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INSULIN NANOPARTICLES LOADED SUPPOSITORES INTENDED FOR THE SYSTEMIC DRUG DELIVERY

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ABSTRACT

The main objective of the present work was to develop colon targeted insulin nanoparticle loaded suppositories intended for systemic delivery of the active. This delivery provides sustained release delivery of the drugs through the rectal route. Nanoparticles based on PLGA were loaded with insulin using w/o/w solvent evaporation technique. The prepared nanoparticles were characterized for various in vitro properties. Particle size and charge were measured using zeta sizer and SEM. Integrity of the drug at the end of formulation development was determined using FTIR, DSC and XRPD. The duration of drug release was determined using in vitro release testing methods. After selecting suitable nanoparticle formulation, they were incorporated into cocoa butter as suppositories. The drug release was also determined at the end of formulation development and a suitable formulation was proposed. The results demonstrated that sustained released of insulin was observed over one week with improved stability of insulin. These suppository formulations loaded with insulin nanoparticles are intended for colon delivery so as to achieve systemic levels of insulin as an alternate route of delivery of this drug.

KEYWORDS: Colon drug delivery, insulin, lyophilization, suppository.

INTRODUCTION

For many a years the treatment of an acute disease or a chronic disease has been mostly accomplished by the delivery of drugs using various dosage forms such as tablet, capsules, pills, suppositories, ointments, liquids, aerosols, and injectables. All these are the conventional drug delivery systems. These systems are the primary pharmaceutical products

RP-HPLC Method for simultaneous Estimation of Metformin and lingaliptin in Pharmaceutical formulation.

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Abstract

A simple, Accurate, precise method was developed for the simultaneous estimation of the Linagliptin and Metformin in Tablet dosage form. Chromatogram was run through Ascentis C18 150 x 4.6 mm, 5□m. Mobile phase containing Buffer: Acetonitrile taken in the ratio 65:35 was pumped through column at a flow rate of 0.9 ml/min. Buffer used in this method was 0.1% OPA (2.2ph) buffer. Temperature was maintained at 30°C. Optimized wavelength selected was 216.0nm Retention time of Linagliptin and Metformin were found to be 2.965 min and 2.247 min. %RSD of the Linagliptin and Metformin were and found to be 0.9 and 0.7 respectively. %Recovery was obtained as 100.04% and 99.66% for Linagliptin and Metformin respectively. LOD, LOQ values obtained from regression equations of Linagliptin and Metformin were 0.03, 0.05 and 0.002, 0.005 respectively. Regression equation of Linagliptin is y = 572521x + 1811.1.and y = 132021x + 122105 of Metformin. Retention times were decreased and that run time was decreased, so the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

Keywords: Metformin, Linagliptin, RP-HPLC.

Introduction

The quality of a drug plays an important role in ensuring the safety and efficacy of the drugs. Quality assurance and control of pharmaceutical and chemical formulations is essential for ensuring the availability of safe and effective drug formulations to consumers. Hence Analysis of pure drug substances and their pharmaceutical dosage forms occupies a pivotal role in assessing the suitability to use in patients. The quality of the analytical data depends on the quality of the methods employed in generation of the data (1) . Hence, development of rugged and robust analytical methods is very important for statutory certification of drugs and their formulations with the regulatory authorities.

The quality and safety of a drug is generally assured by monitoring and controlling the assay and impurities effectively. While assay determines the potency of the drug and impurities will determine the safety aspect of the drug. Assay of pharmaceutical products plays an important role in efficacy of the drug in patients.

The wide variety of challenges is encountered while developing the methods for different drugs depending on its nature and properties. This along with the importance of achieving the selectivity, speed, cost, simplicity, sensitivity, reproducibility and accuracy of results gives an opportunity for researchers to come out with solution to address the challenges in getting the new methods of analysis to be adopted by the pharmaceutical industry and chemical laboratories. Different physico-chemical methods (1) are used to study the physical phenomenon that occurs as a result of chemical reactions. Among the physico-chemical methods, the most important are optical (refractometry, polarimetry, emission and fluorescence methods of analysis), photometry (photocolorimetry and spectrophotometry covering UV-Visible, IR Spectroscopy and nepheloturbidimetry) and chromatographic (column, paper, thin layer, gas liquid and high performance liquid chromatography) methods. Methods such as nuclear magnetic resonance (NMR) and para magnetic resonance (PMR) are becoming more and more popular. The combination of mass spectroscopy (MS) with gas chromatography is one of the most powerful tools available. The chemical methods include the gravimetric and volumetric procedures which are based on complex formation; acid-base, precipitation and redox reactions. Titrations in non-aqueous media and complexometry have also been used in pharmaceutical analysis. The number of new drugs is constantly growing. This requires new methods for controlling their quality. Modern pharmaceutical analysis must need the following requirements.

1. The analysis should take a minimal time.

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ISOLATION AND CHEMICAL CHARACTERIZATION OF POTENTIAL BIOACTIVE COMPOUNDS FROM *ALBIZIA STIPULATA* BARK

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Keywords:

In-situ gel, Acyclovir, Anti-viral, HPMC E50 LV, Pluronic F-127

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ABSTRACT: The present research effort was undertaken to isolate phytoconstituents from pharmacologically active extracts of stem bark *of Albizia stipulata* based on in-vitro pharmacological screening and their subsequent characterization. **Methods:** Crude extracts of bark of *Albizia stipulata* were prepared using various solvents such as methanol, hydro alcohol, and water. These extracts were screened for *in-vitro* pharmacological activities like antioxidant, anti-inflammatory, and anti-diabetic activities. The active extract was subjected to column chromatography through a mixture of solvents to get fractions and eluted fractions were run in TLC using various mobile phases with different solvent ratios. The isolated compounds were subjected to IR, 1H NMR, 13CNMR and LC-MS spectral analysis for chemical characterization. **Results:** The methanol extract of bark of *Albizia stipulata* was potent compared to other extracts. This extract was subjected to column chromatography to get fractions, and eluted fractions were run in TLC. The fractions with similar R_f values to standard were united and crystallized. The spectral analysis confirmed that the isolated compounds were found to be β-Sitosteryl-3-O-β-D-glucoside and 3 -O methyl D- Chiro Inositol. **Conclusion:** Various extracts from the bark of the plant *Albizia stipulata* were prepared. B-sitosteryl-3-O-β-D-glucoside and 3-O methyl D-Chiro Inositol were isolated from the methanol extract of bark and characterized.

INTRODUCTION: Herbs used in Ayurveda offer biologically active molecules and lead structures for modification. Derivatives with improved activity and reduced toxicity hereafter, research to stagger on the technical evidence for assumes of plants used for the Indian Ayurvedic system of medicine has accentuated. Furthermore, these preparations are evaluated and distributed properly; our indigenous population can be given better access to effective drug treatment and enhanced health status. Thorough research on the chemistry and pharmacology of plant origin products is significantly necessary and may eventually lead to

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ALBIZIA CHINENSIS- A POTENTIAL MEDICINAL PLANT: A COMPLETE REVIEW

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ABSTRACT

Albizia chinensis is a genus of *Albizia*, a member of the legume family (Fabaceae) and subfamily Mimosoideae. *Albizia chinensis* is an important medicinal plant found throughout India and South-East Asia. The entire plant possess pharmacologically active constituents of great Interest. The present article gives an update on bioactive compounds and the therapeutic significance of *Albizia chinensis*. This plant has been used as an imperative folk medicine for the treatment of several diseases like Helminthic infections and skin diseases. Further, phytochemical examination exposed the presence of a wide variety of bioactive compounds such as triterpene saponins, flavonoid glycosides, phenolic compounds, sterols, tannins, and alkaloids in the plant extract of *A. chinensis*. Besides, the plant extracts and isolated compounds possess pharmacological properties like anticancer, antiulcer, antioxidant, antimicrobial, anti-inflammatory, thrombolytic, and spermicidal activities. Because of the presence of several phytoconstituents, pharmacological activities, and wide distribution, this will be a model plant resource for the treatment of numerous endemic diseases. This review will be helpful to explore the knowledge about *Albizia chinensis* for the researchers.

KEYWORDS: *Albizia chinensis*, Medicinal plant, Active constituents, Pharmacological activities.

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Research Article

A New Validated RP-HPLC Method for Simultaneous Estimation of Lumacaftor and Ivacaftor in Pharmaceutical Dosage Form

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ABSTRACT

A simple, selective, linear, precise and accurate reverse phase high performance liquid chromatography method was developed and validated for the simultaneous estimation of Lumacaftor and Ivacaftor in tablet dosage form. The chromatographic separation was achieved on Symmetry C18 4.6×150mm, 5µ column using a mobile phase consisting a mixture of Methanol: Water in the ratio of 65:35 v/v at a flow rate of 1ml/min at an ambient temperature and detection was carried out at 270 nm. The clear chromatography peaks were identified with retention times of 2.460 min for lumacaftor and 4.312 min for ivacaftor. The proposed technique was validated according ICH guidelines in respect to specificity, linearity, accuracy, precision, LOD, LOQ and robustness. The linearity was observed in the concentration range of 45-225 µg/ml for lumacaftor and 10-50µg /ml for ivacaftor. Linear regression coefficient for both drugs was 0.999. The percentage recovery of lumacaftor and ivacaftor was in between 98-102%.The %RSD for repeatability and intermediate precision was less than 2%. LOD was 0.83 and 1.3 and LOQ was 2.5 and 3.95 for lumacaftor and ivacaftor respectively. The results of validation parameters were met ICH requirements. Hence, the proposed method can be used for the determination of lumacaftor and ivacaftor in various pharmaceutical dosage forms during regular and quality-control analysis.

Keywords: Lumacaftor, Ivacaftor, Simultaneous estimation, RP-HPLC, tablets.

INTRODUCTION

Cystic fibrosis (CF) is a hereditary disease affects the endocrine, gastrointestinal, reproductive, and respiratory systems. It causes the assemblage of abnormally thick mucus, leading to the obstruction. CF is caused by any one of several defects in the cystic fibrosis transmembrane conductance regulator (CFTR) protein, such as F508del mutation, G551D mutation that causes the disease.[1] This life-restriction disease requires multiple daily medications to extend the life and get a better quality of life. Many conventional regimens including pancreatic enzyme supplements, multivitamins, mucolytics, antibiotics, *bronchodilators,* and *anti-*inflammatory agents have been used for the treatment of CF. Lumacaftor (CFTR corrector) and Ivacaftor (Potentiator) are new drugs used in combination (brand name **Orkambi**) for the treatment of cystic fibrosis. Lumacaftor (LMF) is an aromatic amide, is a chemically 3-[6-[[1-(2, 2-difluoro-1, 3-benzodioxol-5-yl) cyclopropane carbonyl] amino]-3-methylpyridin-2-yl] benzoic acid, Figure 1 with the molecular formula of $C_{24}H_{18}F_2N_2O_5$ and molecular weight is 452.414. It is a white to off-white powder that is practically insoluble in water (0.02 mg/mL). Lumacaftor acts as a chaperone during protein folding and increases the number of cystic fibrosis transmembrane conductance regulator proteins which are trafficked to the cell surface by targeting the defective F508del CFTR gene. [2] Ivacaftor (ICF) is an aromatic amide, chemically it is a N-(2,4-di tert-butyl-5-hydroxyphenyl)-4-oxo-1H-quinoline-3-carboxamide, Figure 2 with a molecular formula of $C_{24}H_{28}N_2O_3$ and molecular weight is 392.498. Ivacaftor is a white to off-white powder that is virtually insoluble in water (<0.05 mg/mL). Ivacaftor is the first drug that treats the original cause rather than the symptoms of the disease. Ivacaftor is a potentiator of the CFTR protein a chloride channel present at the surface of epithelial cells in multiple organs, it increases chloride transport by potentiating the channel-open probability (or gating) of the G551D-CFTR protein. [3,4] Lumacaftor and Ivacaftor fixed-dose combination oral tablets are developed by Vertex Pharmaceuticals and both were approved by the FDA in 2015. [5] These drugs, when given in a fixed dose combination product rather than individual entities, has shown to get potential therapy in a condition of cystic fibrosis by correcting the defective protein. [6,7] Number of drugs are introducing into the market yearly. There is a time lag between the date of the prologue of a drug into the market and the date of its enclosure in pharmacopeias. Hence, standards and analytical methods either for the individual or combination of drugs may not be official in the pharmacopeias. Some analytical procedures are not accessible in the literature due to patent regulations. Analytical methods for the drugs in formulations are not available owing to the interference caused by the excipients. Therefore, it becomes essential to build up a newer analytical procedure for such drugs.

Literature survey reveals many analytical methods have been published for simultaneous estimation of Lumacaftor and Ivacaftor in bulk, pharmaceutical dosage forms and in biological samples. These methods are UV Spectrophotometric techniques, HPLC methods, UPLC method, stability indicating methods, and LC-MS/MS methods. [8-17] The objective of our study is that High

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RP- HPLC METHOD FOR SIMULTANEOUS DETERMINATION OF LAMIVUDINE, ZIDOVUDINE AND NEVIRAPINE FROM THEIR COMBINED TABLET DOSAGE FORM

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ABSTRACT

A novel, sensitive and selective reverse phase high performance liquid chromatographic method was developed and validated for the simultaneous determination of lamivudine, zidovudine, and nevirapine in tablet formulation. The chromatographic separation was achieved on Inertsil, ODs C18 4.6 x 150mm, 3.5mm column by means of a mobile phase containing a mixture of Ammonium acetate buffer pH 5.5, acetonitrile and methanol in the ratio of 50:30:20 v/v at a flow rate of 1.2 ml/min at an ambient temperature and detection was carried out at 260nm.Clear chromatography peaks were identified with retention times of 2.457min for lamivudine, 3.327 min for zidovudine and 4.813 min for nevirapine. The urbanized technique was validated as per ICH guidelines regarding specificity, linearity, accuracy, precision, LOD, LOQ and robustness and the method shows excellent linearity and correlation coefficients of lamivudine, zidovudine and nevirapine were 0.9997, 0.9998 and 0.9998 correspondingly. The % means recoveries of drugs were in between 98.5-100.03 and %RSD for repeatability and intermediate precision was less than 2%. Therefore, the proposed method can be in use for the determination of Lamivudine, Zidovudine, and Nevirapine in various pharmaceutical dosage forms during regular and quality-control analysis.

Keywords: lamivudine, zidovudine and nevirapine, Simultaneous determination, RP-HPLC, tablets

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Rapid and Sensitive Ultra Performance Liquid Chromatography Tandem Mass Spectrometry for Quantitation of Tacrolimus in Human Whole Blood

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Abstract

Therapeutic drug monitoring of immunosuppressive agents in organ transplanted Patient's is crucial to prevent intoxication or transplant rejection due to inadequate dosage. The commonly used immune assays have been gradually undergoing replacement by mass spectrometry since this physical method offers both a higher Sensitivity and specificity. A simple rapid, novel, sensitive Ultra performance liquid Chromatography (UPLC) coupled with electron spray mass spectrometry method was developed and validated for quantification of tacrolimus (I) in human plasma. The analyte and internal standard (Sacrolimus II) were extracted by liquid-liquid extaction with hexane and four levels of quality control samples of k2 EDTA human whole blood were used. The chromatographic separation was performed on reverse phase thermo hypurity advance column (46 x 50 mm, 5um) with mobile phase of 90% methanol and 10mM ammonium acetate buffer (90:10)low at a flow rate of 0.5ml/min and run time of 2.5 minute .The retention time of both analyte and ISD were 1.37mints.The deprotonate of analyte was quantitated in positive ionization by multiple reaction monitoring (MRM)with mass spettrometry. The mass transitions m/z 821-768.54 and m/z 931.6-864.8 were used to measure I&II in whole blood –I(Q1)and m/z 821.5-768.54 and m/z 931.5-884.6for I&II in whole blood –II(Q2) respectively. The method exhibited a linear response in the range of 0.495-99.430ng/ml for tacrolimus in human plasma with co-relation coefficient of greater than 0.998.The lower limit of quantification was 0.5ng/ml with C.V % of 5%.The %accuracy for QC samples were 98.33%LQC, 93.03%, GMQC 93.60%MQC and 96.87%HQC.The %CV for QC samples were 5.19%LQC 931.78%GMQC, 3.94%MQC and 0.21%HQC. The % stability by freeze and thaw stability was 97.27%for LQC, 96.42%for HQC and by bench top stability was 100.33% & 98.20% for LQC and HQC respectively. The % accuracy and CV% for dilution integrity in the ratio of 1:5 was 159.248&4.02%. This method can be used for the quantification of tacrolimus in human whole blood in routine and bioequivalence studies.

Keywords: Tacrolimus, UPLC-MS/MS, Liquid phase extraction, Bioequivalence, sensitive

Introduction

Tacrolimus (also FK-506 or Fujimycin) is a 23-membered macrolide lactone discovered in 1984 from the fermentation broth of a Japanese soil sample that contained the bacteria *Streptomyces tsukubaensis*. **Tacrolimus** is the most frequently used immunosuppressive drugs in organ transplantation [1] mainly used after allogeneic organ transplant to reduce the activity of the patient's immune system and so lower the risk of organ rejection.). Initially, it was employed in the management of liver transplants; it is now routinely used in the management of kidney, heart, pancreas, small bowel, lung and bone marrow transplants [2, 3] FK-506 acts by binding to a cytoplasmic protein called immunophilin; the resultant complex then inhibits the function of an intracellular protein calcineurin, a Ca and calmodulin-dependent serine/threonine phosphatase. Furthermore, this interaction leads to the inhibition of T-lymphocyte signal transduction and decreases IL-2 transcription, which gives rise to immune suppression [2-4] These immunosuppressive drugs have narrow therapeutic ranges it is also used in a topical preparation in the treatment of severe atopic dermatitis (eczema) severe refractory uveitis after bone marrow transplants, and the skin condition vitiligo) FK-506 is a critical dose drug with a narrow therapeutic index; i.e., it exhibits the desired therapeutic effect [illegible] acceptable tolerability within a narrow range of blood concentration. As a result, at low blood levels there is a risk of rejection of the organ transplant, while elevated circulating concentration can lead to serious toxicity and long-term morbidity [5, 6] In addition, there is important variation for blood levels of these immunosuppressive drugs in different individuals, and ethnicities may also affect these parameters [7, 8]. Thus, the accurate determination of FK-506 is essential to correlate its blood concentration and clinical outcomes for therapeutic drug monitoring [9-11]. TDM has been used to monitor drug levels in routine patient care. The methodology of TDM must be precise and accurate for immunosuppressive drugs [12].

There are two main analytical methods for determination of immunosuppressive drugs in transplant patients: immunoassays (micro particle enzyme immunoassay, cloned enzyme donor immunoassay, etc.) and liquid chromatography-based methods (high-performance liquid chromatography (HPLC) with ultraviolet detection, LC-mass spectrometry (LC-MS), and LC-tandem mass spectrometry (LC-MS/MS)) [13]. Immunoassays are widely used for the routine determination of FK-506; however, they lack specificity due to endogenous compounds and cross reactivity of monoclonal antibodies with the metabolites of the drug [14, 15] On the other hand, LC–MS-MS based methods are highly selective because

RESEARCH ARTICLE

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Design, One Pot Synthesis and Molecular Docking Studies of Substituted-1H-Pyrido[2,1-b] Quinazolines as Apoptosis-Inducing Anticancer Agents

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Abstract

Objective: The present study focused to build pyridine and quinazoline rings in a single molecule and designed a new fused Pyrido[2,1-b] quinazoline to have a better pharmacological activity. **Material and Methods:** A three component, one-pot synthesis of substituted-1H-Pyrido[2,1-b] quinazoline derivatives has been described by conventional and microwave synthesis using triflic acid as catalyst. These compounds were screened for *in vitro* cytotoxic activity against the panel of cancer cell lines A549, NCI-H460, HT-29, HCT-15, DU-145, and HFL. **Results:** Among the tested compounds, 11-(1-benzyl-1H-indol-3-yl)-2, 3, 4, 11-tetrahydro-1H-pyrido[2,1-b] quinazoline (**4i**) showed most potent cytotoxicity against A549 and NCI-H460 lung cancer cell lines with IC_{50} values 4.57±0.25 and 5.53±0.49 μM, respectively. Moreover, compound 4i was found to be most potent considerable cell growth inhibition with GI_{50} values of 2.70±0.18 and 3.24±0.40 μM against A549 and NCI-H460 cell lines, respectively. In addition, induction of apoptosis for compound 4i on A549 was investigated by morphological changes, Acridine orange/ethidium bromide (AO/EB) and DAPI staining. Furthermore, a strong anti-clonogenic effect of compound 4i on lung cancer cells was observed. The flow cytometric analysis investigation reveals that compound **4i** arrests the A549 cancer cell lines at the G0/G1 phase of the cell cycle. Molecular docking were also performed on **4i, 4j**, and erlotinib to predict the binding mode towards the EGFR kinase (PDB code: 1M17) and the compounds have displayed similar interactions and compared with erlotinib. **Conclusion:** Overall, these findings could suggest that the compound 4i would be an ideal lead as an anticancer agent.

Keywords: One Pot- quinazoline- molecular docking- cytotoxicity- anticancer.

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Introduction

Cancer is one of the leading causes of death worldwide and accounts for almost 13% deaths than any other infectious diseases (Thun et al., 2010). According to World Health Organization (WHO), projections of cancer prevalence is expected to raise by 21.7 million cases of oncological patients and 13 million deaths by 2030 (El-Azab et al., 2017; Boussari et al., 2018). With the increase in prevalence of cancer and thereby rapidly escalating costs, there are still types of cancer with massive unmet medical needs (Kummar and Takimoto, 2018). Therefore, the development of novel chemotherapeutic agents to fight against this deadly disease is needed urgently (Chakraborty and Rahman, 2012). Nitrogen containing heterocyclic compounds like quinolines and pyridines core rings plays a very important role in drug discovery and development on cancer. (Taylor et al., 2016, Jabir et al., 2018) Some of the marketed drugs have core structure of quinazoline which includes Afatinib (I, as metastatic non-small cell lung cancer) (Shagufta and Ahmad, 2017), Barasertib (II, acute myeloid leukemia) (Helfrich et al., 2016), Tandutinib (III, Antisolid tumors) (Motyckova and Stone, 2015) and Cediranib (IV, Hematological cancers). (Fiedler et al., 2010) The structural moieties of quinazoline exhibit broad range of biological activities viz., anticancer (Zaki et al., 2018), analgesic (Samiksha and Gupta, 2018), antimalarial(Gupta et al., 2018), anti-inflammatory (Moussa et al., 2018) and anticonvulsant activities. (Oluwaseye et al., 2018) Moreover, Pyridine derivatives have known as antifungal, antiviral, anticancer, antidepressant and anti-inflammatory properties (Kurumurthy et al., 2014; Helal et al., 2015) (Figure 1).

Pyrido [2,1-b]quinazoline (V) is a nitrogen containing fused heterocyclic compound and widely distributed in many bioactive compounds, natural products with interesting biological activities (Tilley et al., 1987; Mikhalev et al., 1995; Gálvez et al., 2018; Samiksha and Gupta, 2018). Pyrido [2,1-b] quinazolines have

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Evaluation of antitumor potential of synthesized novel 2-substituted 4-anilinoquinazolines as quinazoline-pyrrole hybrids in MCF-7 human breast cancer cell line and A-549 human lung adenocarcinoma cell lines

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Abstract

Background: A series of novel 2 substituted 4-anilinoquinazolines-pyrrole hybrids were synthesized, and cytotoxic activity were evaluated using MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyl tetrazolium bromide) assay.

Methods: The cell line used for the activity was MCF-7 breast cancer cell line and A459 human lung adenocarcinoma cell line. The newly quinazoline-pyrrole hybrid compounds have been synthesized from the 4-chloro-7-(3-chloropropoxy)-6-methoxy-2-phenylquinazoline derivatives. The chemical structure of the synthesized compounds has been confirmed by FTIR, ^{1}HNMR, ^{13}C NMR, and mass spectral data. The cytotoxic study was conducted using morphological study and MTT assay against adenocarcinoma and human breast cancer cell lines.

Results: The results of cytotoxic evaluation revealed that few compounds show moderate to promising activity when compared with standard doxorubicin (IC_{50} value 41.05 μM at 72 h). The synthesized compounds 7d and 7f were found effective in breast cancer cell line with IC_{50} values 40.64 μM and 44.98 μM at 72 h, respectively. The synthesized compounds 7d, 7f, 7g, and 7h were found effective in adenocarcinoma cell line with IC_{50} values of 41.05 μM, 45.54 μM, 46.93 μM, and 48.62 μM, respectively.

Conclusion: Based on the experimental evidences, we proposed structure activity relationship to provide significant information for the design and development of further potent anticancer agents.

Keywords: Quinazolines, Pyrrole, Cytotoxic, Breast cancer, Adenocarcinoma

Background

The heterocyclic molecule combined with quinazoline has drawn a colossal thought attributable to their extended applications in pharmaceutical science. Quinazolines are accounted for their enhanced natural exercises and mixes with different substitutions unite to provide information on an objective with comprehension of the molecule types that may collaborate with the objective receptors. Quinazolines are considered as a significant compound for the union of different physiological noteworthiness and pharmacologically used molecule. Quinazolines are the classes of combined heterocycles that are of extensive intrigue as a result of the various scopes of their natural properties [1]. Many substituted quinazoline subsidiaries

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RESEARCH ARTICLE

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Evaluating The Neurochemistry of Ptsd and Its Relationship to The Brain Function-Related Consequences of Neurochemical

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ABSTRACT

Neuroscientists have made significant advancements in their knowledge of the brain and nervous system over the course of the last few decades, which has led to the discovery of interesting and vital new information on the inner workings of these organs. In spite of these significant advances, our efforts to understand, cure, and prevent pathogenic changes have not yielded particularly beneficial results. The objective of completely treating mental illness is still difficult to achieve, despite the fact that it creates a huge financial burden on our society, affects more people in more ways for longer periods of time than any other disease, and is the leading cause of disability worldwide. As of right now, we do not know if schizophrenia or any other mental condition reflects the expression of separate diseases. If this is the case, then we do not know what biological similarities and differences exist across the diagnostic categories that we utilize. Naturally, even short-term assistance that reduces the symptoms of the illness and the accompanying suffering of the targeted hospital populations is very valuable and constitutes a significant contribution. This is because the symptoms of the illness and the accompanying suffering are a direct result of the illness. Mental illness certainly has an effect on more than just the person who is experiencing it; it is a burden on families as well as on society as a whole, diminishing the sufferer's ability to have a positive societal influence, their capacity to work, and their general quality of life.

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INTRODUCTION

What exactly does "neurochemistry" mean? Neurochemistry is a subfield of chemistry that focuses on the study of the many kinds of chemical components present in the nervous system as well as their structures and activities. These components, in turn, have an effect on the physiological functioning of the nervous system. Small organic molecules, neurotransmitters, and neuropeptides are examples of the types of chemicals that are the primary focus of neurochemistry. This branch of chemistry is primarily concerned with the substances that are unique to the nervous system. Alzheimer's disease and Parkinson's disease, for example, are both examples of neurological conditions that are often caused by changes in the neurochemistry of the body.

KEYWORDS:
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Neurochemical,
Alzheimer's disease,
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Research Article

Synthesis, Molecular Docking Studies, *In Vitro* Antibacterial and Antifungal Activities of Some Novel N-4 Piperazinyl Derivatives of Gatifloxacin

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ABSTRACT

A series of gatifloxacin derivatives were synthesized (O1-O10) Via N-Piperazinyl linkage. The structural conformation was done by infra-red, nuclear magnetic resonance, mass spectrometry and elemental analysis technique. In present investigation, we screened docking simulation for synthesized compounds (O1-O10) to find out binding modes of derivatives with 5IWM and 3FV5. The compound O5 showed good antibacterial activity against gram positive (*S. Aureus*) and compound O6 showed good antibacterial activity against gram negative (*E.coli*) in comparison with standard drugs (Ciprofloxacin and Gatifloxacin). Compound O9 showed mild antifungal activity against (*A. niger*) and (*A. fumigatus*) in comparison with standard drug ketoconazole. The Zone of inhibition and MIC studies were performed to synthesized compounds. The correlation between experimental data (minimum inhibition concentration) versus docking score suggested that penetration for docking simulation were good in reproducing experimental orientation of these synthesized compounds.

Keywords: N-Piperazinyl derivatives, Ciprofloxacin, Gatifloxacin, DNA Gyrase, Anti-microbial, Topoisomerase-IV, Docking studies.

INTRODUCTION

Quinolone antibacterial agents have potent activity against gram-positive and gram-negative bacteria and are currently used as therapy for various bacterial infections. The antibacterial activities of quinolones are related in their inhibitory activities against DNA Gyrase (Topoisomerase-II) and topoisomerase-IV.[1,2] Both enzymes are members of the type-II topoisomerase family that controls bacterial DNA topology by passing a DNA double helix through another, by using a transient double -standard break.[3] It has recently been reported that the primary target of several quinolones in Escherichia coli is DNA gyrase and that in staphylococcus aureus is topoisomerase-IV.[2,4-11] Quinolones also inhibit mammalian type-II topoisomerase such as topoisomerase-IIVand their inhibitory potencies for topoisomerase-II have been correlated with their cytotoxicity.[12-16] Since the introduction of fluoroquinolones in late 1970s, they have generated great excitement, opportunities and applications in the antibacterial chemotherapeutic world, as these agents potentially offer's all the general attributes of ideal antibacterial agents. Over the last 15 years, researchers have attempted and proved these attributes as reality.[17]

Gatifloxacin, a newly developed quinolone, has shown potent activity against gram-negative bacteria and it has been reported that Gatifloxacin inhibits DNA gyrase of Escherichia Coli, Pseudomonas aeruginosa, Micrococcus luteus, and Staphylococcus aureus, like other quinolones,[18,19] Its structure and ball stick three-dimensional model have shown in Figs. 1 and 2, respectively.

It inhibits both bacterial DNA gyrase and topoisomerase-IV.[20, 21] The structure of gatifloxacin differs from earlier fluoroquinolones by the presence in the C-8 position of a methoxy group that enhances its antibacterial activity against gram positive bacteria improves its activity against DNA gyrase mutants of Escherichia coli.[22,23] The methoxy group in C-8 position also diminishes photosensitivity reactions.[24] Gatifloxacin, Ciprofloxacin, Levofloxacin inhibited members of the family Enterobacteriaceae comparably.[25,26] Gatifloxacin is more potent than ciprofloxacin against methicillin-resistant S. Aureus (MRSA),[26] although clinical significance of this still needs to be investigated. Gatifloxacin was recently investigated for the treatment of non-gonococcal urethritis.[27] Gatifloxacin is usually similar to moxifloxacin and levofloxacin and more active than ciprofloxacin against susceptible streptococci.[28-30] Dysglycemia has been noted as the life-threatening adverse effect of gatifloxacin, which led to its withdrawal from the market in the united states in 2006.[31] Gatifloxacin is reportedly highly active against atypical genitourinary pathogens such as chlamydia trachomatis and urea plasma urealyticum.[32,33] It is extensively distributed into many tissues and body fluids.[34-36] Due to structural characteristics, of gatifloxacin mechanism of killing action is not dependent on bacterial life cycle.[37]

The present study reports on the synthesis, spectroscopic analysis including IR and ^{1}H NMR, mass spectrometry and their biological activities of N-piperazinyl derivatives of gatifloxacin (O_1-O_{10}). Molecular docking was performed.

METHOD DEVELOPMENT AND VALIDATION FOR DETERMINATION OF LENALIDOMIDE IN API FORM AND MARKETED FORMULATION BY RP-HPLC

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ABSTRACT: A new analytical, simple, rapid, accurate, precise, robust RP-HPLC method has been developed and validated for estimation of Lenalidomide in bulk and pharmaceutical dosage forms. The method involves separation on Symmetry ODS (C_{18}) RP Column, 250 mm x 4.6 mm, 5µm. The optimized mobile phase consists of Phosphate Buffer and Methanol in the ratio of 46:54% v/v (pH-3.2) with a flow rate of 1.0ml/min and UV detection at 206nm. Retention time of Lenalidomide was found to be 3.622min. Linearity range was 20-60ug/ml of Lenalidomide. Accuracy was in the range of 98-102% for Lenalidomide drug. The % RSD for Method Precision was found to be 0.609%. LOD and LOQ are 0.8µg/ml and 0.24µg/ml for Lenalidomide respectively. The method developed is more sensitive, accurate and precise than the methods reported earlier. Retention time and run time were also less and hence the method is economical. When applied for tablet assay, drug content was within 98 -102% of labeled content. The proposed method was found to be simple and sensitive for routine quality control application of Lenalidomide used in bulk form and pharmaceutical tablet dosage forms.

Key Words: Lenalidomide, RP-HPLC, Method Development, Validation, Accuracy, Robustness.

I. INTRODUCTION

Lenalidomide[1] is a dicarboximide that consists of 1-oxoisoindoline bearing an amino substituent at position 4 and a 2, 6-dioxopiperidin-3-yl group at position 2. Inhibits the secretion of TNF-alpha. 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. In hematological malignancies, the immune system is deregulated in the form of altered cytokine networks in the tumour microenvironment, defective T cell regulation of host-tumour immune interactions, and diminished NK cell activity. Lenalidomide[2] is an immunomodulatory agent with antineoplastic, antiangiogenic, and anti-inflammatory properties. Lenalidomide exerts direct cytotoxicity by increasing apoptosis and inhibiting the proliferation of hematopoietic malignant cells. It delays tumour growth in nonclinical hematopoietic tumour models in vivo, including multiple myeloma. Lenalidomide[3] also works to limit the invasion or metastasis of tumour cells and inhibits angiogenesis. Lenalidomide acts by a novel drug mechanism—modulation of the substrate specificity of the CRL4CRBN E3 ubiquitin ligase. In multiple myeloma, lenalidomide induces the ubiquitination of IKZF1 and IKZF3 by CRL4CRBN. Subsequent proteasomal degradation of these transcription factors kills multiple myeloma cells. The IUPAC Name of Lenalidomide is 3-(7-amino-3-oxo-1H-isoindol-2-yl) piperidine-2, 6-dione. The Chemical Structure of Lenalidomide is as following

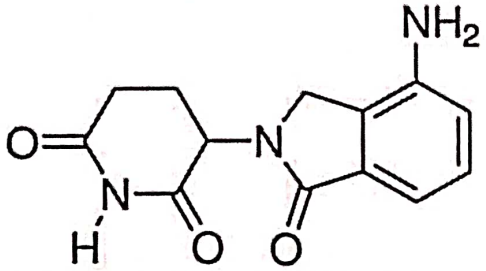

Fig.1. Chemical Structure of Lenalidomide

The literature survey[31-34] shows that there are few methods for the determination of Lenalidomide individually in bulk and pharmaceutical dosage forms by using various analytical instruments like UV-Vis spectrophotometer, HPLC, RP-UPLC, and LC-MS/MS. So, the attempt has been made to develop a new validated RP-HPLC[4] method

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Method development and validation of anti-protozoal agent- Nitazoxanide by RP-HPLC and it's stability related impurities studies

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ABSTRACT

A simple and new Reverse Phase High Performance Liquid Chromatographic (RP-HPLC) method was developed for the simultaneous estimation of Nitazoxanide in Pure form and Marketed Pharmaceutical Dosage form. The separation involved an isocratic elution of this component on Symmetry C18 (4.6 x 150mm, 5µm, Make: XTerra) using a mobile phase composition Methanol: Phosphate buffer = 60:40. The flow rate was 1.0 ml/min and the analyte monitored at 242nm. The performance of the method was validated according to the present ICH guidelines for specificity, linearity, accuracy, precision and robustness. Retention times of Nitazoxanide were found to be 2.96 min respectively. The percentage recoveries for Nitazoxanide were found to be within the limits i.e. 97-102% respectively. Calibration curves were linear with coefficient correlation between 0.990 to 0.999. Typically the regression equation for the calibration curve was found to be y = 26326x + 38649 (R^2=0.995) Nitazoxanide respectively. The developed method can be successfully employed for routine quality control analysis of Nitazoxanide marketed formulation.

Keywords: Nitazoxanide, Method development, Method Validation, Retention time.

INTRODUCTION [1 2 3]

Reversed Phase Chromatography: Since 1960's chromatographers started modifying the polar nature of silanol group by chemically reacting silica with organic silanes. The objective was to make less polar or non polar so that polar solvents can be used to separate water-soluble polar compounds. Since the ionic nature of the chemically modified silica is now reversed i.e. it is non-polar or the nature of the phase is reversed. The chromatographic separation carried out with such silica is referred to as reversed- phase chromatography. A large number of chemically bonded stationary phases based on silica are available commercially. Silica based stationary phases are still most popular in reversed phase chromatography however other absorbents based on polymer (styrene-di-vinyl benzene copolymer) are slowly gaining ground. The retention decreases in the following order: aliphatic > induced dipoles (i.e. CCl_4) > permanent dipoles (e.g.$CHCl_3$) > weak Lewis bases (ethers, aldehyde, and ketones) > strong Lewis bases (amines) > weak Lewis acids (alcohols, phenols) > strong Lewis acids (carboxylic acids). Also the retention increases as the number of carbon atoms increases. As a general rule the retention increases with increasing contact area between sample molecule and stationary phase i.e. with increasing number of water molecules, which are released during the adsorption of a compound. Branched chain compounds are eluted more rapidly than their corresponding normal isomers. In reversed phase systems the strong attractive forces between water molecules arising from the 3-imentional inter molecular hydrogen bonded network, from a structure of water that must be distorted or disrupted when a solute is dissolved. Only higher polar or ionic solutes can interact with the water structure. Non- polar solutes are squeezed out of the mobile phase and are relatively insoluble in it but with the hydrocarbon moieties of the stationary phase. Chemically bonded octadecyl silane (ODS) an alkaline with 18 carbon atoms is the most popular stationary phase used in pharmaceutical industry. Since most pharmaceutical compounds are polar and water soluble, the majority of HPLC methods used for quality assurance, decomposition studies, quantitative analysis of both bulk drugs and their formulations use

RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR THE QUANTITATIVE DETERMINATION OF TIPRANAVIR IN BULK FORM AND MARKETED PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A rapid, accurate, robust, rugged and precise reverse phase high performance liquid chromatographic method has been developed for the validated of Tipranavir in its pure form as well as in tablet dosage form. Chromatography was carried out on a Symmetry C18, 250 mm x 4.6 mm i.d.5µm particle size column using a mixture of Methanol and Acetonitrile (70:30% v/v) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 245nm. The retention time of the Tipranavir was 2.768 ±0.02min respectively. The method produce linear responses in the concentration range of 6-14mg/ml of Tipranavir. 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.

Keywords: Tipranavir, RP-HPLC, Method Development, Validation.

INTRODUCTION

Tipranavir is an antiretroviral protease inhibitor used in the therapy and prevention of human immunodeficiency virus (HIV) infection and the acquired immunodeficiency syndrome (AIDS). Tipranavir can cause transient and usually asymptomatic elevations in serum aminotransferase levels and is a rare cause of clinically apparent, acute liver injury. In coinfected patients, hepatic injury during highly active antiretroviral therapy including Tipranavir may be a result of exacerbation of the underlying chronic hepatitis B or C, rather than a direct effect of the medication. Tipranavir[1] is a non-peptidomimetic agent that inhibits both wild type and drug resistant forms of human immunodeficiency virus (HIV) protease. Tipranavir[2] is a pyridine-2-sulfonamide substituted at C-5 by a trifluoromethyl group and at the sulfonamide nitrogen by a dihydropyrone-containing m-tolyl substituent. It is an HIV-1 protease inhibitor. It has a role as a

DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR THE ESTIMATION OF TICAGRELOR IN API FORM AND MARKETED TABLET DOSAGE FORM

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ABSTRACT: A novel, economical, rapid, precise, robust, rugged and accurate RP-HPLC method for estimation of Ticagrelor in bulk form and marketed Tablet Dosage form. The Chromatographic Separation was 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 and pH was adjusted with orthophosphoric acid) in the ratio of 45:55% v/v at a flow rate of 1.0mL/min and the detection was carried out at 255nm. The proposed 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 Ticagrelor. The correlation coefficient was found to be 0.9995 for Ticagrelor. The LOD and LOQ for Ticagrelor were found to be 5.004µg/mL and 15.164µg/mL respectively. The proposed method was found to be good percentage recovery for Ticagrelor, which indicates that the proposed method is highly accurate. Therefore, the proposed method specifically determines the analyte in the sample without interference from excipients of pharmaceutical dosage forms.
Keywords: Ticagrelor, RP-HPLC, Accuracy, Precision, ICH Guidelines.

I. INTRODUCTION

Ticagrelor is an oral antiplatelet drug that is used with low dose aspirin to decrease the risk of myocardial infarction and stroke in patients with acute coronary syndromes. Ticagrelor[1] has been linked to rare instances of hypersensitivity reactions accompanied by mild liver injury. Ticagrelor[2] is a triazolopyrimidine that is an adenosine isostere; the cyclopentane ring is similar to ribose and the nitrogen-rich [1, 2, 3] triazole [4, 5-d] pyrimidine moiety resembles the nucleobase adenine. A platelet aggregation inhibitor which is used for prevention of thromboembolic events in patients with acute coronary syndrome. It has a role as a platelet aggregation inhibitor and a P2Y12 receptor antagonist. It is a member of triazolopyrimidines, an organofluorine compound, an aryl sulfide, a secondary amino compound and a hydroxyether. Ticagrelor, or AZD6140, was first described in the literature in 2003. Ticagrelor[3] is an ADP derivative developed for its P2Y12 receptor antagonism. Unlike [Clopidogrel], Ticagrelor is not a prodrug. It is marketed by Astra Zeneca as Brilinta in the US and Brilique or Possia in the EU. Ticagrelor was granted EMA approval on 3 December 2010. Ticagrelor was granted FDA approval on 20 July 2011. Ticagrelor is a P2Y12 platelet inhibitor used in patients with a history of myocardial infarction or with acute coronary syndrome (ACS) to prevent future myocardial infarction, stroke and cardiovascular death. The IUPAC Name of Ticagrelor is (1S, 2S, 3R, 5S)-3-[7-[[(1R, 2S)-2-(3, 4-difluoro phenyl) cyclo propyl] amino]-5-propyl sulfanyl triazole [4, 5-d] pyrimidin-3-yl]-5-(2-hydroxy ethoxy) cyclopentane-1, 2-diol. The Chemical Structure of Ticagrelor is in fig-1.

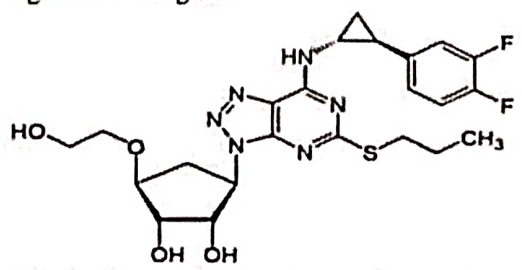

Fig.1. Chemical Structure of Ticagrelor

Therefore, it was thought of interest to develop simple, accurate, fast and cost effective method for the analysis of Ticagrelor in its tablet formulation. This paper describes development and validation[4] of simple, specific, sensitive, accurate and precise Chromatographic method[5] for the estimation of Ticagrelor in bulk and its formulation.

METHOD DEVELOPMENT AND VALIDATION BY RP-HPLC FOR THE QUANTITATIVE DETERMINATION OF POLATUZUMZB IN BULK FORM AND MARKETED PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A rapid, accurate, robust, rugged and precise reverse phase high performance liquid chromatographic method has been developed for the validated of POLATUZUMZB in its pure form as well as in tablet dosage form. Chromatography was carried out on a Symmetry C18, 250 mm x 4.6 mm i.d.5µm particle size column using a mixture of Methanol and Acetonitrile (70:30% v/v) as the mobile phase at a flow rate of 1.0ml/min, the detection was carried out at 245nm. The retention time of POLATUZUMZB the was 2.768 ±0.02min respectively. The method produce linear responses in the concentration range of 6-14mg/ml of POLATUZUMZB. 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.

Keywords: POLATUZUMZB, RP-HPLC, Method Development, Validation.

INTRODUCTION

POLATUZUMZB is used in the CANCER therapy and prevention of human immunodeficiency virus (HIV) infection and the acquired immunodeficiency syndrome (AIDS). A drug used with bendamustine hydrochloride and rituximab to treat adults with diffuse large B-cell lymphoma that came back or did not get better after treatment with at least two other anticancer therapies. It is also being studied in the treatment of other types of cancer. Polatuzumab vedotin contains a monoclonal antibody that binds to a protein called CD79B, which is found on B cells (a type of white blood cell) and some lymphoma cells. It also contains an anticancer drug, which may help kill cancer cells. Polatuzumab vedotin is a type of antibody-drug conjugate. Also called Polivy.

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INSULIN NANOPARTICLES LOADED SUPPOSITORES INTENDED FOR THE SYSTEMIC DRUG DELIVERY

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ABSTRACT

The main objective of the present work was to develop colon targeted insulin nanoparticle loaded suppositories intended for systemic delivery of the active. This delivery provides sustained release delivery of the drugs through the rectal route. Nanoparticles based on PLGA were loaded with insulin using w/o/w solvent evaporation technique. The prepared nanoparticles were characterized for various in vitro properties. Particle size and charge were measured using zeta sizer and SEM. Integrity of the drug at the end of formulation development was determined using FTIR, DSC and XRPD. The duration of drug release was determined using in vitro release testing methods. After selecting suitable nanoparticle formulation, they were incorporated into cocoa butter as suppositories. The drug release was also determined at the end of formulation development and a suitable formulation was proposed. The results demonstrated that sustained released of insulin was observed over one week with improved stability of insulin. These suppository formulations loaded with insulin nanoparticles are intended for colon delivery so as to achieve systemic levels of insulin as an alternate route of delivery of this drug.

KEYWORDS: Colon drug delivery, insulin, lyophilization, suppository.

INTRODUCTION

For many a years the treatment of an acute disease or a chronic disease has been mostly accomplished by the delivery of drugs using various dosage forms such as tablet, capsules, pills, suppositories, ointments, liquids, aerosols, and injectables. All these are the conventional drug delivery systems. These systems are the primary pharmaceutical products

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DEVELOPMENT OF FORMULATIONS AND SYSTEMATICALLY EVALUATED IN-VITRO DIFFUSION OF BUCCAL PATCHES OF KETOROLAC

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ABSTRACT

The objective of present study was to develop matrix type buccal patch therapeutic systems of Ketorolac using various hydrophilic and hydrophobic polymers as matrix formers. Results revealed that prepared patches showed good physical characteristics, no drug-polymer interaction was observed. The in vitro release study revealed that F1 formulation showed maximum release in 16 hrs. The release kinetics of formulation F1 followed Higuchi model. Formulation F1 was subjected for accelerated stability studies. The F1 formulation was found to be stable as there was no drastic change in the Physico-chemical properties of the patchesF1, F2, F3, F4, F5, F6, F7 and F8 formulations showed highest cumulative percentage drug release of 98.38%, 97.92%, 99.10%, 97.32% were obtained during in vitro drug release studies after 16 hrs. The release of Ketorolac appears to be dependent on lipophilicity of the matrix. Moderately lipophillic matrices showed best release. 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 F1 formulation was concluded as optimized formulation.

KEYWORDS: Buccal patch, Buccal delivery system, Ketorolac, Sodium aliginate & Eudragit, Diffusion mechanism.

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Ai models predicting risk of cardio vascular diseases - the limitations, challenges and necessity for regulatory framework

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Abstract

Artificial intelligence (AI) algorithms have changed the landscape of Cardio Vascular Disease (CVD) risk assessment and demonstrated a better performance mainly due to its ability to handle the input nonlinear variations. Further, it has the flexibility to add risk factors derived from medical imaging modalities using Computer Vision (CV). Most commonly used algorithms in CVD risk predications were classification and regression tress (CART).

Though most of the developed models have shown good accuracy but have not considered risks factors or dependent variables related to specific population which plays an integral role in predicting the risk of CVDs. This Include gender specific clinical risk factors (hormonal changes, bone density etc.), metrological, chronological data, exposure to environmental pollutants, race, genotype, hereditary, dietary intake, physical inactivity, psychological stress etc. Secondly the existing models have not included the weighing and grading of the risks, as all factors won't contribute equally to the Cardiac Risk. Importantly predictive models can be readily used within the populations in which they were developed but practically they often give a less than satisfactory performance, when applied to another population because of the Inter genetic variations especially in CVDs.

India accounts for one-fifth of these deaths worldwide especially in younger population. The results of Global Burden of Disease study state age-standardized CVD death rate of 272 per 100000 populations in India, which is much higher than that of global average of 225. CVDs strike Indians a decade earlier than the western population. For Indians, particular causes of concern in CVD are early age of onset, rapid progression and high mortality rate. Indians are known to have the highest coronary artery disease (CAD) rates, and the conventional risk factors fail to explain this increased risk.

In Indian context, aggressive screening tests should begin at an early age and will be beneficial for early detection and treatment to reduce the mortality. Hence there is necessity to develop upgraded AI models specific to a subset of population (Indian, Caucasoid, Dravidian etc.) inclusive of the risk factors in that specific population. Secondly allotting weighing, grading of risk factors in the model will provide accurate cardiac risk prediction compared to other approaches.

The regulatory and policy landscape for AI is an emerging issue in jurisdictions globally, including in the European Union and in supranational bodies like the IEEE, OECD and others. Since 2016, a wave of AI ethics guidelines has been published in order to maintain social control over the technology.

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The Novel Drug Delivery Systems in Liver Disfunction

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Abstract
The liver is a vital organ present in vertebrates and some other animals. Its wide functions include detoxification, protein synthesis, and production of biochemical necessary for digestion. This organ is necessary for survival. Currently there is no option to compensate for the absence of liver function. Drug targeting for various liver diseases can focus on various cells of liver including kupffer cells, sinusoidal endothelial cells, hepatic stellate cells or hepatocytes. In one or the other diseases, the involvement of these diseases has been clarified. Several diseases afflict liver. The major diseases of liver include HBV infection, liver fibrosis/cirrhosis, hepatocellular cancer. Several cells of the liver which are exposed to blood circulation or not exposed to blood circulation are involved in these diseases. Although conventional routes of administration can lead to drug access into these varieties of cells, means to increase the effectiveness of these by various drug delivery approaches has been attempted recently. This review briefly covers the latest and retrospective drug delivery system approaches published in the scientific literature.

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I. Introduction

The past 30 years have witnessed major progress in the knowledge and management of liver disease[1]. This report reviews several studies published in the last five years to survey the current state of evidence to be able to treat various liver disorders using drug delivery strategies. The incidence and prevalence of two conditions, cirrhosis and primary liver cancer, are key to understanding the burden of liver disease. They represent the end-stage of liver pathology and thus are indicative of the associated mortality. Literature on the prevalence and incidence of cirrhosis and liver cancer is scarce. Data here is illustrated taking Europe's data on cirrhosis and liver cancer. Available data suggest that about 0.1% of the European population is affected by cirrhosis, corresponding to 14-26 new cases per 100,000 inhabitants per year or an estimated 170,000 deaths per year. There are, however, large intra-European variations. About 0.1% of Hungarian males will die of cirrhosis every year compared with 0.001% of Greek females. Hepatocellular carcinoma (constituting 70-90% of cases of primary liver cancer) is the fifth most common cause of cancer in Europe and one of the most serious outcomes of cirrhosis. European epidemiological data show that there are 1-13 new cases of hepatocellular carcinoma and 1-10 deaths per 100,000 inhabitants per year. WHO estimate that liver cancer is responsible for around 47,000 deaths per year in the EU? The four leading causes of cirrhosis and primary liver cancer in Europe are harmful alcohol consumption, viral hepatitis B and C and metabolic syndromes related to overweight and obesity. Chronic alcohol consumption is the main cause of cirrhosis in Europe. Alcohol consumption decreased in the 1990s, but has increased again in the last decade to stabilize at a high level of >9 litres of pure alcohol per year on average, although there are large variations among European countries. Chronic viral hepatitis B is the second major cause of both cirrhosis and liver cancer. Between 0.5% and 0.7% of the European population is affected by chronic hepatitis B, with the highest prevalence being recorded in Romania (5.6%) and Greec (3.4%). By comparison, HIV prevalence is only 0.2% (HIV is 50-100 times less infectious). The availability of a vaccine has resulted in a decrease in the prevalence of HBV, although it remains responsible for 30% of cases of cirrhosis and 15% of cases of primary liver cancer. Chronic hepatitis C is an important risk factor for hepatocellular carcinoma, which develops several decades after infection. Since the discovery of the virus in the late eighties, the number of new cases of infection has dropped substantially. Prevalence rates of hepatitis C virus (HCV) infection in the last decade in the European population were between 0.13 and 3.26%, the highest rates being found in Italy and Romania. These HCV –infected populations will develop complications in the years to come, leading to a substantial increase in the burden of disease. It is of great concern that about 90% of people in Europe infected by viral hepatitis are unaware of their status. Non-alcoholic fatty liver disease (NAFLD) is becoming a major concern with the increasing incidence of obesity in Europe. In this condition

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Proliposome technique for enhancement of bioavailability of metformin hydrochloride

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Abstract

The aim of the present study was to develop and characterized a vesicular drug carrier system (proliposome) for oral delivery of metformin hydrochloride to overcome the problems related with conventional drug delivery system. Proliposomes of metformin hydrochloride were prepared by spray gun technique by varying the composition drug and excipiets. Proliposome formulations were characterized for compatibility, Vesicle size, % Drug content, % Entrapment efficiency, Surface morphology, Surface charge, *in vitro* drug release and stability studies. The proliposomal dry powder was prepared for optimized proliposomal formulation MPF9. Drug and physical mixture were characterized by FTIR, the result of FTIR study showed that no interaction between drug and polymers and other formulation parameters of formulated proliposomes and proliposomal dry powder are evaluated which showed better results.

Top

Keywords

Proliposome, Metformin hydrochloride, FTIR, *In vitro* drug release.

Top

Aukunuru Venkata Jithan

Preparation and Evaluation of Controlled Release Parenteral Nanosuspensions of Anastrazole

Authors Rajakumar Devara, Mohammed Habibuddin, Kiran Thadkala, Jithan Aukunuru

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Description Anastrazole is a class of medication called non steroidal aromatase inhibitors. It works by decreasing the amount of estrogen in the body makes this can slow or stop the growth of many types of breast cancer cells that need estrogen to grow. As it is having poor water solubility and poor wettability, anastrazole leads to poor dissolution and hence shows poor bioavailability. The present study is aimed at increasing dissolution rate/solubility of drug and its sustained release property of drug, used as parenteral nanosuspension. Nanosuspension formulations of anastrazole were prepared by anti-solvent solvent precipitation technique. The formulations were characterized by scanning electron microscopy, zeta potential, powder X-ray diffractometry, saturation solubility and in-vitro drug release. The evaluation studies were performed by using optimum formulation based on the particle size and saturation solubility, formulations were selected and further studies with the formulation were conducted. As a result of this method, it was found that the dissolution rate and saturation solubility of the nanosuspension formulation was significantly higher compared to the conventional suspension formulation. Further, the optimum formulation controls the drug release for 24 hours. Therefore, in this study a parenteral nanosuspension formulation of anastrazole were successfully developed and evaluated. The formulation is intended for controlled release delivery of the drug after iv administration with enhanced Cmax. The formulation can be successfully used in breast cancer as it reduces the production of estrogen after intravenous administration.

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Preparation, characterization and *In Vivo* evaluation of dexamethasone nanoparticles for the treatment of liver fibrosis

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Abstract

Background: The purpose of this study was to formulate nanoparticles containing Dexamethasone and to investigate their potential in the prevention of carbon tetrachloride induced liver toxicity. Methods: Dexamethasone nanoparticles were formulated using o/w emulsion solvent evaporation technique using poly-e-caprolactone as polymer. Four different nanoparticle formulations (DXMNP1, DXMNP2, DXMNP3 and DXMNP4) were prepared by taking different drug to polymer ratios. The prepared particles were characterized for particle size, drug content, PDI, surface charge potential and in-vitro drug release. The pharmacokinetics and pharmacodynamics of the Dexamethasone formulations were evaluated in male Wistar rats following *iv* administration, using Dexamethasone solution as reference. The pharmacokinetic parameters in rats were calculated and compared by statistical analysis. Serum glutamic pyruvic transaminase (SGPT) and Serum glutamic oxaloacetic transaminase (SGOT) were elevated. Results: The DXM nanoparticles were successfully prepared using double emulsion solvent evaporation technique. The nanoparticle formulations effectively sustained the release of the drug for more than 10 days both in vitro and in vivo. They also offered better pharmacokinetic properties to the drug than that afforded by the free drug itself. Intravenous nanoparticular administration reversed serum liver enzyme levels by 92%, compared to 60% for repeated *iv* administration of the solution form. Conclusion: DXM Nanoparticles showed better pharmacokinetic properties and had better prevention of liver toxicity when compared with solution.

Top

Keywords

Dexamethasone, Nanoparticles, Pharmacokinetics, Pharmacodynamics, Hepatoprotection.

Top

Research Article

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Analytical method development and validation for the estimation of DACLATASVIR in bulk and pharmaceutical dosage form using RP-HPLC

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ABSTRACT

A simple, precise, accurate and linear reverse phase isocratic HPLC was developed and validated for the determination of Daclatasvir in bulk and tablet dosage forms. Method development was carried out on Zorbax Eclipse XDB-C18 isocratic column, (250mm × 4.6mm, particle size 5µ, maintained at ambient temperature). The mobile phase was a mixture of 0.01M Potassium dihydrogen orthophosphate and Acetonitrile (15:85), with apparent pH of 2.5 and the flow rate was set at 1.0ml/min and UV detection at 284nm. The statistical analysis shows that the method was found to be accurate, reliable, simple and reproducible. The proposed method was successfully applied for the quantitative determination of Daclatasvir in bulk form and could be used for routine analysis with phenomenal accuracy and precisions.

Keywords: Daclatasvir, RP-HPLC, Reliable, Validation, Assay, Hepatitis, Isocratic.

INTRODUCTION

Chromatographic separations are based on a forced transport of the liquid (mobile phase) carrying the analyte mixture through the porous media and the differences in the interactions of analytes with the surface of this porous media resulting in different migration times for a mixture of components. In the above definition, the presence of two different phases is stated and consequently there is an interface between them. One of these phases provides the analyte

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Preparation and standardization of ayurvedic polyhedral formulation; patoladi kvatha churna for skin diseases

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ABSTRACT

An Ayurvedic formulation of Patoladi kvatha Churna was selected for the present work. Developing a generation to prefer Ayurvedic medicines than the allopathic drugs. Patoladi kvatha churna has traditionally used to treat skin diseases which have not been proved scientifically. So, the patoladi kvatha churna has chosen to prove their activity with scientific evidence.

Keywords: Patoladi kvatha, Churna, Ayurvedic, skin diseases.

INTRODUCTION

Herbal Medicine[10-11,]

Herbal and products containing herb(s) have been in trade and commerce and are currently used for variety of purpose. The WHO defined an herb as being fresh (or) dried, fragmented (or) powdered plant material; it can be used in this order state (or) further processed and formulated to become the final herbal product. Treatment of herbs by squeezing, steaming, roasting, detecting (or) infusing in water. Extracting with alcohol (or) sweetening and baking with honey can create herbal products such as juices, tinctures, decoctions, infusions, gums, fixed oil, essential oil and resins. These may be used medically (or) as the starting material for additional processing and as food ingredients.

Herbal formulation[5]

The herbal formulation consists of a selective combination of individual herbal ingredients that are formulated for a specific ailment or group of diseases conditions. When herbs combine together, they become more potent and effective within the body than individual herb due to their activating or catalyzing influence over one another. Herbal medicines are prepared from plant materials which are prone to contamination, deterioration and variation in composition. Therefore, quality control of herbal medicine offers a host of problems. To solve this problem, first and foremost task is the selection of the right kind of plant material which is therapeutically efficacious.

Advantages of Herbal Medicines

They have large amount of use they have better patient tolerance as well as acceptance the medicinal plants have renewable source of cheaper medicines. Improvements in the quality, efficacy and safety of herbal medicines with the development of science and technology.

Prolong and apparently uneventful use of herbal medicines may offer testimony of their safety and efficacy. They are cheap in cost. They are not harmful. They are more effective than any synthetic drug. Throughout the world herbal medicines have provided many of the most potent medicines to the vast arsenal of drugs available to modern medical science, both in crude form. In India, drugs of herbal origin have been used in traditional systems of medicines such as Unani, Ayurveda and Siddh

STANDARDISATION OF POLYHERBAL GEL FOR REJUVENATION OF HAIR GROWTH

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Abstract

The present study was designed to formulate and evaluate polyherbal gel containing extracts of Lagenaria siceraria, Trichosanthis cucumarina ,Tridax procumbens . Preliminary phytochemical screening were carried out for all the plants and its extracts to determine the presence of active principle in plants.Poly herbal gel was prepared with water soluble polymer Carbopol, propylene glycol400, povidone, triethanolamine to bring a good absorption capacity of the plant extracts on scalp. The standardization parameters of the gel are viscosity, pH, Homogeneity, Spreadability, content uniformity, skin irritation test all were carried out to bring a quality, purity and safety of the prepared gel formulation with the reference who applied gel without the extract. The growth of hair measured by trichoscope and the growth was completely observed after the 90 days Hence, from these studies it is concluded that the prepared poly herbal gel containing Lagenaria siceraria, Trichosanthis cucumarina, Tridax procumbens proved hair growth activity

Keywords: *Carbopol 934, Hair growth initiation, Hair growth completion, Histopathology, Hair follicles*

Introduction

Recently, the number of men and women who suffered from hair loss and/or hair thinning is increasing in worldwide. Hair loss is a dermatological disorder, and the surge for discovering natural products with hair growth promoting potential is continuous [1,2]. Hair loss or alopecia is a common patient complaint and a source of significant psychological and physical distress [3]. Many factors such as metabolism, hormones, heredity and side effects of antineoplastic and immunosuppressant drugs, have been negatively affecting the healthy growth of hair. According to one survey, androgenic alopecia on its own eventually affects approximately 50% of the world's adult population [4,5]. In androgenic alopecia it is assumed that the genetically predisposed hair follicles are the target for androgen - stimulated hair follicle miniaturization, leading to gradual replacement of large, pigmented hairs (terminal hairs) by barely visible, depigmented hairs (vellus hairs) in affected areas [4]. It is dyhydrotestosterone medicated process, characterized by continuous miniaturization of androgen reactive hair follicles and accompanied by per follicular fibrosis of follicular units in histological examination [6-9].

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A New Validated RP-HPLC Method for Determination of Antiemetic Drug (Granisetron) In Bulk and Pharmaceutical Dosage Form

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ABSRACT

RP-HPLC technique has been created and approved for the examination of Granisetron API. Promote the proposed RP-HPLC technique has magnificent affectability, exactness and reproducibility to develop a precise, linear, specific & suitable stability indicating RP-HPLC method for analysis of Granisetron, different chromatographic conditions were applied Isocratic elution is simple, requires only one pump & flat baseline separation for easy and reproducible results.. RP-HPLC various columns are Symmetry ODS (C_{18}) RP Column, 250 mm x 4.6 mm, 5µm column was preferred because using this column peak shape, resolution and absorbance were good. Mobile Phase &diluents for preparation of various samples were finalized after studying the solubility of API in different solvents of our disposal (methanol, Acetonitrile, dichloromethane, water, 0.1N NaOH, 0.1NHCl). The drug was found to be Soluble in DMSO (100 mM), Acetonitrile and methanol. Sparingly Soluble in ethanol and Water. Using these solvents with appropriate composition newer methods can be developed and validated. Recognition wavelength was chosen in the wake of checking the standard arrangement of medication more than 200 to 400nm. From the U.V range of Granisetron it is apparent that a large portion of the HPLC works can be refined in the wavelength scope of 206 nm helpfully. Further, a stream rate of 1 ml/min and an infusion volume of 10µl were observed to be the best examination. The outcome demonstrates the created strategy is amazingly, one more appropriate technique for test and steadiness related contamination thinks about which can help in the examination of Granisetron in various definitions.

Keywords: RP-HPLC, Granisetron, Determination, Validation parameters

INTRODUCTION [1, 2]

Analytical instrumentation plays an important role in the products and evaluation of new products and in the protection of consumers and the environment. This instrumentation provides the lower detection limits require to assure safe food, drugs, water and air. An instrumental method of Chemical analysis has now become the backbone of experimental chemistry.

Points to be considered in the selection of a procedure include:

- Stability of the absorbance with respect to time, minor variations in pH, ionic strength and temperature.
- Degree of selectivity of a complexing agent including the effect of other species likely to be present and the effect of an excess reagent.
- Conformity of the Beer–Lamberts law and plot calibration data for the range of concentration measured.

The pharmaceutical analyst frequently encounters the situation where the concentration of one or more substance is required in samples known of containing other absorbing substances which potentially interferes in the assay, if the recipe of the sample formulation is available to the analyst, the identity and

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Research article Open Access

DEVELOPMENT AND VALIDATION OF A HPLC METHOD FOR THE DETERMINATION OF ANTIDIABETICS (CANAGLIFLOZIN AND METFORMIN) IN API AND PHARMACEUTICAL DOSAGE

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ABSTRACT

A sensitive & selective stability indicting RP-HPLC method has been developed & validated for the analysis of Canagliflozin & Metformin API. Based on peak purity results, obtained from the analysis of samples using described method, it can be concluded that the absence of co-eluting peak along with the main peak of Canagliflozin & Metformin indicated that the developed method is specific for the estimation of Canagliflozin & Metformin. Further the proposed RP-HPLC method has excellent sensitivity, precision and reproducibility.

Keywords: RP-HPLC, Canagliflozin, Metformin, method development, validation parameters

INTRODUCTION[1,2,3]

The development of any new or improved method usually tailors existing approaches and instrumentation to the current analyte, as well as to the final needs or requirements of the method. Method development usually requires selecting the method requirements and deciding on what type of instrumentation to utilize and why.

There are several valid reasons for developing new methods of analysis:

- There may not be a suitable method for a particular analyte in the specific sample matrix.
- Existing methods may be too error, artifact, and/or contamination-prone, or they may be unreliable (have poor accuracy or precision).

Reversed phase mode is the most popular mode for analytical and preparative separations of compound of interest in chemical, biological, pharmaceutical, food and biomedical sciences. In this mode, the stationary phase is non polar hydrophobic packing with octyl or octa decyl functional group bonded to silica gel and the mobile phase is polar solvent. An aqueous mobile phase allows the use of secondary solute chemical equilibrium (such as ionization control, ion suppression, ion pairing and complexation) to control retention and selectivity. The polar compound gets eluted first in this mode and non polar compounds are retained for longer time. As most of the drugs and pharmaceuticals are polar in nature, they are not retained for longer times and hence elute faster. The different columns used are octa decyl silane (ODS) or C_{18}, C_8, C_4, etc., (in the order of increasing polarity of the stationary phase).

There may be a need for an alternative method to confirm, for legal or scientific reasons, analytical data originally obtained by existing methods.