delivery system because of their small size and other efficient properties. Microspheres are characteristically free flowing solid powders, which consist of proteins or synthetic polymer, which are biodegradable in nature. The present study aimed to formulate and evaluate Pregabalin in microspheres. Ionotropic gelation technique was employed for microsphere preparation using different ratios of ethyl cellulose polymer and drug. Prepared microspheres were evaluated for drug entrapment efficiency, micromeritic characters and *In vitro* drug release. The particle size of all the formulations were ranged between 152.2 to 142.9 μm . The entrapment efficiency was ranged between 78.95 to 82.14 %. Stability studies showed almost negligible changes in particle size, entrapment efficiency and drug release throughout the study period.

Keywords: Pregabalin, FTIR studies, Sodium alginate, Ionotropic gelation technique, *In vitro* drug release studies

Introduction

Microspheres are defined as solid, approximately spherical particles ranging in size from 1 to 1000 μm . They are made up of polymeric, waxy or other protective materials such as synthetic polymers (PLA, PGA) and modified natural polymers [1]. Pregabalin (S) - 3 - amino methyl hexanoic acid, is a structural analogue of γ -amino butyric acid (GABA). They constitute an important group of compounds that are used in the treatment of epilepsy and neuropathic pain. Pregabalin has been studied for use in a variety of disorders, including monotherapy in refractory partial seizures, diabetic neuropathy, surgical dental pain and other pain syndromes, postherpetic neuralgia, and social anxiety disorders [2]. The aim of this study was to prepare microspheres containing Pregabalin by ionotropic gelation method to achieve a controlled drug release profile and to study the effect of different formulation variables such as drug: polymer ratio and particle size, encapsulation efficiency, and its *In vitro* release behavior.

Materials

Pregabalin was obtained from Micro labs, HYD. Sodium alginate and tragacanth were procured from Synpharma Research Labs, Hyderabad, and other chemicals the reagents used were of analytical grade.

Methodology

Drug and excipient compatibility studies [3]

Drug excipients compatibility studies were performed to know the compatibility of excipient with drug at accelerated conditions. The study was conducted by preparing homogenous mixture of excipient with drug and filled in HDPE bags and LDPE bags. Glass vials were exposed to 600 C and 400C/75 %RH for 4 weeks and LDPE bags were exposed to 400C \pm 75 %RH for 4 weeks. Samples were observed periodically for any physical change.



International Journal of Multidisciplinary Research and Growth Evaluation.

Development and *In vitro* evaluation of Niosomal drug delivery system

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Abstract

The present study was focused on formulating and evaluating Glipizide containing niosomes formulation for *In vitro* studies. Niosomal formulations were prepared by using different ratio of surfactant (Span 20 and span 80) and cholesterol by thin film hydration method and were evaluated for invitro characteristics, stability studies. Span 20 containing niosomal formulation displayed highest entrapment efficiency with desired particle size. SEM analyses showed that niosomal formulation was spherical in shape. Niosomes containing span 20 displayed higher percentage of drug release after 8h as compared to other formulations. F-1 formulation was found to be stable at the end of the study on storage condition. The present study suggested that niosomal formulations provide sustained and prolonged delivery of drug with enhance bioavailability.

Keywords: niosomes, Glipizide, bioavailability, thin film hydration technique, *In vitro* drug release studies

Introduction

The role of the novel drug delivery system is not only limited to a drug package convenience and ease of administration but along with this it is also needed to provide better therapeutic efficacy and safety by delivering the drug molecules to the target site in the most convenient manner [1]. Niosomes represent one of the promising options for entrapment of drugs with hydrophilic and hydrophobic solubility. Niosomes are self-assembly based amphiphilic structures which are formed when a polar lipid (such as cholesterol) and a non-ionic surfactant are mixed in a specific ratio [2]. Niosomes as a nano-carrier have offered various benefits such as economical fabrication, high stability for nano drug delivery, low systemic toxicity etc. Niosomes have also shown improved bioavailability, high biocompatibility, reduction in dose concentration, and a sustained drug release. [3] Niosomes can be prepared by hydration of synthetic nonionic surfactants either with or without cholesterol. Niosomes may be unilamellar or multilamellar depending on the method used to prepare them. The niosome is made of a surfactant bilayer with its hydrophilic ends exposed on the outside and inside of the vesicle while the hydrophobic chains face each other within the bilayer [4]. Hence, the vesicle holds hydrophilic drugs within the space enclosed in the vesicle while the hydrophobic drugs are embedded within the bilayer itself. The application of niosomal technology is widely varied and can be used to treat a number of diseases [5]. Glipizide is one of the most frequently used sulfonylureas for the treatment of type 2 diabetes which requires twice daily administration. In the present study, Glipizide encapsulated Niosomes were formulated and evaluated for their *In vitro* characteristics and an attempt was made to improve the oral bioavailability of the drug.

Materials

Glipizide was obtained from Sun Pharma Pvt Ltd. HYD. Cholesterol and Surfactants were procured from Synpharma Research Labs, Hyderabad, and other chemicals the reagents used were of analytical grade.

Methodology

Fourier transform infrared spectroscopy [6]

Fourier transform IR spectra were obtained on Bruker FT-IR spectrometer. Samples were prepared in KBr disks (2mg sample in 200mg KBr). The scanning range was 450-4000 cm⁻¹ and the resolution was 4 cm⁻¹.





International Journal of Multidisciplinary Research and Growth Evaluation.

A new analytical method development and validation for the estimation of bedaquiline by reverse-phase high -performance liquid chromatography

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Abstract

An efficient and simple RP-HPLC method has been developed and validated for the determination of Bedaquiline in bulk and was applied on marketed Bedaquiline products. The mobile phase used for the chromatographic runs consisted of Acetonitrile and Phosphate buffer (0.01M, pH-3.2) in the ratio of 30:70% v/v. The separation was achieved on a Symmetry C18 ODS (4.6mm×250mm) 5µm particle size column using isocratic mode. Drug peak were well separated and were detected by a UV detector at 246 nm. The method was linear at the concentration range 6–14 µg/ml for Bedaquiline. The method has been validated according to ICH guidelines with respect to system suitability, specificity, precision, accuracy and robustness. Bedaquiline limit of detection (LOD) and limit of quantification (LOQ) were 0.487µg/ml and 1.477µg/ml respectively.

Keywords: Bedaquiline, RP-HPLC, Accuracy, Precision, Robustness, ICH Guidelines

1. Introduction

Bedaquiline ^[1] is a quinoline-based antimycobacterial drug used (as its fumarate salt) for the treatment of pulmonary multi-drug resistant tuberculosis by inhibition of ATP synthase, an enzyme essential for the replication of the mycobacteria. It has a role as an antitubercular agent and an ATP synthase inhibitor. It is a member of quinolines, a member of naphthalenes, an organobromine compound, aromatic ether, a tertiary alcohol and a tertiary amino compound. It is a conjugate base of a Bedaquiline (2+). Bedaquiline is a diarylquinoline antimycobacterial used in combination with other antibacterials to treat pulmonary multidrug resistant tuberculosis (MDR-TB). Bedaquiline ^[2] is primarily subjected to oxidative metabolism leading to the formation of N-monodesmethyl metabolite (M2). M2 is not thought to contribute significantly to clinical efficacy given its lower average exposure (23% to 31%) in humans and lower antimycobacterial activity (4 to 6-fold lower) compared to the parent compound. M2 concentrations appeared to correlate with QT prolongation. Bedaquiline ^[3] inhibits mycobacterial TB at a minimal inhibitory concentration (MIC) from 0.002-0.06 µg/ml and with a MIC50 of 0.03µg/ml. Furthermore, bacteria that have smaller ATP stores (usually in dormant, nonreplicating bacilli) are more susceptible to Bedaquiline. Bedaquiline is a diarylquinoline antimycobacterial drug that inhibits the proton pump of mycobacterial ATP (adenosine 5'-triphosphate) synthase, an enzyme that is essential for the generation of energy in Mycobacterium tuberculosis. Bacterial death occurs as a result of Bedaquiline. The IUPAC Name of Bedaquiline is (1R,2S)-1-(6-bromo-2-methoxyquinolin-3-yl)-4-(dimethylamino)-2-naphthalen-1-yl-1-phenylbutan-2-ol. The Chemical Structure of Bedaquiline is follows



International Journal of Multidisciplinary Research and Growth Evaluation.

Analytical method development and validation for the estimation of Revaprazan in bulk form and marketed pharmaceutical dosage form by RP-HPLC

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Abstract

Objective: The current investigation was pointed at developing and progressively validating novel, simple, responsive and stable RP-HPLC method for the measurement of active pharmaceutical ingredient and Marketed Pharmaceutical Dosage form of Revaprazan.

Methods: A simple, selective, validated and well-defined stability that shows isocratic RP-HPLC methodology for the quantitative determination of Revaprazan. The chromatographic strategy utilized Symmetry ODS (C₁₈) RP Column, 250 mm x 4.6 mm, 5µm, using isocratic elution with a mobile phase of Phosphate Buffer (0.02M) and Acetonitrile were consists of 48:52% v/v (pH-2.80). A flow rate of 1.0 ml/min and a detector wavelength of 248 nm utilizing the UV detector were given in the instrumental settings. Validation of the proposed method was carried out according to an international conference on harmonization (ICH) guidelines.

Results: LOD and LOQ for the two active ingredients were established with respect to test concentration. The calibration charts plotted were linear with a regression coefficient of R²>0.999, means the linearity was within the limit. Recovery, specificity, linearity, accuracy, robustness, ruggedness were determined as a part of method validation and the results were found to be within the acceptable range.

Conclusion: The proposed method to be fast, simple, feasible and affordable in assay condition. During stability tests, it can be used for routine analysis of the selected drug.

Keywords: Revaprazan, RP-HPLC, Method Development, Validation, Accuracy, Robustness

Introduction

Revaprazan is a member of isoquinolines. Revaprazan is under investigation in clinical trial NCT01750437 (Phase 2 Clinical Trial to Investigate the Safety, Tolerability and Efficacy of YH1885L in Patients with Non-erosive Reflux Disease (nerd)). Revaprazan ^[1] (trade name Revanex) is a drug that reduces gastric acid secretion which is used for the treatment of gastritis. It acts as an acid pump antagonist (potassium-competitive acid blocker). Revaprazan is approved for use in South Korea, but is not approved in Europe or the United States. Revaprazan is under investigation in clinical trial NCT01750437 (Phase 2 Clinical Trial to Investigate the Safety, Tolerability and Efficacy of YH1885L in Patients with Non-erosive Reflux Disease (nerd)). Revaprazan ^[2] is a member of isoquinolines. Revaprazan is a proton pump inhibitor that is currently being investigated for the management of gastric and duodenal ulceration, functional dyspepsia and GERD. Revaprazan is prescribed for the treatment of duodenal ulcer, gastric ulcer and gastritis. Revaprazan ^[3] is prescribed for the treatment of duodenal ulcer, gastric ulcer and gastritis. Revaprazan is classified a reversible acid pump antagonist (potassium-competitive acid blocker) since it acts in a mechanism different from irreversible proton pump inhibitor such as omeprazole. Revaprazan is not dependent upon secretion status of a proton pump or acid activation of a drug in a stomach. Revaprazan has long-lasting acid-suppressive effects. Revaprazan is approved for use only in Korea and India.

International Journal of Multidisciplinary Research and Growth Evaluation.

Development and characterization of chlorambucil polymeric nanoparticles

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Abstract

The goal of this study was to assess the efficacy of a method based on the creation of polymeric nanoparticles as an innovative formulation of Chlorambucil with enhanced therapeutic efficacy. Chlorambucil has low solubility and permeability, which result in limited and variable bioavailability; its low stability makes it difficult to develop stable aqueous liquid formulations. The Chlorambucil Polymeric nanoparticles were created using the solvent evaporation process. The numerous formulations with varied drug-polymer and surfactant ratios were analyzed and improved. Chlorambucil Polymeric nanoparticles containing PLGA were created using the solvent evaporation method, then the particle size was decreased by sonication. Particle size, surface morphology by SEM, drug excipient compatibility by FTIR, and in-vitro drug release experiments were used to characterize the produced nanoparticles. The formulation with the best encapsulation efficiency was (F-4) A drug encapsulation effectiveness of up to 92.85 % has been attained in this study. It was discovered that the efficiency of encapsulation improved along with the polymer content. According to the results of the current investigation, the manufacture of Chlorambucil Polymeric nanoparticles can be done using a solvent evaporation process followed by sonication.

Keywords: Chlorambucil drug, Polymeric Nano Particles, Solvent Evaporation, lipid, FTIR, *in vitro* drug release

Introduction

Polymeric nanoparticles (NPs) are particles within the size range from 1 to 1000 nm and can be loaded with active compounds entrapped within or surface-adsorbed onto the polymeric core. The term "nanoparticle" stands for both nanocapsules and nanospheres, which are distinguished by their morphological structure ^[1]. Polymeric NPs have shown great potential for targeted delivery of drugs for the treatment of several diseases. Polymeric nanoparticles (NPs) have attracted considerable interest over recent years due to their properties resulting from their small size ^[2]. Advantages of polymeric NPs as drug carriers include their potential use for controlled release, the ability to protect drug and other molecules with biological activity against the environment, improve their bioavailability and therapeutic index ^[3]. The main aim of this study is to achieve prolonged release of Chlorambucil such that the dosing frequency of the drug can be reduced by which we may reduce the side effects and increase the patient compliance ^[4]. By formulating Chlorambucil as nanoparticles we can directly deliver the drug to the cancer cell and prevent the normal cells from the adverse effects of Chlorambucil. Chlorambucil is an antineoplastic in the class of alkylating agents that is used to treat various forms of cancer ^[5].

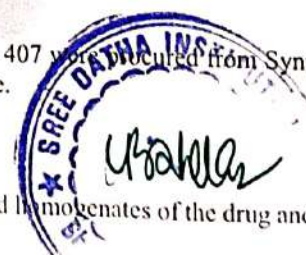
Materials

Chlorambucil was obtained from Micro lab. PLGA, SLS, and Poloxamer 407 were procured from Synpharma Research Labs, Hyderabad, and other chemicals the reagents used were of analytical grade.

Methodology

Compatibility study (IR spectroscopy) ^[6]

The drug-polymer compatibility was ascertained by subjecting the drug and homogenates of the drug and polymer to an Infrared spectrophotometric study.



International Journal of Multidisciplinary Research and Growth Evaluation.

Formulation and evaluation of doxorubicin liposomal drug delivery system

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Abstract

The drug release from Liposomes depends on many factors including the composition of Liposomes, the type of drug encapsulated and nature of the cell. Once it is released a drug that normally crosses the membrane of a cell will enter the cell, other drugs will not enter. Doxorubicin is a drug with narrow therapeutic index and short biological half-life. This study aimed at developing and optimizing liposomal formulation of Doxorubicin in order to improve its bioavailability. In evaluation study the effect of the varying composition of lipids on the properties such as encapsulation efficiency, particle size and drug release were studied. Phase transition study was carried out to confirm the complete interaction of Doxorubicin with bilayer structure of liposome. Moreover, the release of the drug was also modified and extended over a period of 8 h in all formulations. F2 emerged as the most satisfactory formulation in so far as its properties were concerned. Further, release of the drug from the most satisfactory formulation (F2) was evaluated through dialysis membrane to get the idea of drug release.

Keywords: Liposomes, Doxorubicin, bioavailability, thin film hydration technique, in vitro drug release studies

Introduction

Vesicles composed of a bilayered phospholipids membrane surrounding water entrapped from the environment. Phospholipids form closed, fluid-filled spheres when they are mixed with water in part because the molecules are amphipathic; they have a hydrophobic "tail" and a hydrophilic or polar "head". ^[1] Liposomes represent versatile Nano platforms for the improved delivery of pharmaceutical drugs and active compounds in a large variety of biomedical and nano medicine applications. ^[2] They are characterized by easily controllable properties such as lipid composition, size, structure and morphology, surface charge, and the possibility of functionalizing their surfaces with polymers or ligands. ^[3] The industrial applications of liposome Nano platforms include their use as drug-delivery vehicles in nano medicine, cancer, antimicrobial therapy, as signal carriers in biomedical diagnostics and biochemistry, as adjuvants in vaccination, and as solubilizers and support matrices for various active compounds and macromolecules. ^[4] Moreover, owing to their high biocompatibility and non-toxicity, liposomes are the most important category of clinically approved therapeutic drug nanocarriers for cancer treatment. Doxorubicin (DOX) is a very potent anticancer drug and has shown strong activity against various tumors. However, it shows many adverse effects such as cardio-toxicity and congestive heart failure limiting its use. ^[5]

Materials

Doxorubicin was obtained from Micro lab. Phosphatidylcholine and cholesterol were procured from Synpharma Research Labs, Hyderabad, and other chemicals the reagents used were of analytical grade.

Methodology

FT-IR study ^[6]

Compatibility of the drug with excipients was determined by FT-IR spectral analysis. This study was carried out to detect any changes on chemical constitution of the drug after combined with the excipients. The samples were taken for FT-IR study.





Novel Method Development and Validation for The Quantitative Estimation of Lenalidomide in Api Form and Marketed Capsule Dosage Form by Using RP-HPLC

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Abstract

A new, simple, rapid, precise, accurate and reproducible RP-HPLC method for estimation of Lenalidomide in bulk form and marketed formulation. Separation of Lenalidomide was successfully achieved on a Develosil ODS HG-5 RP C₁₈, 5µm, 15cmx4.6mm i.d. column in an isocratic mode of separation utilizing Methanol: Phosphate buffer (0.02M, pH-3.6) in the ratio of 45:55% v/v at a flow rate of 1.0 mL/min and the detection was carried out at 255nm. The method was validated according to ICH guidelines for linearity, sensitivity, accuracy, precision, specificity and robustness. The response was found to be linear in the drug concentration range of 12-28mcg/mL for Lenalidomide. The correlation coefficient was found to be 0.9995 for Lenalidomide. The LOD and LOQ for Lenalidomide were found to be 5.004µg/mL and 15.164µg/mL respectively. The proposed method was found to be good percentage recovery for Lenalidomide, which indicates that the proposed method is highly accurate. The specificity of the method shows good correlation between retention times of standard solution with the sample solution. Therefore, the proposed method specifically determines the analyte in the sample without interference from excipients of pharmaceutical dosage forms.

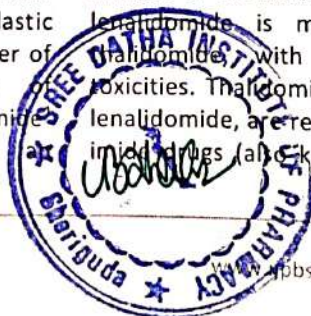
Keywords

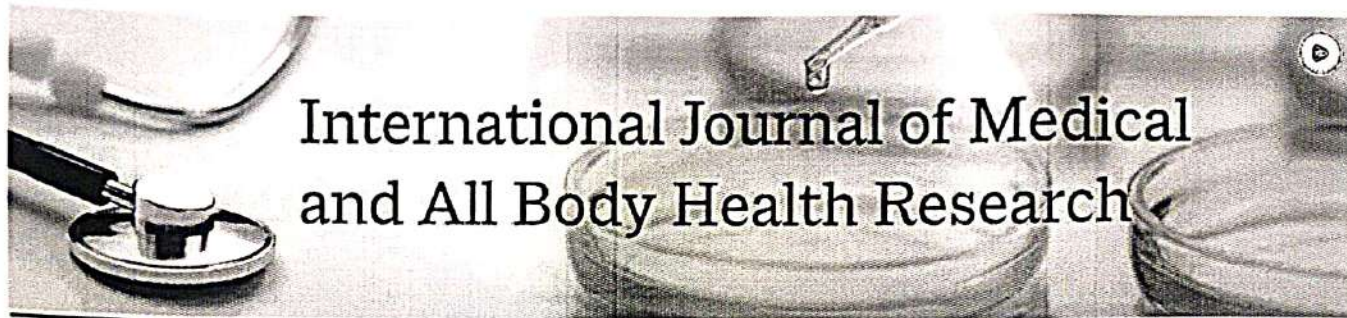
Lenalidomide, RP-HPLC, Accuracy, Precision, Robustness, ICH Guidelines.

INTRODUCTION

Lenalidomide is a dicarboximide that consists of 1-oxoisindoline bearing an amino substituent at position 4 and a 2,6-dioxopiperidin-3-yl group at position 2. Inhibits the secretion of TNF- α . It has a role as an angiogenesis inhibitor, an antineoplastic agent and an immunomodulator. It is a member of isoindoles, a dicarboximide, a member of piperidones and an aromatic amine. Lenalidomide (previously referred to as CC-5013) is

immunomodulatory drug with potent antineoplastic, anti-angiogenic, and anti-inflammatory properties. It is a 4-amino-glutamyl analogue of [thalidomide] and like thalidomide, lenalidomide exists as a racemic mixture of the active S (-) and R(+) forms. However, lenalidomide is much safer and potent than thalidomide, with fewer adverse effects and toxicities. Thalidomide and its analogues, including lenalidomide, are referred to as immunomodulatory imidazole drugs (also known as cereblon modulators),





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Development and validation of a new analytical RP-HPLC method for the determination of flavoxate hydrochloride in bulk form and pharmaceutical dosage form

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Abstract

A rapid and precise reverse phase high performance liquid chromatographic method has been developed for the validated of Flavoxate HCL, in its pure form as well as in tablet dosage form. Chromatography was carried out on a Symmetry C18 (4.6 x 150mm, 5µm) column using a mixture of Methanol and water (45:55% v/v) as the mobile phase at a flow rate of 0.8ml/min, the detection was carried out at 260nm. The retention time of the Flavoxate HCL was 2.379 ± 0.02min respectively. The method produce linear responses in the concentration range of 24-120mg/ml of Flavoxate HCL. The method precision for the determination of assay was below 2.0%RSD. The method is useful in the quality control of bulk and pharmaceutical formulations. The method was validated for accuracy, precision, linearity, robustness, ruggedness and LOD & LOQ of standard solution. The developed RP-HPLC method was found to be accurate, precise, linear, and robust and was successful applied to a pharmaceutical tablet formulation for qualitative estimation of Flavoxate HCL in Bulk form and Marketed Pharmaceutical Dosage forms.

Keywords: Flavoxate HCL, RP-HPLC, Method Development, Validation, Accuracy

Introduction

Flavoxate is a muscarinic antagonist and spasmolytic used for the symptomatic relief of conditions associated with lack of muscle control in the bladder, such as dysuria, urgency, and nocturia. A drug that has been used in various urinary syndromes and as an antispasmodic. Its therapeutic usefulness and its mechanism of action are not clear. It may have local anesthetic activity and direct relaxing effects on smooth muscle as well as some activity as a muscarinic antagonist. Flavoxate Hydrochloride ^[1] is the hydrochloride salt form of Flavoxate, a parasympatholytic agent with antispasmodic activity. Flavoxate hydrochloride competitively binds to muscarinic receptors, thereby preventing the actions of acetylcholine. This relaxes vascular smooth muscle, mainly of the urinary tract, and prevents smooth muscle contractions. Flavoxate is a spasmolytic flavone derivative that acts by relaxing the smooth muscle in the urinary tract. Flavoxate ^[2] is a competitive muscarinic receptor antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. Flavoxate ^[3] (flay vox' ate) is a synthetic quaternary ammonium anticholinergic which inhibits the muscarinic actions of acetylcholine on autonomic nerve endings, decreasing the smooth muscle tone of bladder and gastrointestinal tract. Flavoxate hydrochloride ^[4] is contraindicated in patients who have any of the following obstructive conditions: pyloric or duodenal obstruction, obstructive intestinal lesions or ileus, achalasia, gastrointestinal hemorrhage and obstructiveuropathies of the lower urinary tract. The IUPAC Name of Flavoxate HCL ^[5] is 2-piperidin-1-ylethyl 3-methyl-4-oxo-2-phenylchromene-8-carboxylate; hydrochloride. The Chemical Structure of Flavoxate HCL is as follows

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Analytical method development and validation for the estimation of clomipramine HCL in API form and marketed pharmaceutical dosage form by reverse phase- high performance liquid chromatography

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Abstract

Objective: The current investigation was pointed at developing and progressively validating novel, simple, responsive and stable RP-HPLC method for the Quantitative Determination of Clomipramine HCL in active pharmaceutical ingredient and Marketed Pharmaceutical Dosage form.

Methods: A simple, selective, validated and well-defined stability that shows isocratic RP-HPLC methodology for the quantitative determination of Clomipramine HCL. The chromatographic strategy utilized Symmetry C18, 250 mm x 4.6 mm i.d. 5µm particle size, using isocratic elution with a mobile phase consists of Methanol and Phosphate Buffer (0.02M) (pH-3.8) was taken in the ratio of 70: 30% v/v. A flow rate of 1.0 ml/min and a detector wavelength of 245nm utilizing the UV detector were given in the instrumental settings. Validation of the proposed method was carried out according to an international conference on harmonization (ICH) guidelines.

Results: LOD and LOQ for the active ingredients were established with respect to test concentration. The calibration charts plotted were linear with a regression coefficient of $R^2 > 0.999$, means the linearity was within the limit. Recovery, specificity, linearity, accuracy, robustness, ruggedness were determined as a part of method validation and the results were found to be within the acceptable range.

Conclusion: The proposed method to be fast, simple, feasible and affordable in assay condition. During stability tests, it can be used for routine analysis of the selected drugs.

Keywords: Clomipramine HCL, RP-HPLC, Method Development, Validation, Accuracy, Precision

1. Introduction

Clomipramine ^[1] is a Tricyclic Antidepressant. Clomipramine ^[2] is a dibenzoazepine that is 10,11-dihydro-5H-dibenzo[b,f]azepine which is substituted by chlorine at position 3 and in which the hydrogen attached to the nitrogen is replaced by a 3-(dimethylamino)propyl group. One of the more sedating tricyclic antidepressants ^[3], it is used as the hydrochloride salt for the treatment of depression as well as obsessive-compulsive disorder and phobias. It has a role as a serotonergic antagonist, a serotonergic drug, a serotonin uptake inhibitor, an EC 1.8.1.2 (trypanothione disulfide reductase) inhibitor, an antidepressant and an anticoronaviral agent. It is functionally related to an imipramine. It is a conjugate base of a clomipramine ^[4] (1+). Clomipramine is a tricyclic antidepressant used in the treatment of obsessive-compulsive disorder and disorders with an obsessive-compulsive component, such as depression, schizophrenia, and Tourette's disorder. May be used to treat obsessive-compulsive disorder and disorders with an obsessive-compulsive component (e.g. depression, schizophrenia, Tourette's disorder).

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Formulation and evaluation of olmesartan midoxomiltopical gel

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Abstract

The objective of the study is to formulate and evaluate olmesartan midoxomiltopical gel for their skin infections. Four gel formulations were prepared using gelling agents HPMC (F1-F2) and carbopol (F3-F4) and they were evaluated for physical appearance, drug content, viscosity, extrudability, pH, spreadability, *In vitro* diffusion profile. The formulated gel showed good physical characteristics. The formulation F2 (96.96%) show good drug content as the polymer concentration in them was higher. The spread ability of gel decreases with an increase in polymer concentration. The pH of the formulation was in the range of 6-8 which is considered acceptable to avoid the risk of irritation upon application to the skin. Among the formulations, F2 showed better release (97.24%) characteristics than other formulations. The stability study for the topical gel formulation was done as per ICH guidelines. Formulated gels were homogenous, stable and complied with the guidelines.

Keywords: Olmesartan midoxomil, Carbopol 934, FTIR Studies, Topical gel, *In vitro* drug release studies

Introduction

Topical gel formulations provide a suitable delivery system for drugs because they are less greasy and can be easily removed from the skin. Percutaneous absorption of drugs from topical formulations involves the release of the drug from the formulation and permeation through skin to reach the target tissue. ^[1] The release of the drug from topical preparations depends on the physicochemical properties of the vehicle and the drug employed. ^[2] In order to enhance drug release and skin permeation, methods such as the selection of a suitable vehicle, co-administration of a chemical enhancer have been studied. Gel base formulation makes the drug molecules more easily removable from the system than cream and ointment. ^[3] Olmesartan medoxomil (OLM) is a potent first-line antihypertensive drug as it is a selective angiotensin II receptor blocker. It has few side effects such as tachycardia. OLM is classified as BCS class II. ^[4] OLM has low oral bioavailability (28.6%) due to having poor water solubility and oral problems such as the extensive hepatic first-pass effect and the efflux pumps in the gastrointestinal tract that interfere with the drug's absorption. ^[5]

Materials

Olmesartan Midoxomil was obtained from Micro Lab, HYD. Carbopol 934 and HPMC were procured from Synpharma Research Labs, Hyderabad, and other chemicals the reagents used were of analytical grade.

Methodology

FTIR Studies ^[6]

Drug polymer interactions were studied by FT-IR spectroscopy. One to 2mg of drug, polymer and physical mixtures of samples were weighed and mixed properly to a uniform mixture. A small quantity of the powder was compressed into a thin semi-transparent pellet by applying pressure. The IR spectrum of the pellet from 400-4000 cm^{-1} was recorded taking air as the reference and compared to study any interference.





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A Study on the Effectiveness of Mono and Dual Antiplatelet Therapy in Secondary Prevention of Vascular Events

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Abstract:

The aim of the study was to determine whether addition of aspirin to clopidogrel could have a greater benefit than clopidogrel alone in the prevention of secondary vascular events in patients after TIA or ischemic stroke. Out of the total patients, 34.2 % of patients had recurrence of vascular events. 36.3 % patients reached the primary endpoint in the group receiving dual therapy compared to 20% in the monotherapy group. 31% in dual therapy group had Ischemic stroke as qualifying event compared to 5 % in monotherapy. Our study focused on the prevalence of risk factors in patients with recurrence of vascular events. Risk factors found were previous ischemic stroke in 12 % of dual therapy group and 1% in mono group. Hypertension was found in 30 % of dual group and 3 % of mono group. Diabetes was risk factor in 16% of dual therapy patients and 4% in mono group Hypercholesterolemia was found in 19% of dual group and 4 % of mono group 11% of dual therapy patients and 2 % of mono therapy patients were smokers. The primary events were found to have a significant association with gender, risk factors and therapy. No bleeding complications were observed in the study population.

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Keywords: Dual Antiplatelet Therapy, Secondary Prevention, Vascular Events

INTRODUCTION

According to the Center's for Disease Control and Prevention (CDC), stroke is the fifth leading cause of death in Americans.¹ The most common type of stroke is ischemic stroke and represents about 87% of all strokes in the United States.¹ More than 795 000 people in the United States have a stroke every year, and about 25% of strokes are recurrent strokes.¹ A recent study demonstrated that minor strokes and transient



Patients With Type II Diabetes Mellitus At A Tertiary Care Hospital: A Prospective Study On Anti-Diabetic Drug Prescribing Patterns

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Abstract

The main aim is to study on prescribing patterns of anti-diabetic drugs for patients with type- II diabetes mellitus. Out of 457 patients screened, 426 patients were enrolled according to inclusion and exclusion criteria. Among them 62.44% were males and 37.55% were females. The study found to be a higher incidence of diabetes among elderly patients, with a high incidence in the age group between 41-60 years (50.70%) and followed by 61-80 years (19.24%). The study resolved that most of the patients were suffering from diabetes for 5 to 10 years, 221 (73.94%) of duration years followed by 1 to 5 years, 94 (22.06%). A total of 1565 drugs were prescribed in the overall study period. 68.62% were diabetic drugs, 13.41% hypertensive drugs, 07.85% NSAIDs, 07.66% asthmatic drugs, 03.57% antidepressants, and 04.40% supplements of drugs. The study resolved that drugs were prescribed as monotherapy was 49.76%, two drug therapy were 36.61%, three-drug therapy were 08.45% and four-drug therapy was 05.16%. In this study, 426 anti-diabetic drugs prescribed, among that, the physician's most well-liked single-drug therapy more than multiple drug therapy and also the most often prescribed category was Biguanides category of anti-diabetic agents. Among Biguanides, Metformin was the foremost often utilized anti-diabetic drugs. The foremost prevalent combination of the drug was a two-drug therapy of Biguanides +sulfonylureas, among these combinations, Metformin + Glimipride was the foremost often utilized anti-diabetic drugs. Followed by 3 drug therapy were Biguanides +sulfonyl ureas+ thiazolidinedione and 4 drug therapies were Biguanides + sulfonylureas + DPP 4 inhibitors + thiazolidinedione. Pharmacists can contribute drastically to promote the rational use of medicines, even in resource-limited settings. This course requires strong collaboration between different institutions and components of the pharmacists to the cause. Pharmacist medication review, patient counseling and telephone follow-up can limit the Adverse Drug Reactions. Medication discrepancies before and after discharge were common targets of intervention.