3.3: Research Publications and Awards

3.3.1: Number of research papers published per teacher in the Journals notified on UGC care list during the last five years

Technical Article | Published: 13 October 2022

On Mechanical, Physical, and Bioactivity Characteristics of Material Extrusion Printed Polyether Ether Ketone

Ranvijay Kumar, Gurminder Singh, Amutha Chinappan, Erfan Rezvani Ghomi, Sunpreet Singh, Kamalpreet Sandhu, Seeram Ramakrishna, Roger Narayan & Prakash Katakam

Journal of Materials Engineering and Performance (2022)

Abstract

High-performance polyether ether ketone (PEEK) thermoplastic is considered to be one of the most desirable materials for its intended biomedical implications, including oral implantology, prosthodontics, dental implants, and orthopaedics. Therefore, the processing of PEEK through material extrusion (ME) as a 3D printing process has been preferred due to its affordability, better process parameters, and mass customization. In the present study, attempts have been made to study the effects of various input process parameters of an in-house modified ME system on tensile strength, surface finish, and bioactivity. Underlining the scientific importance of input process parameters of ME, including nozzle temperature (Nt), printing speed (Ps), layer thickness (Lt), and build-platform temperature (Bt), their effects on the aforementioned characteristics of 3D printed PEEK specimens have been studied through employing Taguchi's statistical analysis. The in-vitro cell viability test has been performed using Sprague–Dawley rat bone marrow-derived cells for 21 days. In addition to this, Scanning electron microscopic analysis has also been performed at various stages of this experimental study for supporting micro-characterization. This study indicated that the selected input process parameters strongly influence the tensile strength and surface finish of the as-printed

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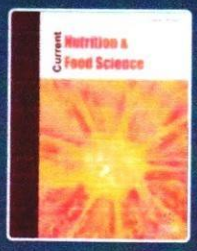

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Review Article

Phytosomes: A Novel Phytoconstituent Delivery Approach to Improve the Efficacy of Obesity Treatment

Author(s): Shanta Kumari Adiki, Shanmugasundaram Sangeetha, Srikala Kamireddy, Prakash Katakam and Iswarya Obilineni

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Abstract

Research article | Published: 04 February 2022

Amelioration of diabetes and its complications by *Manilkara zapota* (L) P. Royen fruit peel extract and its fractions in alloxan and STZ-NA induced diabetes in Wistar rats

Pravin P. Karle, Shashikant C. Dhawale & Vijay V. Navghare

Journal of Diabetes & Metabolic Disorders **21**, 493–510 (2022)

Abstract

Purpose

This study aims to evaluate the effects of *Manilkara zapota* (L) P. Royen fruit peel extract (EMZFP) and its fractions in ameliorating diabetes and its complications in alloxan and STZ-NA induced diabetes in Wistar rats.

Methods

Antidiabetic effects of EMZFP were assessed in alloxan (150 mg kg^{-1}) induced diabetes in differently grouped rats (n=6). Diabetic rats were treated with EMZFP 150, 300, and 600 mg kg^{-1} while, glimepiride (0.09 mg kg^{-1}) was used as a reference standard. Treated animals were assessed for various biological parameters i.e. blood glucose, serum lipids, nephroprotective markers, cardiovascular risk indices, liver glycogen, neuropathy, body weight, and histopathology of kidneys. However, for evaluating antidiabetic effects of fractions (chloroform, acetone, ethyl acetate, and remaining ethanol fraction) of EMZFP, diabetes was induced by streptozotocin (60 mg kg^{-1})–nicotinamide (120 mg kg^{-1}/ml) in differently grouped male rats (n=6). Diabetic rats were treated with EMZFP fractions 200 mg kg^{-1} however; glibenclamide (10 mg kg^{-1}) was a reference standard and evaluated for blood glucose, serum lipids, cardiovascular risk indices, and diabetic neuropathy.

Results

Karle *et al.*
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Bulletin of the National Research Centre

RESEARCH Open Access

Screening of *Manilkara zapota* (L) P. Royen stem bark ethanolic extract for in vitro α-glucosidase inhibition, preliminary antidiabetic effects, and improvement of diabetes and its complications in alloxan-induced diabetes in Wistar rats

Pravin P. Karle[1*], Shashikant C. Dhawale[1], Rajesh J. Mandade[2] and Vijay V. Navghare[1]

Abstract

Background: A perusal of the literature suggested that *Manilkara zapota* (L.) P. Royen stem bark (MZSB) is enriched with several bioactive phytoconstituents but had not been yet screened for its in vitro and in vivo antidiabetic potentials. Thus, the present study aimed to investigate the effects of 70% ethanolic extract of *Manilkara zapota* (L) P. Royen stem bark (EMZSB) in DPPH- and H_2O_2-scavenging assay, in vitro α-glucosidase inhibition assay, ameliorating diabetes and its complications in alloxan-induced diabetes in Wistar rats.

Results: With a maximum extractive yield of 9.16% w/w, EMZSB has shown the presence of various phytochemicals like flavonoids, phenolic compounds, tannins, anthraquinone glycosides, steroids, terpenoids, and alkaloids. EMZSB has elucidated a considerable in vitro free radical scavenging potential by DPPH and H_2O_2 assays when compared with absolute ethanolic extract of *Manilkara zapota* (L) P. Royen stem bark (AEMZSB), while ascorbic acid was taken as the standard. Further, EMZSB demonstrated high in vitro α-glucosidase enzyme inhibition potential ($IC_{50} = 119.79 \pm 1.52$ µg/mL) than AEMZSB ($IC_{50} = 129.92 \pm 2.29$ µg/mL) with a significant difference ($p < 0.01$), when acarbose was taken as reference inhibitor ($IC_{50} = 86.43 \pm 1.26$ µg/mL). During acute toxicity studies EMZSB was safe up to 2000 mg kg^{-1} doses while, found causing moribund status followed by mortality in mice at 3000 mg kg^{-1} and above doses. A preliminary antidiabetic study with EMZSB-250 mg kg^{-1} in normal rats showed no sign of hypoglycemia; however, a dose-dependent antihyperglycemic effects were observed in oral glucose tolerance test in glucose-loaded rats. In vivo assessment with EMZSB-250 mg kg^{-1} in alloxan-induced rats demonstrated significant blood glucose-lowering effects with perfection in serum lipid profile, body weight enhancement, cardiovascular risk indices, nephroprotective effects, augmentation in liver glycogen content, and histopathological evidence of normal architecture of kidneys with no marks for nephritis.

Conclusions: EMZSB-250 showed significant antidiabetic effects and ameliorated diabetic complications by improving glycemic control and accompanying biochemical alteration.

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Review Article

Precision medicine: Recent progress in cancer therapy

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Abstract

This review was aimed to describe a new approach of healthcare performance strategy based on individual genetic variants. Personalized medicine is a model for health care which is a combination of preventive, personalized, participatory and predictive measures. It is an approach for a better treatment by identifying the disease causing genomics makeup of an individual. This work features key advancements in the improvement of empowering advances that further the objective of customized and precision medication and the remaining difficulties that, when tended to, may produce phenomenal abilities in acknowledging genuinely individualized patient consideration. Customized treatment for patients determined to have strong tumors has brought about a few advances as of late. To improve a multi-drug approach ready to coordinate DNA and RNA adjustment, proteomics and metabolomics will be essential. The execution of translational examinations dependent on fluid biopsy and organoids or xenografts to assess molecular changes because of clonal weight produced because of the utilization of target specialists or tumor heterogeneity would help in the recognition of systems of opposition, proposing opportunities for novel mixes. The investigation of massive data in oncology can profit altogether from being engaged by artificial intelligence and machine learning strategies.

Keywords: *Accuracy medication, artificial intelligence, cancer therapy, machine learning, personalized medicine, precision medicine, translational oncology*

Introduction

Personalized medicine is a special strategy which refers to a tailoring of clinical treatment for the individual characteristics of patients. These drugs are made based upon the genetic setup of the human genome. It becomes the fundamental difficulty for the diagnosis, prevention and therapy of any disorder and personalized medicine is based totally on the pharmacogenomics and genomics. Personalized medicine is a model for health care which is a combination of preventive, personalized, participatory and predictive measures. It is an approach for better treatment by identifying the disease causing genomic makeup of an individual. Personalized medicine is a broad field and it can be used for the diagnosis of various diseases like cancer, Alzheimer, hepatitis, cardiac diseases etc. Precision medicine according to the National Institutes of Health (NIH), precision medicine is "an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment and lifestyle for each person" [1]. On January 30, 2015, US president, Obama, declared subsidizing for an Initiative in Precision Medicine [2]. After three years, National Academy of Sciences Board of Trustees report clarified exactly how an activity could quicken progress in clinical consideration and exploration [3]. This methodology will allow doctors and investigators to anticipate more definitively which treatment and anticipation techniques for an extraordinary disease will work at gatherings of individuals. It is in conflict with a one-size-fits-all approach in which infection treatment

Review Article

Precision medicine: Recent progress in cancer therapy

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Article

Development and Characterization of Calcium-Alginate Beads of Apigenin: In Vitro Antitumor, Antibacterial, and Antioxidant Activities

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Abstract: The objective of this work was to develop sustained-release Ca-alginate beads of apigenin using sodium alginate, a natural polysaccharide. Six batches were prepared by applying the ionotropic gelation technique, wherein calcium chloride was used as a crosslinking agent. The beads were evaluated for particle size, drug loading, percentage yield, and in vitro drug release. Particle size was found to decrease, and drug entrapment efficiency was enhanced with an increase in the polymer concentration. The dissolution study showed sustained drug release from the apigenin-loaded alginate beads with an increase in the polymer proportion. Based on the dissolution profiles, BD6 formulation was optimized and characterized for FTIR, DSC, XRD, and SEM, results of which indicated successful development of apigenin-loaded Ca alginate beads. MTT assay demonstrated a potential anticancer effect against the breast cancer MCF-7 cell lines. The antimicrobial activity exhibited effective inhibition in the bacterial and fungal growth rate. The DPPH measurement revealed that the formulation had substantial antioxidant activity, with EC50 value slightly lowered compared to pure apigenin. A stability study demonstrated that the BD6 was stable with similar ($f2$) drug release profiles in harsh condition. In conclusion, alginate-based beads could be used for sustaining the drug release of poorly water-soluble apigenin while also improving in vitro antitumor, antimicrobial, and antioxidant activity.

Keywords: apigenin; antimicrobial; beads; Ca-alginate; DSC; DPPH; FTIR; in vitro dissolution; MTT; SEM; XRD

Citation: Aldawsari, M.F.; Ahmed, M.M.; Fatima, F.; Anwer, M.K.; Katakam, P.; Khan, A. Development and Characterization of Calcium-Alginate Beads of Apigenin: In Vitro Antitumor, Antibacterial, and Antioxidant Activities. *Mar. Drugs* **2021**, *19*, 467. https://doi.org/10.3390/md19080467

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1. Introduction

Marine-based polysaccharides originate from ocean life plants, sea animals, or marine bacteria. Marine polycarbohydrates—agar, alginic acid, chitin, chitosan, cellulose, glucan, including long-chain polymeric carbohydrates and low-molecular-weight carbohydrates—are isolated from fungi, algae, and organisms [1]. Marine-derived polymers have anticancer, antioxidant, antimicrobial, anticoagulant, and anti-inflammatory bioactivities [2,3]. A natural hydrophilic polysaccharide-alginic acid, also called algin, with metals such as sodium, calcium, and its salts, are known as alginates. Sodium alginate (sodium 3,4,5,6-tetrahydroxyoxane-2-carboxylate) is extracted from the cell wall of brown seaweed and it appears as yellowish fibrous or granular powder jelly bodies [4]. The biosynthesis of alginate is materialized by D-fructose-6-phosphate precursor, followed by epimerization of d-mannuronic residues, catalyzed by mannuronan C-5-epimerases. Sodium alginate (SAG) is viscous, has non-Newtonian consistency in water, is insoluble with ether and ethanol,

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FORMULATION AND EVALUATION OF CONTROLLED RELEASED AT ORVASTATIN INSITUGELS FOR THE TREATMENT OF PERIODONTAL DISEASES

PrakashKatakam[1],Ala NB VinayKumar[1]*,ShantaKumariAdiki[2]

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ABSTRACT

Thetreatmentforperiodontaldiseasesincludessystemictreatmentwithantibiotics.Localadministrationusing intra-pocketdrugdeliverywithsolgeltechniquesisrecentlyevaluated.Bonetissueregenerationisanimportantfactortobeconsidered fortreatmentassociatedwithchronicperiodontitis.Thisresearchworkrevealstheformulationandinvitroevaluationofperiodontalpocketeddrugdeliveryofatorvastatin,abonetissueregenerator,usingsol-geltechnique.Atotalof sixformulationswerepreparedwithpolylacticcoglycolicacid(PLGA)andsolventconcentrationskeepingthedrugconcentration50mgthroughoutthestudy.Thedrugexcipientcompatibilitieswereperformedusing IRspectroscopy.Formulationstudiesweredonebyconsideringspreadabilitystudies,viscosities,solgeltransitiontemperaturesandinvitrodrugrelease.Noabnormalorshiftinpeakswereidentifiedandsupportstheselectionofpolymerforfurtherformulationstudies.Itwasidentifiedthatthereleaseratewasdirectlyproportionaltodrugconcentrationindicatingthefirstorderreleasekineticsof atorvastatin.Also,basedontheHiguchiandKorsmeyerpeppasmodels,itcouldbeinterpretedthatthepreparedformulationsfollowNonFickiandiffusiontransportmechanisms.Itwasidentifiedthatalltheformulationsshowedgoodphysicalappearance byformingclearsolutionswhenprepared. The pHofalltheformulationswereinbetween5.9to6.1indicating that they were slightlyacidictoneutraland could beadministeredtothecoralcavity. Basedongellingproperties, spreadability and syringeability andviscosityprofiles, the formulationF4showed betterprofilecomparedtotherestoftheformulations.In vitrodrugreleasestudiesrevealedthattheformulationsfollowedfirstorderkineticswithnonFickiandiffusionmechanism.Sustainedandprolongedrelease was achievedforalltheformulations.FormulationsF5 and F6 had prolonged drug releaseofupto50days.However,consideringallthephysicochemicalparametersandinvitroreleaseprofilesintoaccounttheoptimizedformulations was considered to be F4.Thisformulationisfurtherproposedto be considered forin vivostudies.

Keywords: Atorvastatin, Periodontal diseases,Bonetissueregeneration,In situgels,PLGA,Controlledrelease

INTRODUCTION

Periodontaldiseaseisagroupofillnesseslocatedinthegumsanddentalsupportstructures(ligamentandalveolarbone)andare producedbycertainbacteriaencounteredinsubgingivalplaque.Themainsymptomscomprisegingivalinflammation,formationofperiodontalpocket,alveolarboneloss,abscess,ortoothmobility[1].Theconventionaltreatmentcomprisingscalingandrootplaning(SRP)presentslimitationsincertaincasesinvolvingdeepperiodontalpockets,inaccessibleareas,orsevereperiodontitis.Therefore,severaladjunctpharmacologicaltherapieshavebeentestedtoimproveitsoutcomes.Systemicandlocaldeliveriesofdrugssuchasantibiotics,bisphosphonates,anti-inflammatorydrugs,anticytokines,probiotics,andprebioticshavebeentestedsofartoreducebacterialloadandtocontrolinflammation[2].Mitigationinbonetissuelossandfurtherbone-regenerationhelpsinmanagementofchronicperiodontitis.Likewise,theuseofstatinsinperiodontaltreatmenthasbeenexplored recently.Statins,orinhibitorsof3-hydroxy-3-methylglutarylcoenzyme-Areductase(HMG-CoAreductase),areagroupofdrugs,usedprimarilytotreathyperlipidemiaandtopreventcardiovasculardiseases.Theydiffermainlyintheirringstructure,andthesestructuraldifferencesmodifytheirpharmacologicalpropertiesincludinghydrophilicityandlipophilicity.Thelactoneringispresentinanactiveform(alreadyhydrolyzed)inallstatinsexceptforsimvastatin,lovastatin,andmevastatin,inwhichthelactoneringisactivatedintheliver.Thelactoneformofthestatinsenablestheirtransport,metabolism,andclearance.

Apartfromtheirlipid-loweringproperties,statinspossesspleiotropiceffectsduetotheirantiinflammatory,antioxidative,antibacterial,andimmunomodulatoryproperties.Statinshavealsobeenreportedtohaveanaboliceffectsonthebonebyaugmentingbonemorphogenetic protein-2(BMP-

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Thetreatmentforperiodontaldiseasesincludessystemictreatmentwithantibiotics.Localadministrationusing intra-pocketdrugdeliverywithsolgeltechniquesisrecentlyevaluated.Bonetissueregenerationisanimportantfactortobeconsidered fortreatmentassociatedwithchronicperiodontitis.Thisresearchworkrevealstheformulationandinvitroevaluationofperiodontalpocketeddrugdeliveryofatorvastatin,abonetissueregenerator,usingsol-geltechnique.Atotalof sixformulationswerepreparedwithpolylacticcoglycolicacid(PLGA)andsolventconcentrationskeepingthedrugconcentration50mgthroughoutthestudy.Thedrugexcipientcompatibilitieswereperformedusing IRspectroscopy.Formulationstudiesweredonebyconsideringspreadabilitystudies,viscosities,solgeltransitiontemperaturesandinvitrodrugrelease.Noabnormalorshiftinpeakswereidentifiedandsupportstheselectionofpolymerforfurtherformulationstudies.Itwasidentifiedthatthereleaseratewasdirectlyproportionaltodrugconcentrationindicatingthefirstorderreleasekineticsof atorvastatin.Also,basedontheHiguchiandKorsmeyerpeppasmodels,itcouldbeinterpretedthatthepreparedformulationsfollowNonFickiandiffusiontransportmechanisms.Itwasidentifiedthatalltheformulationsshowedgoodphysicalappearance byformingclearsolutionswhenprepared. The pHofalltheformulationswereinbetween5.9to6.1indicating that they were slightlyacidictoneutraland could beadministeredtotheoralcavity. Basedongellingproperties, spreadability and syringeability andviscosityprofiles, the formulationF4showed betterprofilecomparedtotherestoftheformulations.In vitrodrugreleasestudiesrevealedthattheformulationsfollowedfirstorderkineticswithnonFickiandiffusionmechanism.Sustainedandprolongedrelease was achievedforalltheformulations.FormulationsF5 and F6 had prolonged drug releaseofupto50days.However,consideringallthephysicochemicalparametersandinvitroreleaseprofilesintoaccounttheoptimizedformulations was considered to be F4.Thisformulationisfurtherproposedto be considered forin vivostudies.

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INTRODUCTION

Periodontaldiseaseisagroupofillnesseslocatedinthegumsanddentalsupportstructures(ligamentandalveolarbone)andare producedbycertainbacteriaencounteredinsubgingivalplaque.Themainsymptomscomprisegingivalinflammation,formation ofperiodontalpocket,alveolarboneloss,abscess,ortoothmobility[1].Theconventionaltreatmentcomprisingscalingandrootplaning(SRP)presentslimitationsincertaincasesinvolvingdeepperiodontalpockets,inaccessibleareas,orseverepriodontitis.Therefore,severaladjunctpharmacologicaltherapieshavebeentestedtoimproveitsoutcomes.Systemicandlocaldeliveriesofdrugssuchasantibiotics,bisphosphonates,anti-inflammatorydrugs,anticytokines,probiotics,andprebioticshavebeentestedsofartoreducebacterialloadandtocontrolinflammation[2].Mitigationinbonetissuelossandfurtherbone-regenerationhelpsinmanagementofchronicperiodontitis.Likewise,theuseofstatinsinperiodontaltreatmenthasbeenexplored recently.Statins,orinhibitorsof3-hydroxy-3-methylglutarylcoenzyme-Areductase(HMG-CoAreductase),areagroupofdrugs,usedprimarilytotreathyperlipidemiaandtopreventcardiovasculardiseases.Theydiffer mainlyintheirringstructure,andthesestructuraldifferencesmodifytheirpharmacologicalpropertiesincludinghydrophilicityandlipophilicity.Thelactoneringispresentinanactiveform(alreadyhydrolyzed)inallstatinsexceptforsimvastatin,lovastatin,andmevastatin,inwhichthelactoneringisactivatedintheliver.Thelactoneformofthestatinsenablestheirtransport,metabolism,andclearance.

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Future Journal of Pharmaceutical Sciences

RESEARCH Open Access

Experimental design optimization of RP-HPLC method for simultaneous estimation of metsulfuron-methyl, chlorantraniliprole and chlorimuron-ethyl residues in stems of *Oryza sativa*

Shanta Kumari Adiki[1*], Prakash Katakam[2] and Fathi H. Assaleh[3]

Abstract

Background: The study aims to develop a chemometrics optimized D-optimal mixture design approach assisted RP-HPLC method for the determination of pesticide residues of metsulfuron-methyl, chlorantraniliprole, and chlorimuron-ethyl in the stems of *Oryza sativa*. Chromatographic separation was achieved on a C18 column using a mobile phase consisting of a pH 3.5 phosphate buffer and acetonitrile in the ratio 85:15.

Results: The optimized HPLC method gave a sharp resolution of metsulfuron-methyl, chlorantraniliprole and chlorimuron-ethyl at a retention time of 2.599 min, 3.805 min and 4.661 min receptively. Linearity was observed in the range 100–500 µg/mL for metsulfuron-methyl ($r^2 = 0.999$), 4–20 µg/mL for chlorantraniliprole ($r^2 = 0.999$) and 100–500 µg/mL for chlorimuron-ethyl ($r^2 = 0.999$). The developed method was validated as per ICH guidelines.

Conclusion: The proposed chemometrics optimized RP-HPLC method was found to be successful in the resolution of pesticide residues in the stems of *O. sativa*. The developed method can be applied to routine quantification of metsulfuron-methyl, chlorantraniliprole and chlorimuron-ethyl.

Keywords: Pesticides, *Oryza sativa*, Metsulfuron-methyl, Chlorantraniliprole, Chlorimuron-ethyl, Chemometrics, Validated

Background

Pesticides and herbicides are used to destroy the insects or other organisms harmful to cultivated plants in modern agricultural practices to enhance the yield and upgrade the quality of the agricultural crops. Nearly 30% of the food production is lost in third world countries due to insects, pests, plant pathogens, weeds, rodents, birds during storage. However, the unregulated and indiscriminate application of pesticides has raised serious concerns regarding environmental pollution and human health issues [1–6]. The pesticides ought to be checked for viability, natural, and toxicological tests to get enrolled by the government for legitimate use in determining applications. Sustained accumulation of pesticides in agrarian items is a matter of grave concern for its far-reaching adverse health consequences [2–4]. *Oryza sativa* is the most widely consumed cereal grain as a staple food for a large part of the world's human population, especially in Asia.

Metsulfuron-methyl (CAS 74223-64-6, molecular formula $C_{14}H_{15}N_5O_6S$, and MW 381.37) is methyl

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Design and Evaluation of Press Coated Formulation of Aceclofenac and Comparison with Marketed Preparations.

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Abstract

The primary objective of the studies is to investigate whether compression coating could be used to produce tablets providing maximum drug plasma concentration 6 to 8 hours after an evening dose taken at approximately 22:00. Fast Dispersible core tablets containing Aceclofenac were prepared using superdisintegrants like Ac-Di-Sol, Crospovidone and Sodium starch glycolate through wet granulation method and evaluated for various parameters. Prepared press coated tablets were characterized for physical parameters, drug content, lag time, in vitro drug release characteristics. Aceclofenac formulation tablets of batch F4 containing combination Methocel K4M and Methocel K100M showed desired lag time along with drug release as compare to other formulations. The Comparative dissolution study of optimized formulation containing Aceclofenac was carried with marketed preparations also showed good results.

Keywords: Press coated Tablets, lag time, Aceclofenac.

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DESIGN AND OPTIMIZATION OF DILTIAZEM MATRIX TABLETS AS SUSTAINED RELEASE

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ABSTRACT

In present day pharmaceutical innovation the continued and controlled medication exchange frameworks are the more celebrated frameworks. Presentation of framework measurements structure as supported release(SR) has given another leap forward for novel dynamic substance move framework in the field of Pharmaceutical innovation. Diltiazem was generally indicated for the management of chronic stable angina. The sustained release (SR) form of the drug has been found to result in better compliance. The medication and the excipient compatability examines are finished by utilizing the FTIR studies. Dry granulation method with the help of excipients was attempted for the formulation development of matrix tablets of Diltiazam. The tablets were characterized for various parameters like bulk density, tapped density, Angle of repose, Hauner's ratio, carr's index. All results are within the limits and tablets were evaluated for thickness, weight variation, friability, Disintegration and dissolution studies. The formulation F7 shows the sustained-release matrix tablets of diltiazem.

KEYWORDS: Diltiazem, Matrix tablets, HPMC, EC, Dry granulation, *Invitro* studies.

1. INTRODUCTION

Present days novel medication conveyance frameworks are critical for transportation of the medicine to the human body. Presently the customary frameworks are recuperated by the novel medication conveyance frameworks.[1-2] In present day pharmaceutical innovation the continued and controlled medication exchange frameworks are the more celebrated frameworks. Presentation of framework measurements structure as supported release (SR)

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Research Article

Formulation and *In Vitro*evaluation of Simvastatin Insituperiodontal Gels

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Abstract

Objective of the study: The aim of the present study is to prepare and evaluate biodegradable *in situ* gels of simvastatin for treatment of periodontal diseases. In the present research work is focused to formulate periodontal injectable *in situ* gels containing bone regenerating agent simvastatin, using biodegradable polymer.

Methodology: Appropriate amounts of polymer and solvent were weighed into 5 ml glass vials with proper airtight polypropylene caps. After initial mixing of the contents, vials were placed aside with occasional shaking overnight at room temperature to completely dissolve the polymer. Weigh accurately finely powdered drugs and add to above solution, close the lid and shake well and keep aside with occasional shaking and store in refrigerator at 8°C. The resulting solutions can be directly injected into subgingival pockets. The studies are further done to evaluate the prepared *in situ* gels for various pre-formulation studies, physicochemical characterization, drug content, *in vitro* drug release studies and stability studies.

Conclusion: Periodontal diseases are the conditions that affect the supporting structure of teeth leading to the formation of pocket due to which tooth loss occurs, for which site specific injectable drug delivery systems are gaining importance.

Based on physicochemical characteristics, the *in situ* gel formulation of simvastatin (F3) was optimized. It was concluded that *in situ* gel delivery system is a novel approach that can be developed for the treatment of Periodontitis. The present research showed that the optimized *in situ* gel formulations are more promising for successful delivery of simvastatin and to treat bone regeneration.

Keywords: Simvastatin; Periodontitis; *In situ* gel

Introduction

Periodontitis can be classified based on disease activity (chronic or aggressive), etiology (specific bacterial, fungal or viral infection), by response to treatment (responsive or refractory), by site (localized or generalized). Chronic Periodontitis, formerly known as "adult periodontitis" or "chronic adult periodontitis" is the most prevalent form of periodontitis. It is generally considered to be a slowly progressing disease. However, in the presence of systemic or environmental factors that may modify the host response to disease progression may become more aggressive as shown in **Figure 1** [1].

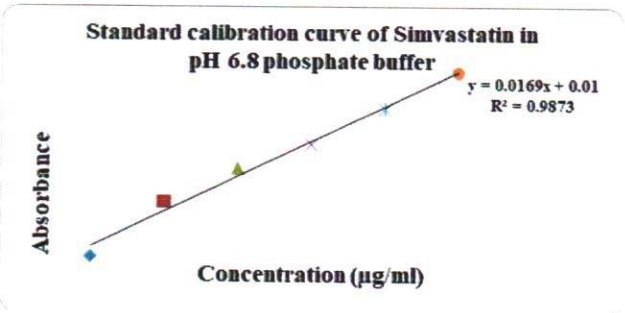

Figure 1: Standard calibration graph of SVS.

Methods

Gels

A gel is a solid or semisolid system of at least two constitutes, consisting of condense mass enclosing and interpenetrated by a liquid. When the coherent liquid is matrix and is rich in liquid, the product is often called a jelly and when the liquid is removed leaving only the framework, the gel is known as xero gels. In a typical polar gel, a natural or synthetic polymer builds a three dimensional matrix throughout a hydrophilic liquid [2].

***In situ* gel:** The *in situ* gelling systems consist of polymer that exhibit sol-to-gel phase transitions due to change in specific physicochemical parameters in the environment [3].

Advantages of *in situ* system

1. These systems reduce toxic effects on the healthy tissue and reach sites that are conventionally inaccessible due to the presence of various barriers.

2. Increase the half life of [illegible] preventing their rapid

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An Update on Therapeutic Repurposing Strategies for COVID-19

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Keywords
COVID-19; SARS-CoV-2; Repurposing; Therapeutic Strategies; Treatment.

ABSTRACT: The severe acute respiratory syndrome coronavirus 2, well known as COVID-19 has become the current health distress to the entire world. In the pandemic scenario the research on the rapid development of new drug molecules is highly risky and tedious process. The current COVID-19 emergency demands an urgent development of possible strategies to protect people at high risk of infection and hence the drug repurposing became an emerging approach to fight COVID-19. This review summarizes an update on various therapeutic strategies with special attention on repurposing of drugs to fight against SARS-CoV-2 worldwide. The investigation of existing drugs for new therapeutic purposes is one line of scientific research followed to develop safe and effective COVID-19 treatments. Broad-spectrum antiviral agents (BSAAs) that have been believed to be safe through testing on early phase clinical trials have been hyped as good drug repurposing candidates. Broad-spectrum antiviral drugs such as Ribavirin, Umifenovir were advised for COVID-19 treatment. Some antibiotics may be repurposed as COVID-19 treatments such as teicoplanin, oritavancin, dalbavancin, monensin and azithromycin. Ivermectin an antiparasitic is recently repurposed. Hydroxychloroquine and chloroquine, having immunomodulating effect on humans, have been shown to have antiviral activity at starting and post-entry stages of the SARS-CoV-2 infection. There is a need for global health emergency to call for a courageous, global response at the political and governmental levels. Therefore, the regulatory agencies must act swiftly to lessen any financial obstacles involving private companies and update guidelines for drug licenses by repurposing if necessary.

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INTRODUCTION

The severe acute respiratory syndrome coronavirus 2, well known as COVID-19 has become the current health distress to the entire world. Initially appeared in Wuhan, Hubei, China around December 2019, it had spread to almost 210 countries due to its high contagious nature.[1] Preventive measures remain the only way to stop the person to person transmissions until any successful method of treatment or vaccine is developed. In the pandemic scenario the research on the rapid development of new drug molecules is highly risky and tedious process.

The genetically varied *Orthocoronavirinae* (coronavirus, CoV) family occurs in many avian and mammalian species. Phylogenetically, CoVs are divided into four genera: α (group 1), β (group 2), γ (group 3) and δ (group 4). Three new human CoV have emerged in the past two decades; in the year 2002 severe acute respiratory syndrome CoV (SARS-CoV), in 2012 Middle East respiratory syndrome CoV (MERS-CoV), and now in December 2019 SARS-CoV-2.[2-4] All human CoV are expected to have emerged firstly as zoonoses[5]. The current SARS-CoV-2 pandemic referred to as COVID-19 (Coronavirus disease 2019), has resulted in over 2,630,000 infections and over 184,000 deaths in 213

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FORMULATION AND EVALUTION OF TELMISARTAN SOLID DISPERSION USING DIFFERENT POLYMERS

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ABSTRACT

The goal of this examination was to plan and assess solid dispersion of Telmisartan to build dissolvability and for improvement of bioavailability. The solid dispersion were set up by physical blend strategy utilizing PEG 20000, PEG 6000, HPMC E15, HPC LH21, β-Cyclodextrin as a bearer in different proportions. Improved solid dispersion was assessed for % CDR and Time for CDR, FTIR, and in vitro tranquilize discharge study. The outcomes indicated that among the different groups containing the polymer being utilized in the examination, F8 plan containing critical improvement in solvency and disintegration profile of the medication.

KEYWORDS: Telmisartan, Solid dispersion, Physical Mixture method, Invitro studies.

INTRODUCTION

The oral course of prescription association is the course of choice for the formulators and continues telling the zone of drug movement progresses. Regardless, anyway notable, this course isn't liberated from imperatives of ingestion and bioavailability in the milieu of gastrointestinal tract. At whatever point an estimation shape is coordinated orally, sedate in the portion outline is released and separates in the including gastrointestinal fluid to outline an answer.[1] This technique is dissolvability limited. When the medicine is in the course of action outline, it goes over the movies of the phones covering the gastro-Intestinal tract. This method is permeability confined. By then onwards the medicine is acclimatized into major scattering. To lay it out simply, the oral digestion and therefore bioavailability of drug is constrained by the level of prescription dissolvability and vulnerability. Medication

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Design, characterization and *In vitro* evaluation of polymeric nanoparticles containing decitabine

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Abstract
The point of this investigation is to figure the Decitabine stacked nanoparticles Guar gum and PEG for anticancer treatment, so as to improve the bioavailability and to diminish the portion recurrence. Plans of Decitabine stacked nanoparticles were set up by Nano precipitation strategy. Fourier transmission infrared spectroscopy considers demonstrated no compound association among medication and polymer. Scanning electron microscope instrument indicated nanoparticles having a discrete circular structure without conglomeration the normal molecule size was discovered 141±132 nm. % yield was appeared in the middle of 54.29 ± 0.02 to 61.42 ± 0.02 and Entrapment effectiveness was appeared in the middle of 48.32 ± 0.02 to 74.62 ±0.02. The zeta potential was seen as - 4.2mV. *In vitro* discharge examines were performed by utilizing Franz diffusion cell apparatus. The FN9 detailing indicated sedate arrival of 94.16% for a time of 12hrs.

Keywords: Decetabine, nano precipitation, FTIR, franz diffusion, Zeta potential

1. Introduction
Leukaemia is a clonal illness of hematopoietic immature microorganisms, and it is a harmful tumour that truly undermines human lives [1]. Intense myeloid leukaemia (AML) is a typical sort of leukaemia that happens in the two kids and grown-ups. It is portrayed by a quickly detonating populace of unusual white platelets that aggregate and lead to diminished creation of typical platelets. Nano scale plan has huge low molecule size that may prompt sensational changes in the pharmacokinetics of medications with poor solvency or porousness issues. As an outcome, Nano definition permits progressively detached dissemination and infiltration of medication around 15-250 times more prominent than that of miniaturized scale particles through the natural films [2]. The accomplishment of oral chemotherapy can significantly change the clinical act of chemotherapy and fundamentally improve the personal satisfaction of the disease patients. The oral course is by a wide margin the most favoured course because of higher patient consistence, simplicity of organization, less expensive expenses, and so forth [3]. Leukaemia speaks to a lot of harmful illnesses described by an anomalous collection of platelets, commonly WBCs (white platelets). Based on the movement of the illness and hematopoietic heredities included, leukaemia's arranged as intense versus incessant and myeloid versus lymphoid [4]. Scientists have been attempting to improve the conveyance of decitabine on various frameworks, for example, Nano gels [5], nanostructured lipid bearers [6, 7], liposomes [8] and designed erythrocyte (Erythrocyte-Magneto-Hem agglutinin Virosomes, EMHVs) tranquilize conveyance framework [9]. At all occasions, the significant undertakings for analysts are to improve the capture of the medication in the conveyance framework and to upgrade the bioavailability. Here, the Nano particulate conveyance frameworks expect to improve the dependability of medication, its length of helpful activity, and bioavailability, while limiting its debasement, digestion and cell efflux [10, 11]. Decitabine (DEC) or 5-aza-2′-deoxycytidine, is a particular cytosine simple with a property to repress DNMTs. It synthetically turns around quality quieting of tumour silencer qualities, and has become an energizing methodology for disease treatment [12]. It's endorsed by the US FDA for use as a immunotherapeutic operator against haematological malignancies [13]. It has effectively demonstrated remedial activity in patients with myelodysplastic disorder (MDS) in clinical preliminaries at higher stages. DEC is likewise dynamic in both intense and constant leukaemia's too [14].

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FORMULATION, CHARACTERIZATION AND INVITRO EVALUATION OF LAMIVUDINE MICROSPHERES FOR SUSTAINE RELEASE

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ABSTARCT

In the present work, Microspheres of Lamivudine using Sodium alginate, Chitosan, Eudragit as polymers were formulated to deliver Lamivudine. The results of this investigation indicate that solvent evaporation method can be successfully employed to fabricate Lamivudine microspheres. FT-IR spectra of the Drug and optimised revealed that the drug is compatible. Micrometric studies revealed that the mean particle size of the prepared microspheres and are suitable for microspheres for oral administration. Increase in the polymer concentration led to increase in % Yield, % Drug entrapment efficiency, Particle size, % swelling. The invitro drug release decreased with increase in the polymer concentration. Analysis of drug release mechanism showed that the drug release from the formulations followed zero order release kinetics. Based on the results of evaluation tests formulation coded F4 was concluded as best. formulation.

KEYWORDS: Lamivudine, Sodium alginate, Chitosan, Eudragit, Microspheres.

INTRODUCTION

Oral route drug administration is by far the most preferable route for taking medications. However, their short circulating half life and restricted absorption via a defined segment of intestine limits the therapeutic potential of many drugs. Such a pharmacokinetic limitation leads in many cases to frequent dosing of medication to achieve therapeutic effect.[1]

Novel drug delivery systems (NDDS) offer many advantages, which include improved therapy by increasing the efficacy and duration of drug activity, increased patient compliance through decreased dosing frequency and convenient routes of administration, and improved targeting for a specific site to reduce unwanted side effects. The challenge for both drug and drug delivery companies is to deliver both existing and emerging drug technologies in a manner that improves the current benefits enjoyed by the patients.[2-3] Microencapsulation is used to modify and retard drug release. Due to small particle size of microspheres, they are widely distributed throughout the gastrointestinal tract which improves drug absorption and reduces side effects due to localized build-up of irritating drugs against the gastrointestinal mucosa. Microspheres are small spherical particles, with diameters 1 μm to 1000 μm. They are spherical free flowing particles consisting of proteins or synthetic polymers which are biodegradable in nature.[4-5] There are two types of microspheres; microcapsules and micromatrices, which are described as, Microcapsules are those in which entrapped substance is distinctly surrounded by distinct capsule wall. and micromatrices in which entrapped substance is dispersed throughout the matrix. Microspheres are sometimes referred to as microparticles. Microspheres can be manufactured from various natural and synthetic materials. Microsphere play an important role to improve bioavailability of conventional drugs and minimizing side effects. Ideal characteristics of microspheres.[6-7]

Lamivudine (2′,3′ -dideoxy-3′ -thiacytidine) is an antiretroviral medicine used to avoid and treat HIV/AIDS and used to treat perpetual hepatitis B. It is of the nucleoside simple opposite transcriptase inhibitor (NRTI) class. It can hinder both sorts (1 and 2) of HIV reverse transcriptase.[8] It is phosphorylated to dynamic metabolites that go after fuse into viral DNA. They hinder the HIV reverse transcriptase protein aggressively and go about as a chain eliminator of DNA blend. The absence of a 3'- OH bunch in the joined nucleoside simple keeps the arrangement of the 5' to 3' phosphodiester linkage crucial for DNA chain stretching, and in this manner, the viral DNA development is ended. Fundamental purpose behind determination of this medication is low biological half-life, less protein binding, reduce the harmful impacts, diminish the measurements and expansion the patient consistence.[9]

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HYDROTROPIC SOLUBILIZATION TECHNOLOGY AN ECOFRIENDLY ANALYSIS TO IMPROVE SOLUBILITY, DISSOLUTION AND BIOAVAILABILITY OF VARIOUS POORLY WATER SOLUBLE ANTIVIRAL DRUGS

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ABSTRACT

Solubility is one of the most essential parameter to achieve desired concentration of drug in the systemic circulation for pharmacological response to be shown. Drug efficacy can be severely limited by poor aqueous solubility of various drugs. Several drugs also show side effects due to their poor aqueous solubility. There are various techniques are used to enhance the aqueous solubility of poorly water-soluble drugs and hydrotropic solubilisation technique is one of them. A hydrotrope is one of the compound that solubilizes hydrophobic compounds in aqueous solution. Various antiviral drugs belongs to class iv in biopharmaceutics classification system (BCS). The major problem of this drug having poor solubility in biological fluid which result in poor bioavailability after oral administration. Hydrotropic solubilization technique is the best approach to increase the water solubility of poorly water-soluble drugs and overcome problem-related with organic solvents. This review investigates the characterstic of hydrotropy and hydrotropic agents and their different advance toward the pharmaceutical analysis. This review also provides the future prospective concerned with the green pharmaceutical analysis.

KEYWORDS: hydrotropy, Ecofriendly analysis, solubility, antiviral drugs.

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Recent advances in antiretroviral therapy for HIV/AIDS

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Abstract

Acquired Immune Deficient Syndrome (AIDS) is a deathly human viral infectious disease caused by Human Immune Deficient Virus (HIV) infection. Started as Mono therapy using treatment of HIV, then multiple drugs in schedule given where patients had to eat up 11-16 tablets per day. To apply test and treat policy assisted by WHO, supply of cost effective antiretroviral drugs regularly and newer drugs get approved and challenge for developing countries. Hence we tried reviewing upcoming new molecules which showed potential to be good drugs in various phases of clinical trial. AIDS. First disease killer in US was AIDS in 1993. After one decade hard work, antiviral drug cocktails-high active antiretroviral therapy (HAART) have been invented for almost all HIV infection treatments. HAART medications regularly need to take HIV/AIDS patients and even life-long. Future trends are highlighted.

Keywords: Newer Antiretroviral drugs, HIV, US FDA approved ARV drugs, HAART, antiviral therapy.

Introduction

AIDS is a deadly human disease caused by HIV infections. Due o lack of effective therapeutics at that time, almost every AIDS patient losses his/her life before mid-1990s. HIV/AIDS was once the 1st disease killer in US (1993). Primary treatment using HIV/AIDS patients was chemicals or vaccines. Before the invention of high active antiretroviral therapy (HAART, cocktail therapy), the therapeutic responses of HIV/AIDS patients were very limited. Almost every AIDS patient losses his/her life before mid 1990s-all of the AIDS patients died within 2 years after AIDS episode emergence. At that time, it looks like a capital punishment when a patient infects with HIV.

HIV infected person becomes a easy target for opportunistic infections and diseases. T-helper cell (CD4) multiplies this virus and gradually depletes them. The Two main types are HIV-1 and HIV-2. HIV-1 is the most common type found worldwide And HIV-2 is found mainly in Western Africa, with some cases in India and Europe [1].

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A REVIEW ON: 3D PRINTING IN PHARMACEUTICAL TECHNOLOGY

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Abstract

The 3D PRINTING technology has paid attention towards medical devices industry and pharmaceutical industry due to its applications on various platforms in health care industry. 3D printing is using computer- aided design to plan fast prototyping. The technology allows easy process drug combinations that are required and tailored dosing. It becomes one of the most new and beneficial tools serving as a technology of good manufacturing of developed dosage forms, tissue engineering and disease modeling. It is a valuable strategy to overcome some challenges of conventional pharmaceutical processes The recent introduction of the first FDA approved 3D-printed drug has fulfilled interest in 3D printing technology, which is set for revolutionize the healthcare. Since the use, the rapid prototyping (RP) technology has evolved to such an extent that it is currently being used in a wide range of applications including in tissue engineering, dentistry, construction, automotive and aerospace.

Keywords: *3D printing, Novel drug delivery, personalized medicine.*

1. INTRODUCTION

3D printing plays an important role in multiple active ingredient dosage forms, where the formulation can be a single blend or a multi-layer printed tablets having a sustained release properties. This reduces the frequency and number of dosage form units consumed by the patient on a daily routine. 3D printing technology has a great potential in an individualized dosage form concept i.e the polypill concept [1] This brings about the possibility of all the drugs required for the therapy into a single dosage form unit. Three-dimensional printing is a technology which uses computer aided drafting technology to produce three dimensional objects by layering material onto a substrate.

3DP can be used throughout the drug development process, starting from preclinical development and clinical trials, to the medical care. When compared to the manufacturing process of conventional pharmaceutical product, it

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An Update on Therapeutic Repurposing Strategies for COVID-19

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Keywords
COVID-19; SARS-CoV-2; Repurposing; Therapeutic Strategies; Treatment.

ABSTRACT: The severe acute respiratory syndrome coronavirus 2, well known as COVID-19 has become the current health distress to the entire world. In the pandemic scenario the research on the rapid development of new drug molecules is highly risky and tedious process. The current COVID-19 emergency demands an urgent development of possible strategies to protect people at high risk of infection and hence the drug repurposing became an emerging approach to fight COVID-19. This review summarizes an update on various therapeutic strategies with special attention on repurposing of drugs to fight against SARS-CoV-2 worldwide. The investigation of existing drugs for new therapeutic purposes is one line of scientific research followed to develop safe and effective COVID-19 treatments. Broad-spectrum antiviral agents (BSAAs) that have been believed to be safe through testing on early phase clinical trials have been hyped as good drug repurposing candidates. Broad-spectrum antiviral drugs such as Ribavirin, Umifenovir were advised for COVID-19 treatment. Some antibiotics may be repurposed as COVID-19 treatments such as teicoplanin, oritavancin, dalbavancin, monensin and azithromycin. Ivermectin an antiparasitic is recently repurposed. Hydroxychloroquine and chloroquine, having immunomodulating effect on humans, have been shown to have antiviral activity at starting and post-entry stages of the SARS-CoV-2 infection. There is a need for global health emergency to call for a courageous, global response at the political and governmental levels. Therefore, the regulatory agencies must act swiftly to lessen any financial obstacles involving private companies and update guidelines for drug licenses by repurposing if necessary.

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INTRODUCTION

The severe acute respiratory syndrome coronavirus 2, well known as COVID-19 has become the current health distress to the entire world. Initially appeared in Wuhan, Hubei, China around December 2019, it had spread to almost 210 countries due to its high contagious nature.[1] Preventive measures remain the only way to stop the person to person transmissions until any successful method of treatment or vaccine is developed. In the pandemic scenario the research on the rapid development of new drug molecules is highly risky and tedious process.

The genetically varied *Orthocoronavirinae* (coronavirus, CoV) family occurs in many avian and mammalian species. Phylogenetically, CoVs are divided into four genera: α (group 1), β (group 2), γ (group 3) and δ (group 4). Three new human CoV have emerged in the past two decades; in the year 2002 severe acute respiratory syndrome CoV (SARS-CoV), in 2012 Middle East respiratory syndrome CoV (MERS-CoV), and now in December 2019 SARS-CoV-2.[2-4] All human CoV are expected to have emerged firstly as zoonoses[5]. The current SARS-CoV-2 pandemic referred to as COVID-19 (Coronavirus disease 2019), has resulted in over 2,630,000 infections and over 184,000 deaths in 213

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Research Article

Formulation and *In Vitro*evaluation of Simvastatin Insituperiodontal Gels

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Abstract

Objective of the study: The aim of the present study is to prepare and evaluate biodegradable *in situ* gels of simvastatin for treatment of periodontal diseases. In the present research work is focused to formulate periodontal injectable *in situ* gels containing bone regenerating agent simvastatin, using biodegradable polymer.

Methodology: Appropriate amounts of polymer and solvent were weighed into 5 ml glass vials with proper airtight polypropylene caps. After initial mixing of the contents, vials were placed aside with occasional shaking overnight at room temperature to completely dissolve the polymer. Weigh accurately finely powdered drugs and add to above solution, close the lid and shake well and keep aside with occasional shaking and store in refrigerator at 8°C. The resulting solutions can be directly injected into subgingival pockets. The studies are further done to evaluate the prepared *in situ* gels for various pre-formulation studies, physicochemical characterization, drug content, *in vitro* drug release studies and stability studies.

Conclusion: Periodontal diseases are the conditions that affect the supporting structure of teeth leading to the formation of pocket due to which tooth loss occurs, for which site specific injectable drug delivery systems are gaining importance.

Based on physicochemical characteristics, the *in situ* gel formulation of simvastatin (F3) was optimized. It was concluded that *in situ* gel delivery system is a novel approach that can be developed for the treatment of Periodontitis. The present research showed that the optimized *in situ* gel formulations are more promising for successful delivery of simvastatin and to treat bone regeneration.

Keywords: Simvastatin; Periodontitis; *In situ* gel

Introduction

Periodontitis can be classified based on disease activity (chronic or aggressive), etiology (specific bacterial, fungal or viral infection), by response to treatment (responsive or refractory), by site (localized or generalized). Chronic Periodontitis, formerly known as "adult periodontitis" or "chronic adult periodontitis" is the most prevalent form of periodontitis. It is generally considered to be a slowly progressing disease. However, in the presence of systemic or environmental factors that may modify the host response to disease progression may become more aggressive as shown in **Figure 1** [1].

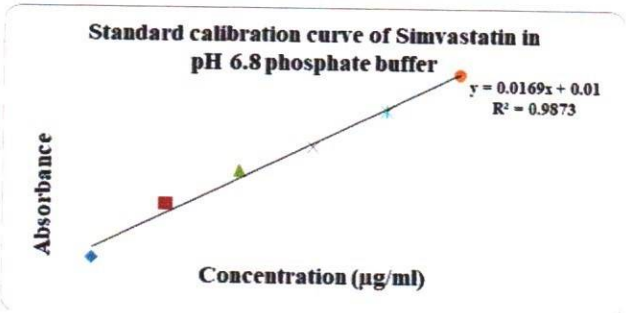

Figure 1: Standard calibration graph of SVS.

Methods

Gels

A gel is a solid or semisolid system of at least two constitutes, consisting of condense mass enclosing and interpenetrated by a liquid. When the coherent liquid is matrix and is rich in liquid, the product is often called a jelly and when the liquid is removed leaving only the framework, the gel is known as xero gels. In a typical polar gel, a natural or synthetic polymer builds a three dimensional matrix throughout a hydrophilic liquid [2].

***In situ* gel:** The *in situ* gelling systems consist of polymer that exhibit sol-to-gel phase transitions due to change in specific physicochemical parameters in the environment [3].

Advantages of *in situ* system

1. These systems reduce toxic effects on the healthy tissue and reach sites that are conventionally inaccessible due to the presence of various barriers.

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DEVISE AND EVALUATION OF CURCUMIN LOADED PERIODONTAL FILMS USING HPMC E15, HPMC E5 AND PVP K30

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ABSTRACT

In present study periodontal films of curcumin were devised and evaluated for faster on set of action using hydrophilic polymers, HPMC E5, HPMC E 15 and PVP K90. Periodontal films were prepared by employing solvent casting method. Propylene glycol was selected as permeation enhancer and plasticizer. Formulations were prepared with the varying concentrations polymers ranging from F1-F12, and all the formulations were evaluated for various physical parameters such as physical appearance, weight variation, thickness, folding endurance, tensile strength, drug content, moisture uptake, moisture content and all the results were found to be were found to be with in the required limits. In vitro drug release studies were conducted by modified method using SS disc with caynoacrylate adhesive. Among all the 12 formulations F6 which contains HPMC E5 350mg shown 94.2% cumulative drug release within 30 min as compared to those those of other HPMC E5, HPMC E15 and poly vinyl pyrolidine-K90. Formulations of HPMC E 15 showed more retarded drug release pattern.

KEY WORDS: ***Periodontal films, Local drug delivery, Curcumin, HPMC E15, HPMC E5, PVP K90, HPMC E 15.***

INTRODUCTION

Periodontal disease is an infection that involves the inflammatory process and the immune response. The presence of periodontal pathogens such as *Porphyromonas gingivalis, Prevotella intermedia* and *Actinobacillus actinomycetemcomitans* are responsible for periodontal destruction. Periodontitis refers to acute and chronic disorder of the soft tissues surrounding the teeth which eventually leads to loss of supporting bone.[1] There is an unmet medical need for new products to confront the high percentage of people with periodontal diseases. Retention of the drug dose at the point of application would facilitate long-term release and more effective treatments.[2] Apart from scaling and root planing, systemic antibiotic therapy is employed in treating periodontitis.[3] Systemic antimicrobials such as adjuncts to mechanical therapy have had a positive effect on clinical as well as microbiological parameters.[4] But the impact of this approach is reduced by the fact that the antibiotic is normally difficult to maintain in therapeutic concentrations at the site over the course of the treatment period. Due to these negative effects, the use of local drug delivery devices containing antibiotics may be explored. These devices can maintain extremely high local concentrations of drug for one month. Several implantable devices like fibers, films[5] and gels were studied. Various biodegradable polymers such as poly (glycolidecold-lactide), polyester poly (capralactone), glycerol mono-oleate, crosslinked atelo-collagen, hydroxypropylcellulose, chitosan[6,7] and alginates were employed as drug carriers. In our earlier studies cross linked sodium alginate[8,9,10] and chitosan were successfully employed as rate retarding polymer for periodontal films for controlled release of drugs. Curcumin is a hydrophobic polyphenolic compound derived from the rhizomes of *Curcuma longa*, shows wide spectrum of antibacterial, anti-inflammatory, and antioxidant properties against a number of periodontal pathogens and hence selected for site-specific delivery in the treatment of periodontitis.[11] Clinical applications of Curcumin as oral gel, prevention of plaque and gingivitis, mouthwash, subgingival irrigant, treating periodontal diseases are reported.[12,13,14,15] As dietary spices, curcumin has been consumed for centuries up to 100 mg/day.[16]Curcumin loaded films of gelatin,[17] ethyl cellulose, HPMC K4M, and Eudragit are formulated and Clinical studies on curcumin-PLGA nanoparticles.18 mucoadhesive films19 and oral curcumin gel were

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NANOBOTS ARE THE FUTURE MEDICINE

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ABSTRACT

Nanorobots (Nanobots) have the advantages of small size, low weight, large thrust-to-weight ratio, high flexibility, and high sensitivity. Due to the characteristics distinguishing from macroscopic robots, nanorobots have stimulated the research interest of the scientific community and opened up numerous application fields such as drug delivery and disease diagnosis. In the past 30 years, research onnanorobots has made considerable progress. This review article aims at giving an overview of the present status of nanorobotics with the aid of biotechnology, molecular biology (as engineered organism) and molecular medicine can develop fully self-sufficient nanorobots/nanobots. The nanorobotics considered as a wonderful vision of medicine in the future are an advanced submicron device generally made of bio-nanocomponents. It has an eminence future in the drug delivery technology target in cancer, the disease that leading cause of death among youngster than 45 years. Nanorobots could carry and deliver large amounts of anti-cancer drugs into cancerous cells without harming healthy cells, reducing the side effects related to current therapies like damage of the conventional chemotherapy. This review presents a comprehensive overview of the development of nano-robots. Further, it also provides an insight to the future scope in this field of study.

KEYWORDS: ***Nanorobots, nanobots, cancer therapy, applications.***

INTRODUCTION

1. Overview of Nanotechnology

Most of the substantial things done and made in this world start from an idea.Scientists have dreamed for long of miniature robots that can be controlled and navigated inside human body, to help the medical doctors to diagnose and treat the diseases. As shown by the old classic movie Fantastic Voyage released in 1966, a submarine with a group of crews was shrunk to the micro-scale so that it can navigate inside the human blood vessel for the removal of a blood clot. To explore the possibility to realize that wild idea, scientists have proposed and developed many types of miniature machines and robots, some of which are aimed to adapt various kinds of physiological environments for diagnosis and disease treatment. A variety of nano-scale robots have been developed among the past decade, which offer promise for diverse biomedical applications.[1,2,3,4,5,6] The original idea of nanotechnology can be attributed to a Physicist, Richard Feynman in 1959.[7] Feynman's vision of nanotechnology became known to all in his classic talk on December 29th 1959 at the annual meeting of the American Physical Society at Caltech, which was first published in the February 1960 issue of Caltech's Engineering and Science. Feynman went on to propose miniaturizing computers to a nano scale. This of course, would require a different manufacturing process. He came up with miniaturization through evaporation and the applications of small moveable machines to. Do assembly. This idea of moveable machines has given the widely used term, 'nanorobots.' He suggested a way to make tiny mechanisms through the use of slave "hands," which are controlled to perform a specific task. Yet, Feynman thinks beyond this point explaining his concept of having hundreds of tiny "hands" that manufacture copies of it doing the same function. Though the word self-replication was not used in his talk, this was definitely the concept that scientists relate to that topic. Nanorobots are promising devices for biomedical and environmental applications. The past few years have witnessed rapid developments in this field. This short review intends to address recent progress on magnetically driven nanorobots by different research groups.

2 What are Nanobots?[8]

Nanobot is a nano-technological robot machine, also called a nanite, which is a mechanical or electro

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ENTERIC COATED CAPSULES FOR EXTENDED RELEASE OF LANSOPRAZOLEMUCOADHESIVE MULTIPLE-UNIT MINI PATCHES

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ABSTRACT

The present study aims to the formulation and evaluation of novel oral mucoadhesive multiple-unit mini patches (MMMP) of lansoprazole (LAN) for extended release. MMMP of LAN in enteric coated capsules were prepared and evaluated using chitosan in combination with xanthan gum, guar gum, tragacanth or acacia in the ratios of 19:1, 9:1, 4:1, 1.5:1 and 0.66:1 employing 2% acetic acid as solvent for chitosan, purified water as solvent for natural gum polymers and glycerin 0.12 mL as plasticizer. The prepared films (0.5 mm dia) were filled into hard gelatin capsules which were enteric coated. The prepared MMMP were characterized for surface texture, thickness, folding endurance, moisture content, moisture uptake, mucoadhesive strength, drug content uniformity, *In vitro* drug release and accelerated stabiliity studies. The SEM photographs showed the rough to smooth pattern of surfaces of patches. The thickness of MMMP found between 43.62±0.27 and 49.53±0.11 µm; mean weight was between 13.81±0.14 and 14.94±0.15 mg; percentage of swelling was between 215±5.39 and 473±6.72; moisture content was between 1.04±0.06 and 2.67±0.24; mucoadhesion was found between 5.5±0.2 and 12.3±0.6 h and the drug content was found between 95.08±3.42% and 99.16±4.73% for all formulations. The FTIR and DSC spectra indicated no drug-polymer interactions. The *in vitro* dissolution studies showed extended release of LAN from MMMP in pH 6.8 phosphate buffer where as no significant drug release found in acidic environment showing that MMMP in enteric coated capsules could be employed to delivery LAN to intestine directly. In all the cases the drug dissolution was reciprocal to the polymer concentration in the formulations. Among all natural polymers employed in this specification the decreasing order of drug release from the polymers was xanthan gum > tragacanth > guar gum > acacia. The prepared novel mucoadhesive multiple-unit mini patches (MMMP) in enteric coated capsules for controlled release of lansoprazole using natural polymers and could be successfully employed for intestinal delivery while minimizing the drug degradation and providing extended release of the drug.

KEY WORDS: *Enteric coated capsules, extended release, lansoprazole, mucoadhesive multiple-unit mini patches, MMMP*

INTRODUCTION

Intestinal patches mostly millimeter sized provide a unique platform for oral delivery of drugs which possess poor oral bioavailability, necessitating their administration by injections. They are inspired by transdermal patches, which in spite of similar conceptual design; operate in very different physiological environments[1]. Several gastrointestinal patch systems provide bioadhesion, drug protection from acidic environment and unidirectional release[2,3,4]. In addition, these devices create a high concentration gradient for drug transport, which facilitate uptake of loaded proteins through the intestinal membrane[5]. Consequently, intestinal patch-based devices are being developed for oral delivery of several drugs such as insulin,6 exenatide, calcitonin, interferon-α, erythropoietin and human granulocyte colony-stimulating factor for the treatment of diabetes, osteoporosis, hepatitis or chemotherapy.**Error! Bookmark not defined.** A patent described pH dependent mucoadhesive patches for unidirectional release of drugs[7]. Commonly used mucoadhesive polymers are chitosan and its thiolated derivatives, pectin, polyacrylic acids, carbopol, alginates, polyvinyl alcohol and cellulose derivatives such as sodium carboxymethyl cellulose (SCMC), hydroxypropylmethyl cellulose and

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Turmeric black tea as a multimodal theronostic dietary adjuvant aiding neuroprotection and ameliorating hypertension

Abstract

This study reports the multifunctional potentiality of turmeric black tea (TBT) in alleviating hypertension in salt induced hypertensive animal model and aiding neuroprotection in colchicines induced Alzheimer rat models. TBT prepared basing on the desirability function of central composite design with 3.11g of black tea and 1.46g of ground turmeric exhibited optimal pharmacologic response and organoleptic acceptability. No signs of mortality were observed till 10g/kg b.w. or any hepato-renal adversities with 5000mg/kg doses. LCMS analysis of TBT showed the presence of several tea catechins, theaflavins, gallic acids and curcuminoids. Incorporation of turmeric in black tea aided in value addition as evidenced by *in vitro* and *in vivo* experimental results and has not affected the chemoprofile of black tea studied by FTIR. The multipotency of TBT is attributed due to presence of the variant pharmacologically active molecules.

Keywords: turmeric black tea, hypertension, neuroprotection, desirability function, multifunctional, organoleptic acceptability

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Abbreviations: ACE, angiotensin converting enzyme; CCBs, calcium channel blockers; AD, Alzheimer's Disease; TBT, turmeric black tea; RSM, Response Surface methodology; ANOV, analysis of variance; BT, black tea decoction; ESI, electrospray ionization; OECD, Organization for Economic Cooperation and Development; ALT, alanine Aminotransferase; AST, aspartate Aminotransferase; ALP, alkaline phosphatase; ROS, Reactive oxygen species; HHL, hippuryl L, histidyl, L, leucine

Introduction

The growing complexities of the diseases is a real challenge to the medical fraternity; thence the treatment strategies have also undergone a radical change and promotes multi-target therapeutic entities, poly therapy, nutraceuticals and food combinatorics, herbo-synthetic combinations as adjuvant therapy to achieve better therapeutic outcomes.[1–3] Hypertension, is a big concern worldwide affecting different levels of socio-economic classes and is the root cause of stroke, cardiovascular disorders, diabetes etc. Excessive stress, sedentary lifestyle, food habits, physical inactivity are other contributing factors. Though several beta blockers, angiotensin converting enzyme (ACE) inhibitors, calcium channel blockers (CCBs) are available in the market but are associated with side effects.[4,5] Alzheimer's Disease (AD), is a progressive worrisome neurodegenerative disorder with devastating complications and till yet with available therapeutic options total curative outcomes has not yet been achieved.[6,7] Epidemiological research evidences has shown that hypertension and dementia are interlinked; sustained hypertension worsens AD conditions by accelerating β-amyloid aggregation, oxidative stress and inflammatory responses; ultimately there is extensive neuronal loss and impairment of neuronal transmission. Patients suffer from cognitive decline.[8–10] Multifaceted health benefits of tea is already on limelight and black tea apart from being a very refreshing beverage specially due to its astringency, its multimodal pharmacology has shown it to be a functional beverage.[11] Researches with functional beverage aim to achieve for value additive synergistic potentials and thus several tea diversification products have captured the global nutraceutical market.[12] Turmeric (*Curcuma longa*), a golden yellow color cooking spice and preservative is specially preferred in Indian subcontinent, hence also called "Indian saffron" is recognized for its versatile applications and health effects.[13] The effectivity of any natural therapeutic entity may it be phytomedicine or phytonutraceuticals are due to the wide array of pharmacologically active molecules present in them that serve as a combinatorial library each exerting its own potential.[14] This research article reports chemometrics guided optimization of TBT for optimal pharmacologic effect and organoleptic acceptability and the ameliorative effect of turmeric black tea (TBT) in hypertension and aiding neuroprotection.

Material and methods

Chemicals

All chemicals and reagents used for the experimentation were all of analytical grade and were purchased either from Merck (India) and Sigma Aldrich. LC-MS grade chemicals were used for LC-MS studies.

Plant material

Fresh tea leaves (TV 25 variety, *Voucher specimen*: IITKGP/HB/2018/T1) used for producing black tea were obtained from the tea garden of IIT Kharagpur and good quality turmeric rhizomes (*Voucher specimen*: IITKGP/HB/2018/T2) from the medicinal garden of Agriculture and food engineering department of IIT Kharagpur.

Maintenance and care of animals

After obtaining permission from the animal ethical committee (Registration No: 1722/RO/ERe/S/13/CPCSEA, Approval No: ARTI/CPCSEA/2015/ARTI 09); animals were purchased from local vendors and healthy, adult male wistar rats weighing 180–200g were used for

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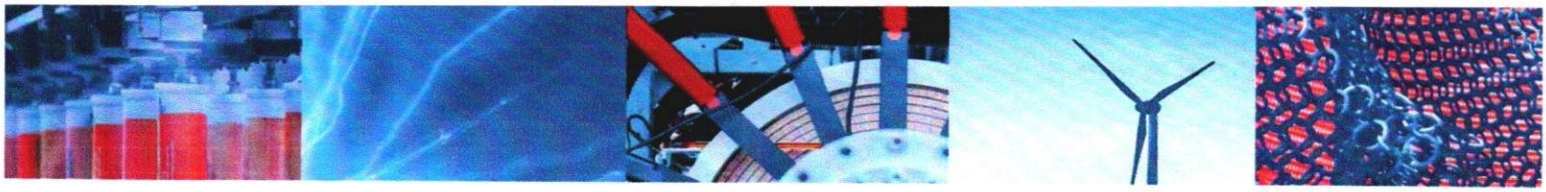

Research Article

Development of a standardized combined plant extract containing nutraceutical formulation ameliorating metabolic syndrome components

Baishakhi De[1] · Koushik Bhandari[2] · Prakash Katakam[1] · Tridib Kumar Goswami[3]

Received: 6 August 2019 / Accepted: 17 October 2019 / Published online: 25 October 2019

Abstract
Plant bioactives have a great role in combating multifactorial disease conditions like metabolic syndrome (MetS). This research work aims to develop a standardized plant extract combination and formulate it to tablets with nutraceutical potentials. The extract was prepared from the bark powder of *Ficus religiosa*, seed powder of *Syzigium cumini* and leaf powder of *Ocimum bacilicum* chemometrically optimized in the ratio of 1.15:1.15:1.68 (Ashwattha: Jamun: Basil or FR: SC: OB). It is enriched in screened and pharmacologically active plant secondary metabolites. The tablets were prepared by direct compression using single-punch tablet machines. The nutraceutical tablets passed all the prescribed quality control tests with a justified pharmacokinetic profile. Results of animal experimentations have shown the hypoglycemic, hypolipidemic effect and antihypertensive effect of the nutraceutical tablets in relevant animal models. Thus, the nutraceutical formulation that showed effectivity in combating MetS can be opted as an adjunct therapy.

Keywords Metabolic syndrome · Standardized plant extract · Hypoglycemic · Hypolipidemic · Antihypertensive · Nutraceutical formulation · Adjunct therapy

1 Introduction

Metabolic syndrome (MetS) is a very heterogenous complex syndrome with a cluster of events such as glucose intolerance, insulin resistance, abdominal obesity, artherogenic dyslipidemia and hypertension. It is also known by the names of 'Syndome X,' 'insulin resistance syndrome,' 'Reaven's syndrome,' 'metabolic cardiovascular syndrome' [1]. Metabolic syndrome is associated with cardio/cerebrovascular and metabolic risks. This non-communicable disease (NCD) though started in the western world has now become a global health problem. This syndrome triggers the spread of other diseases viz. Type 2 diabetes, coronary diseases, stroke and other disabilities [2]. Inspite of life style interventions (dietary changes, increased physical activity, etc.), many patients with MetS require pharmacological treatment. Sibutramine, Orlistat, metformin, glitazones, rimonabant, calcium antagonists, beta blockers, thiazide diuretics and angiotensin converting enzyme inhibitors are one of the several options but not without side effects [1, 3]. Herbal medicine and the nutraceutical products developed from them with its versatile combinations of pharmacologically active plant secondary metabolites are being used in treatment of several ailments in an evidence based manner. Despite immense potency, lack of proper dosage form, perfect dosimetry, organoleptic unacceptability in crude form, storage, preservation and shelf life issues, the rationale use of herbal medicine gets hindered in many circumstances [4]. Just as

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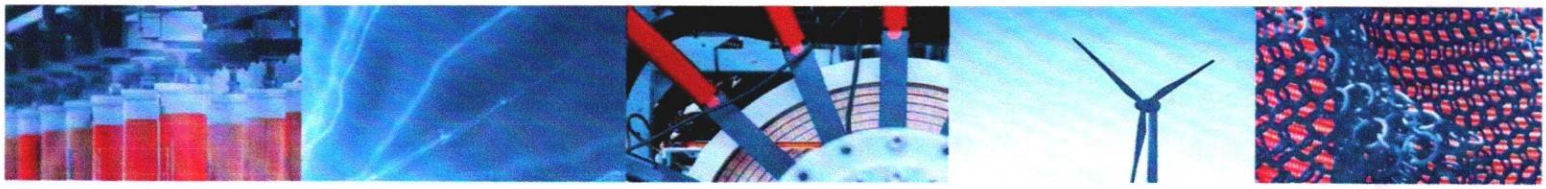

Research Article

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Biosynthesis, characterization and anti-microbial activity of silver nanoparticle based gel hand wash

Mohammed Muqtader Ahmed, Farhat Fatima, Md. Khalid Anwer, Saad M. Alshahrani, Ahmed Alalaiwe and Prakash Katakam

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Abstract

In the current study, silver nanoparticles (AgNPs) were biosynthesised by microwave irradiation using Azadirachta indica. The formation of AgNPs was confirmed by surface plasmon resonance (SPR) band at 408 nm at UV-visible spectroscopy due to reduction of silver metal into (AgNPs) and further confirmed its particles in nano range. Nine different smart-gel hand wash were prepared by dispersing (AgNPs) in the HPMC and/or Pluronic F-127 polymers. The prepared smart gel hand wash was optimized based on pH, viscosity, spreadability, foamability, clarity. The optimized hand wash (NH5) had pH (6.6 ± 0.33), viscosity (66 ± 0.77, cp), spreadability (24.34 g-cm/s), foamability (100 mL). The optimized hand wash (NH5) showed a superior efficacy against pathogenic organisms in comparison to germ protection based marketed hand wash.

Keywords: silver nanoparticles; smart-gel hand wash; anti-microbial efficacy; stability

Introduction

Hand washing is a religious and cultural habit, the relation between handwashing and infectious disease was recognized only two centuries ago by a Hungarian doctor Ignaz Semmelweis, known as the father of hand hygiene [1,2]. He noticed the spread of infection and mortality of new born given birth in his hospital, which was relatively higher than the adjacent midwife-run maternity hospital. In his investigation, he concluded that doctors with bare hands after performing surgery or autopsy visited the maternity ward were the cause to transmit the infection in new-borns and causes death [3]. In the present scenario challenges of the 21st century include infectious diseases; the second leading cause of death that kills 17 million people in a year worldwide [4]. Majorly transmission of infection takes place by contaminated hands, therefore hand plays a vital role in the spread of infectious diseases in the healthcare setups, industrial setting related to the food manufacturing and also in the community to larger extent [5,6]. Hand hygiene as an intervention to prevent the spread

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FORMULATION, EVALUATION AND CYTOTOXIC POTENTIAL OF METRONIDAZOLE LOADED POLOXAMER 407 HYDROGEL IN SCC-29 CELL LINES

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Keywords:

Metronidazole, Poloxamer 407, Hydrogel, Cytotoxicity, Drug stability

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ABSTRACT: The present research work was planned to formulate poloxamer 407 based hydrogel formulations of metronidazole and the evaluation of various parameters like swelling behavior, drug PH stability, *in-vitro* and *in-vivo* drug release, and *in-vitro* cytotoxic activity. Two different concentrations of metronidazole hydrogel formulations were prepared using poloxamer 407 and were assessed by a validated HPLC method for drug content, pH stability, and *in-vivo* drug release. Further, *in-vitro* anticancer activity was evaluated using sulphorhodamine B (SRB) assay in SCC29 cell lines. Both the formulations F1 and f2 showed better pH stability at pH 3.5, 5.5 and 6.8. The formulation F1 was able to absorb about 152% of its weight of water within 80 min, whereas F2 absorbed 167.4% of its weight of water and remains constant over 100 min. *In-vitro* and *in-vivo* drug release pattern showed half-life at 6 h, AUC_{0-t} 692 and 684ng h/ml, C_{max} 1059 and 1142 ng/ml for F1 and F2 respectively. Hydrogel formulation F1 showed improved percentage control growth when compared to F2 hydrogel formulation and metronidazole alone.

INTRODUCTION: Metronidazole (MT) which is chemically 5 nitroimidazole derivatives with the molecular weight of 171.156, gm/mol and with a molecular formula $C_6H_9N_3O_3$. It is a nitroimidazole which is used for the treatment of vaginitis, amebiasis, giardiasis, trichomonas infections and several anaerobic bacterial infections [1]. It shows antibacterial and protozoal activities, by converting itself active intermediate product in reduced form and which breaks DNA strands, thereby inhibiting DNA synthesis and bacterial cell growth [2].

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Ploxomer 407 have been currently received major attention in the field of thermosensitive hydrogels. It is an amphiphilic synthetic copolymer which consisting of a hydrophobic poly (Oxypropylene) (POP) block between two hydrophilic poly (Oxyethylene) (POE) blocks [3-5]. Because of its amphiphilic nature, these molecules can make self-assemble readily to form micelles base on the temperature and concentration.

These hydrogels have been characterized by their ability to carry a significant amount of drug. They are also, nontoxic biodegradable and stable, therefore suitable for uses in controlled release formulations [6]. Extensive literature review on metronidazole revealed that, along with its antiprotozoal and antibacterial activities, the cytotoxic property of MT was also reported.

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Formulation and Evaluation of Maltose-Leucine-Tetanus Toxoid Dry Powder Inhalation for Pulmonary Delivery

Mary Manoranjani Addanki[1, 4], Prakash Katakam[1]*, Shanta Kumari Adiki[2], Jessi Dason Vardhanapu[3], Prameela Rani Avula[1]

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Abstract: Tetanus toxoid vaccination is primarily used for tetanus prevention. The conventional vaccine for tetanus toxoid is characterised by the limitations of pain, sterility issues, and cold storage. Hence, a pulmonary administered tetanus toxoid (TT) vaccine was fabricated to overcome the limitations of conventional intramuscular vaccines. The goal of this study was to make a dry powder of tetanus toxoid that could be inhaled using maltose and leucine as a vaccine carrier. Additionally, TT dry powder inhalation (DPI) was intended to confer antigenicity and stability. Maltose, leucine and tetanus toxoid were homogenised and centrifuged to obtain the particles of Maltose-leucine-tetanus toxoid (MLTT). Particle size analysis, FTIR, encapsulation efficiency, flocculation, in vitro vaccine release tests, and flow characteristics were all performed on the produced particles. MLTT powder combination remained stable during the process and after storage. FTIR analysis, showed no chemical interactions. The homogenization method produced a powder with the geometrical particle size of the DPI formulation, in the range between 95.6 ± 5.7 nm and 1081.1 ± 10.8 nm which was believed to be appropriate for inhalation. Whereas -27 ± 0.6 mV and 0.496 ± 0.013 were found to be the zeta potential and polydispersity index, respectively. The formation of flocculation of tetanus toxoid with antitoxin as at 20 min confirms the antigenicity of the same. TT was released immediately with 83.2 ± 4.9% within 2 h following the diffusion mechanism. The findings revealed the powder blend's potential as a dry powder inhalation for delivering TT.

Keywords: *Tetanus toxoid, Maltose, Leucine, Dry powder inhalation, Pulmonary administration, Mucosal vaccine.*

1 INTRODUCTION

Tetanus is a life-threatening illness that causes convulsions (seizures) and severe muscle spasms, which can lead to spinal fractures. Tetanus causes death in 30% to 40% of the cases. Tetanus vaccine is recommended for infants aged between 6 and 8 weeks of age and older, as well as for children and adults during minor cuts and surgeries. Additionally, a series of three to four shots is prescribed during maternal care to protect the mother and the neonate. Owing to the short term immunity induced by TT vaccine, immunization for every 10 years is recommended. As can be seen, the implementation of vaccination programmes has been shown to be effective in disease control [2]. Despite the advantages of intramuscular tetanus toxoid vaccination, it has drawbacks such as sterility, discomfort, cold chain storage, and mucosal immunity induction. Mucosal linings are exposed to a wide range of microorganisms and are equipped with innate immune components to prevent microbial penetration [4-9]. Mucosal vaccinations, which are known for their non-invasive approach, are available on the market. Oral, nasal, sublingual, vaginal, and pulmonary vaccine administration routes have all been examined and reported for conferring mucosal and systemic immunity [10-13]. Local mucosal immune responses are becoming more widely recognised as it is important for disease prevention [14]. Vaccines delivered by mucosal ports induced greater mucosal immune response, but vaccines administered via injection are observed to be poor inducers of mucosal immunity and thus less effective against infection invading at mucosal surfaces. [14]. Nonetheless, antigen injection has played a large role in clinical vaccination development, and the majority of vaccinations now in use are administered intramuscularly or subcutaneously. Several findings point to a paradigm shift to mucosal vaccination delivery [15]. Pulmonary administration has a variety of

HPLC-UV method for simultaneous determination of sparfloxacin and dexamethasone sodium phosphate in eye drops

Katakam Prakash and Karanam R Sireesha*
S.N. Vanita Pharmacy Mahavidyalaya, Exhibition grounds, Hyderabad, Andhra Pradesh, India

Abstract: A simple, sensitive liquid chromatographic method was developed and validated for the simultaneous estimation of sparfloxacin and dexamethasone sodium phosphate in bulk and pharmaceutical formulations. Optimum separation was achieved in less than 10 min using a C_{18} column (250 mmx4.6 mm i.d, 5µ particle size) by isocratic elution. The mobile phase consisting of a mixture of mixed phosphate buffer (pH 6.8) and acetonitrile (50:50, v/v) was used. Column effluents were monitored at 224nm at a flow rate of 1ml/min. Retention times of sparfloxacin and dexamethasone sodium phosphate were 3.01 and 6.47 min respectively. The linearity of sparfloxacin and dexamethasone sodium phosphate was in the range of 3-18µg/ml and 1-6µg/ml respectively. Developed method was economical because, the time taken and amount of solvent consumed for each analysis was less. The method was validated and was applied to the simultaneous determination of sparfloxacin and dexamethasone sodium phosphate in bulk and pharmaceutical formulations.

Keywords: Simultaneous determination, HPLC, isocratic elution, validation.

INTRODUCTION

Sparfloxacin (SFN) is a third generation fluoroquinolone antibiotic used in bacterial infections. It is chemically (cis) - 5-amino-1-cyclopropyl-7-[(3, 5-dimethyl piperazin-1-yl] –6, 8-difluoro- 1, 4-dihydro 4-oxo-quinoline- 3-carboxylic acid (Merk index, 2001). Dexamethasone sodium phosphate (DSP) is a highly selective glucocorticoid which is widely used in ocular inflammatory diseases. Its chemical name is 9- fluoro-11b, 17, 21-trihydroxy-16α- methylpregna-1, 4- diene-3, 20-dione 21-(dihydrogen phosphate) disodium salt (The Indian Pharmacopeia commission, 2007). Dexamethasone in combination with sparfloxacin is used in several anti-infective eye preparations to treat acute and sub acute conjunctivitis, keratitis and corneal ulcers caused by susceptible strains of the following aerobic gram positive and negative bacteria such as *S. aureus, S. epidermidis, S. pneumonia* and *Haemophilus influenza* (Vyas *et al.*, 2002).

In the literature, methods were described for the individual estimation of fluoroquinolones and dexamethasone in aqueous samples and biological fluids by liquid chromatography (Chen *et al.*, 2008; Hyung *et al.*, 1995) liquid chromatography-fluorescence detection (Joana *et al.*, 2011). A few methods were also given for the simultaneous determination of Dexamethasone and sparfloxacin with other drugs such as Chloremphenicol (Iqbal *et al.*, 2006), ciprofloxacin (Rele and Warkar, 2010) ofloxacin (Tang *et al.*, 2002) and some H_2 receptor antagonists (Najma *et al.*, 2011). But simultaneous determination of SFN and DSP has not been reported in the literature. So an attempt was made to develop a HPLC method for the estimation of these drugs available as eye drops.

The purpose of the present study was to develop a simple, sensitive and economical HPLC method for determination of SFN and DSP in bulk and pharmaceutical formulations simultaneously. The developed method has been validated (The United States Pharmacopeia Convention, 1995; Validation of Analytical Procedures Q2 B, 2003) to determine its suitability for its intended use by parameters such as specificity, linearity, limit of detection and quantification, precision, accuracy by recovery studies and system suitability. The validated method was applied to the commercially available pharmaceutical formulations containing both the drugs.

MATERIALS AND METHODS

Materials

DSP and SFN were obtained as gift samples from Ajanta Pharmaceuticals Ltd., Mumbai. HPLC grade acetonitrile was purchased from SD fine chemicals, India. Triple distilled water was used during the study. The pharmaceutical formulations containing 3mg/ml of SFN and 1mg/ml DSP was purchased from local market.

Instrumentation

A high performance liquid chromatograph (Shimadzu-10 AT VP) equipped with two pumps (Model-10AT VP) and Shimadzu UV-Visible detector (SPD-10AT VP), ultrasonic bath (Spincotech Pvt. Ltd., India).

Chromatographic conditions

For chromatographic analysis, a Chromosil C_{18} column (250 mmx4.6 mm i.d, 5µ particle size) was used.

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Research article Open Access

Retrospective study on antibiotic use in different clinical departments of hospital in Nalut, Libya

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ABSTRACT

A retrospective Study on Antibiotic Use in Different Clinical Departments of Hospital in Nalut, Libya during a period of five months (1/1/2013to 30/5/2013). Data were collected retrospectively from inpatients medical files (600 patient's medical file), prescriptions for outpatients (400 prescriptions studied) and the total number of prescription was 1000. The data then was evaluated by Microsoft Excel software for analysis and descriptive statistics. The World Health Organization (WHO) indicators (utilization in defined daily doses (DDD); DDD/1000 inh/day) were used and the ATC/ DDD method was implemented. The three most frequently used antibiotics for inpatients were cefotaxime, ceftriaxone and metronidazole with 25.57%, 16.54% and 15.34% of the total prescribed antibiotics respectively, and for outpatients they were amoxiclav (26.23%), amoxicillin and azithromycin (12.41%) and ciprofloxacin (11.48%). After calculating the consumption of antibiotics in DDD, the highest consumed antibiotic in DDDs (g) was clarithromycin 10.67 g and 0.119 g in terms of DDD/1000inh/day, while consumption of amoxiclav was the lowest consumption 0.011 g and 0.00012 DDD/1000 in h/day. About 98% of patients given antibiotics without culture sensitivity tests (c/s). Only 2% of the patients undergone the test during the treatment. In conclusion, this study we identified that the DDD for antibiotic consumption data for five months and the clarithromycin was the most consumption over those months and we find out the most prescribed antibiotics and the most of the wards use it. In addition to the demographic data, this also helps physicians to have a more precise idea about prescriptive patterns prevalent in the Libyan community.

Keywords: Drug utilization research, Inpatient, Defined daily dose, Anatomical therapeutic chemical (ATC), Libya

INTRODUCTION

The dawn of antibiotics, which are one of the most booming drug groups used in medicine, dramatically improved the prognoses of patients with microbial infections. Unfortunately, following quite a few years of hopefulness, the over the top and unpredictable utilization of these antiinfection agents in both human and veterinary practices has prompted the development and spread of resistant organisms that imperil their viability, joined by undesirable symptoms and unwanted adverse effects [1].

In spite of the effectiveness of antimicrobials in the treatment of various bacterial diseases, usually they are utilized improperly worldwide [2]. This

SP-04

HEPATOPROTECTIVE ACTIVITY OF *CELASTRUS EMARGINATA* [W] LEAVES METHANOLIC FRACTION OF ETHANOLIC EXTRACT ON CCl_4 INDUCED HEPATOTOXICITY IN RATS

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[1]*Department of Pharmacognosy, CRPS, Nanded Pharmacy College, Nanded-431604*
[2] *Department of Pharmacognosy, Indira College of Pharmacy, Vishnupuri, Nanded-431606*
[3] *Departments of Pharmacology, School of Pharmacy, SRTM University, Nanded-431606*

ABSTRACT

It is a potent hepatotoxin producing centrilobular hepatic necrosis, which causes liver injury. Prolonged administration of CCl_4 can lead to cirrhosis and hepatic carcinoma. However, the protection of *Celastrus emarginata* [W] Leaves Methanolic fraction of Ethanolic extract against hepatic injury on CCl_4 Induced rat, yet remains unclear. The research aimed to investigate the mitigation effect of ME-EE-CE against CCl_4 Induced hepatotoxicity in experimental animals. The rat were administered CCl_4 (1.5 ml/kg i.p.) as a positive control to compare ME-EE-CE. The hepatic function was assessed in liver tissue of control rat. Levels of serum hepatic enzymes (SGOT, SGPT) as well as Total protein and Albumin levels were significantly increased in CCl_4 induced rats. Co-treatment with ME-EE-CE (100 mg/kg and 200 mg/kg, p.o.) significantly decreased the serum levels of liver function biomarkers. Furthermore, ME-EE-CE treatment showed a significant reduction of lipid peroxidation and increase of enzymic and glutathione concentrations. Histopathological analysis was parallel to these biochemical findings. The results clearly demonstrated that ME-EE-CE is effective for ameliorating hepatic cytotoxicity arising from CCl_4.

KEYWORDS: ***Celastrus emarginata, hepatoprotective, Serum hepatic enzymes, CCl_4***

INTRODUCTION

CCl_4 is a well known hepatotoxic industrial solvent [1-2] CCl_4 is commonly used for free radical induced liver injury [3-4] Liver is not the only target organ of CCl_4 but it also affects several organs of the body such as lungs, hearts, testes, kidneys, and brain. [5] It was reported from the investigation carried out on animal models of acute CCl_4 induced liver damage. It is now generally accepted that CCl_4 toxicity results from bioactivation of CCl_4 into trichloromethyl free radical by cytochrome P450 system in liver microsomes and causes lipid peroxidation of membranes that leads to the liver. [6] However, the cellular antioxidant action is reinforced by the presence of dietary antioxidants. [7-8] Antioxidants and anti-inflammatory agents play a critical role against CCl_4 intoxication by scavenging active oxygen and free radicals and neutralizing lipid peroxides. [9] Mounting evidence suggests that natural agents with antioxidant potential use as dietary supplements perform their protective and therapeutic potential against all of the liver diseases such as fatty liver. [10] Based on the above information, antioxidants are proposed to be valid in precaution against some poisoning substances including CCl_4. In fact, a previous report has investigated the protection activities of several naturally-occurring antioxidants against CCl_4 induced acute hepatotoxicity.[11] *Celastrus emarginata* Willd. (CE). Taxonomically *Celastrus paniculatus* belongs to the family Celastraceae is commonly known as Malkangani, Kangani, Jyotishmati, Sphutabandhani, Svarnalota, Black oil tree, Intellect tree, Climbing-staff plant is an important medicinal large, woody, a climbing shrub, distributed almost all over India up to an altitude of 1800-2000 meter is known for its ability to improve memory. [12-13] Ayurveda, the ancient Indian traditional system of medicine has used this plant seed for prevention and treatment of various diseases. [14] The plant has used for prevention and treatment of various diseases as cough, asthma, headache, leprosy, paralysis, leucoderma, rheumatism, and gout. The leaf sap is a good antidote for opium poisoning and leaves are emmenagogue. The bark is reported abortifacient activity. [15] CE Seed oil has been reported to improve memory and it is one of the components of the formulation recommended for memory enhancing and mental disorders "Mentat Syrup". The methanolic extract exhibits free-radical-scavenging properties and antioxidant

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Research article *Open Access*

Development and validation of UV spectroscopic method for simultaneou estimation of dapagliflozin and saxagliptin in synthetic mixture

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ABSTRACT

Aim

Simple, precise and accurate UV-Spectrophotometric Simultaneous Equation method for estimation of Dapagliflozin and Saxagliptin were developed and validated as per ICH guidelines.

Experimental and Results

The objective of the work is to develop UV spectroscopic method for simultaneous estimation of Dapagliflozin (DAPA) and Saxagliptin (SAXA). This Method involve solving of simultaneous equations based on measurement of absorbance at two wavelengths 223 nm and 212 nm. Both the drugs obey the Beer's law in the concentration ranges 4-24 µg/mL and 5-50 µg/mL respectively. Results of the methods were validated statistically. Novel, simple, sensitive, rapid, accurate and economical Spectrophotometric methods have been developed for simultaneous estimation of Dapagliflozin and Saxagliptin .The method can be used to estimate the amount of Dapagliflozin and Saxagliptin in mixture containing Dapagliflozin and Saxagliptin.

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Comparative evaluation of antioxidant, hypoglycemic and hypolipidemic potentials of Black tea from three major tea growing zones of India

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ABSTRACT

Tea is a very popular commercial crop and India is the world's largest consumer of tea in the world and the second largest producer of tea. Black tea is mostly preferred in Indian context and its multifaceted health benefits are being largely explored. This research article made a comparative study of antioxidant, hypoglycemic and hypolipidemic effect of Assam, Darjeeling and Nilgiri varieties of black tea. Research results have shown that Assam variety of tea has the highest antioxidant, hypoglycemic and hypolipidemic potentials followed by Nilgiri and Darjeeling variety.

INTRODUCTION

Tea is a very popular commercial crop, a worldwide popular beverage and being a source of several pharmacologically active molecules has currently attracted research limelight owing to its multifaceted pharmacologic actions. India is the world's largest consumer of tea in the world and the second largest producer of tea. As per historical records, the prevalence of tea drinking in India is since 750 BC [1]. Since 1947, India has approximately 563,980 hectares of land under tea cultivation and the largest tea cultivating states include Assam (304,400 hectares), West Bengal (140,440 hectares), Tamil Nadu (69,620 hectares) and Kerala (35,010 hectares). The versatile health aspects of tea are already being extensively studied [2, 3]. This research article focuses to study the antioxidant, hypoglycemic and hypolipidemic potentials of three different varieties of black tea (Darjeeling tea, Assam tea and Nilgiri tea) grown in three different states of India.

MATERIALS AND METHODS

Research material

Black tea of Darjeeling variety (DBT); Black tea of Assam variety (ABT); Black tea of Nilgiri variety (NBT)

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Enhancement in Iron Absorption on Intake of Chemometrically Optimized Ratio of Probiotic Strain *Lactobacillus plantarum* 299v with Iron Supplement Pearl Millet

Shanta Kumari Adiki[1] · Chandra Kiran Perla[1] · Gargi Saha[2] · Prakash Katakam[3] · Vinaykumar Theendra[1]

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Abstract
This research article aims to establish the intake ratio of probiotic *Lactobacillus plantarum* 299v with iron supplement pearl millet by central composite design of response surface methodology so as to enhance iron absorption. In anemic rat models, the food intake pattern, body weight, hemoglobin content, and hematocrit values were found to be significantly increased on treatment with pearl millet:probiotic; however, incorporation of probiotics at lower dose (0.5 g) was significantly ($p < 0.05$) effective in enhancing iron absorption, and further increment in probiotic doses (1.0 g) did not produce significant increase in hemoglobin and hematocrit values as evidenced by the experimental findings.

Keywords Probiotic · Iron absorption · Pearl millet · Anemia · Central composite design

Introduction

Iron, an essential micronutrient, is a redox metal that switches between the ferrous and ferric, the two oxidation states. It plays a very vital role in different physiological processes, viz., oxidative metabolism, oxygen transport, and cellular proliferation and participates in cell signaling processes [1]. Among the two major dietary irons, non-heme iron can be obtained both from plant and animal sources, and heme iron from the animal source. Non-heme iron is less well absorbed than the heme iron. Iron balance in the body is regulated by absorption, and there is not definitive mechanism for iron excretion; and if proper iron supplementation is not provided, the daily iron needs of the body are met by the breakdown of the circulating red blood cells [2]. The body losses iron either through the skin, urinary tract, respiratory airways, intestine, or menstrual blood loss. Anemia, mostly nutritional anemia with far reaching consequences, is a matter of public health concern [1]. Dietary iron fortification is an effective method for iron compensation [3]. Components like proteins, calcium, and plant secondary metabolites (polyphenols and the phytates) inhibit the iron absorption, whereas ascorbic acid promotes iron absorption.

Polyphenols, phenolic compounds, and tannins are widely distributed in food items like tea, coffee, blueberry, raspberries, apples, and walnuts. All polyphenols can inhibit non-heme iron absorption to a variable extent, and iron absorption inhibiting capacities of tea polyphenolics and catechins like epigallocatechin-3-gallate often range high from 60 to 90%. Phytates that are found in soy proteins, fibers, lentils, peas, cereals, walnuts, almonds, and seasame have the capacity to decrease non-heme iron bioavailability by 50 to 65%. Animal proteins from milk and egg also reduce iron absorption. Calcium affects negatively on both heme and non-heme iron bioavailability [2]. Literature mining reports the effect of probiotic mix on heme and non-heme iron bioavailability in humans; probiotic *Lactobacillus plantarum* 299v (Lp299v) increases non-heme iron absorption [4–6]. However, still scibetween Lp299v consumption and increase in absorption of non-heme iron [7]. This research article aims to establish the probiotic Lp299v to pearl millet (rich source of iron supplement) combination intake ratio by chemometric tools and study the potentiality of the combination ratio in enhancement of iron absorption in an evidence-based manner.

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Research article Open Access

Retrospective study on antibiotic use in different clinical departments of hospital in Nalut, Libya

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ABSTRACT

A retrospective Study on Antibiotic Use in Different Clinical Departments of Hospital in Nalut, Libya during a period of five months (1/1/2013to 30/5/2013). Data were collected retrospectively from inpatients medical files (600 patient's medical file), prescriptions for outpatients (400 prescriptions studied) and the total number of prescription was 1000. The data then was evaluated by Microsoft Excel software for analysis and descriptive statistics. The World Health Organization (WHO) indicators (utilization in defined daily doses (DDD): DDD/1000 inh/day) were used and the ATC/ DDD method was implemented. The three most frequently used antibiotics for inpatients were cefotaxime, ceftriaxone and metronidazole with 25.57%, 16.54% and 15.34% of the total prescribed antibiotics respectively, and for outpatients they were amoxiclav (26.23%), amoxicillin and azithromycin (12.41%) and ciprofloxacin (11.48%). After calculating the consumption of antibiotics in DDD, the highest consumed antibiotic in DDDs (g) was clarithromycin 10.67 g and 0.119 g in terms of DDD/1000inh/day, while consumption of amoxiclav was the lowest consumption 0.011 g and 0.00012 DDD/1000 in h/day. About 98% of patients given antibiotics without culture sensitivity tests (c/s). Only 2% of the patients undergone the test during the treatment. In conclusion, this study we identified that the DDD for antibiotic consumption data for five months and the clarithromycin was the most consumption over those months and we find out the most prescribed antibiotics and the most of the wards use it. In addition to the demographic data, this also helps physicians to have a more precise idea about prescriptive patterns prevalent in the Libyan community.

Keywords: Drug utilization research, Inpatient, Defined daily dose, Anatomical therapeutic chemical (ATC), Libya

INTRODUCTION

The dawn of antibiotics, which are one of the most booming drug groups used in medicine, dramatically improved the prognoses of patients with microbial infections. Unfortunately, following quite a few years of hopefulness, the over the top and unpredictable utilization of these antiinfection agents in both human and veterinary practices has prompted the development and spread of resistant organisms that imperil their viability, joined by undesirable symptoms and unwanted adverse effects [1].

In spite of the effectiveness of antimicrobials in the treatment of various bacterial diseases, usually they are utilized improperly worldwide [2]. This

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EMULGEL: AN OVERVIEW

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ABSTRACT

Emulgel is used to treat aches and pains caused by colds, headaches, muscle aches, backaches, arthritis and other conditions and injuries. The patient adherence to topical formulations is significant in relation to chronic skin diseases, like fungal infections, acne, psoriasis. Emulgel is one of the recent technology in NDDS used topically having characteristics of dual control release i.e. emulsion as well as gel. Emulgels have emerged as one of the most interesting topical delivery systems as it has dual release control system i.e. gel and emulsion. When gel and emulsion are used in combined form, the dosage form are referred as Emulgel.

KEYWORDS: Emulgel, Gelling agents, Topical drug delivery, Skin diseases.

INTRODUCTION[1,2,8]

Topical drug administration is simplest and easiest route of localized drug delivery anywhere in the body by routes as ophthalmic, rectal, vaginal and skin. These are applied as wide spectrum of preparations in case of both cosmetic and dermatological, to the healthy diseased skin. The formulations are available in different forms like from solid through semisolid to liquid. Drugs are administered topically for their action at the site of application or for systemic effects Drug absorption is enhanced through the skin if the drug substance is in solution, if it has a favorable lipid/water partition coefficient and if it is a non electrolyte. Mostly, pharmaceutical preparations applied to the skin are expected to serve some local action and are formulated to provide prolonged local contact with minimal systemic drug absorption. Drugs applied to the skin for their local action include antiseptics, antifungal agent, skin emollients and protectants. Topical drug administration is a localized drug delivery system anywhere in the body through ophthalmic, rectal, vaginal and skin as topical

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INVESTIGATION OF ORANGE PEEL ETHANOLIC EXTRACT AS AN ANTICATARACT AGENT

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ABSTRACT

The lens lies behind the iris and the pupil. It works much like a camera lens. It focuses light onto the retina at the back of the eye where an image is recorded. The lens also adjusts the eye's focus, letting us see things clearly both up close and far away. The lens is made of mostly water and protein. The protein is arranged in a precise way that keeps the lens clear and let's light pass through it. But as we age, some of the protein and clump together and start to cloud a small area of the lens. This is a cataract. Over time, the cataract may grow larger and cloud more of the lens, making it harder to see a leading cause of blindness and poor vision is a major public health problem worldwide. Diabetes and hyperglycemia have long been recognized as risk factor for cataract. The present study evaluated the in vitro Anticataract activities of orange peel Ethanolic Extract has rich source of flavonoids, show magnificent a Antioxidant activity against glucose-induced cataract genesis using goat lenses. using isolated goat lenses are incubated in artificial aqueous humor and divided into four experimental groups. The orange peel Ethanolic Extract at a dose of 500µg/ml is incubated simultaneously with glucose (55 mM) and glucose (5. 5mM) for a period of 72 h. ascorbic acid (20 µg/ml) is used as the standard drug. At the end of the incubation lense opacity is measured by photographic evaluation. The orange peel Extract shows significant inhibition of cataractogenesis of eye lenses at conc. 500 p.p.m. The present study suggested that the ethanol extract of orange peel possesses Anticataract activity.

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DEVELOPMENT AND VALIDATION OF SPECTROPHOTOMETRIC METHOD FOR SIMULTANEOUS ESTIMATION OF CIPROFLOXANCINE, TINIDAZOLE AND DICYCLOMINE HCL

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Abstract:

A Simple, accurate and precise UV Spectrophotometric method has been developed for the simultaneous estimation of Ciprofloxacin, Tinidazole and Dicyclomine Hcl in tablet. The method is based upon formation of simultaneous equation of these drugs and detections were carried out at wavelength of maximum absorbance of drugs; viz, 271nm, 317nm and 212nm for Ciprofloxacin,Tinidazole & Dicyclomine Hcl respectively. The linearity was found to be in the concentration range of 2-10 µg/ml for Ciprofloxacin,2-20 µg/ml for Tinidazole and 100-600 µg/ml for Dicyclomine Hcl respectively. The results of tablet analysis were found to be 99.98% for Ciprofloxacin and 100.05% for Tinidazole, 99.92% for Dicyclomine Hcl.The proposed methods can be effectively applied for the routine analysis of Ciprofloxacin, Tinidazol and Dicyclomine Hcl in bulk and combined dosage form.

Keywords: *UV Spectrophotometric method, Ciprofloxacin, Tinidazole, Dicyclomine Hcl, Simultaneous equation method.*

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Abstract:

A Simple, accurate and precise UV Spectrophotometric method has been developed for the simultaneous estimation of Ciprofloxacin, Tinidazole and Dicyclomine Hcl in tablet. The method is based upon formation of simultaneous equation of these drugs and detections were carried out at wavelength of maximum absorbance of drugs; viz. 271nm, 317nm and 212nm for Ciprofloxacin,Tinidazole & Dicyclomine Hcl respectively. The linearity was found to be in the concentration range of 2-10 µg/ml for Ciprofloxacin,2-20 µg/ml for Tinidazole and 100-600 µg/ml for Dicyclomine Hcl respectively. The results of tablet analysis were found to be 99.98% for Ciprofloxacin and 100.05% for Tinidazole, 99.92% for Dicyclomine Hcl.The proposed methods can be effectively applied for the routine analysis of Ciprofloxacin, Tinidazol and Dicyclomine Hcl in bulk and combined dosage form.

Keywords: *UV Spectrophotometric method, Ciprofloxacin, Tinidazole, Dicyclomine Hcl, Simultaneous equation method.*

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Development and Validation of RP-HPLC Method for the Estimation of Gemigliptin

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Keywords: Gemigliptin, RP-HPLC, Validation.

ABSTRACT

The RP-HPLC method has been developed for the estimation of Gemigliptin. The quantification was carried out C_{18} bonded phase i.e. Zorbax Eclipse XDB-C_{18} (4.6×250mm×5µ) with particle size 5 µm in an isocratic mode with a mobile phase consisting of Methanol: Water (20:80 % v/v). The detection was carried out using a UV detector at 233 nm. The solutions of Gemigliptin was chromatographed at a constant flow rate of 1 ml/min & the retention time of the drug was found to be 2.3 min. The linearity range of Gemigliptin was found to be from 1- 35 µg/ml. linear regression coefficient was 0.999. As per ICH guideline, the method was validated for recovery, Precision, ruggedness and linearity.

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INVESTIGATION OF ORANGE PEEL ETHANOLIC EXTRACT AS AN ANTICATARACT AGENT

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ABSTRACT

The lens lies behind the iris and the pupil. It works much like a camera lens. It focuses light onto the retina at the back of the eye where an image is recorded. The lens also adjusts the eye's focus, letting us see things clearly both up close and far away. The lens is made of mostly water and protein. The protein is arranged in a precise way that keeps the lens clear and let's light pass through it. But as we age, some of the protein and clump together and start to cloud a small area of the lens. This is a cataract. Over time, the cataract may grow larger and cloud more of the lens, making it harder to see a leading cause of blindness and poor vision is a major public health problem worldwide. Diabetes and hyperglycemia have long been recognized as risk factor for cataract. The present study evaluated the in vitro Anticataract activities of orange peel Ethanolic Extract has rich source of flavonoids, show magnificent a Antioxidant activity against glucose-induced cataract genesis using goat lenses. using isolated goat lenses are incubated in artificial aqueous humor and divided into four experimental groups. The orange peel Ethanolic Extract at a dose of 500µg/ml is incubated simultaneously with glucose (55 mM) and glucose (5. 5mM) for a period of 72 h. ascorbic acid (20 µg/ml) is used as the standard drug. At the end of the incubation lense opacity is measured by photographic evaluation. The orange peel Extract shows significant inhibition of cataractogenesis of eye lenses at conc. 500 p.p.m. The present study suggested that the ethanol extract of orange peel possesses Anticataract activity.

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Research Article

Development of An Antidiabetic Phytocomposite Loaded Phytoceutical Formulation, Its Quality Control and Pharmacokinetic Studies and Establishing *In Vitro- In Vivo* Correlation

De Baishakhi[1], Bhandari Koushik[1], Katakam Prakash[2], Adiki K Shanta[3], Mitra Analava[1*]

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ABSTRACT

This study reports the development of solid oral phytoceutical formulations with Phytocomposite (PHC), an antidiabetic poly herbal preparation as the active core material. Spherical, monolithic PHC microspheres of size range (10 -100 µm) were obtained with Hausner ratio, Carr's index and angle of repose of 1.141± 0.010, 12.418±0.769 and 25.17±0.96 respectively. Encapsulation efficiency amongst different batches (F1-F5) ranged from 96.8- 100.7, with 99% release profile up to 12h. Conventional and sustained release tablets were prepared by direct compression and compatibility amongst polymers and the PHC checked by FTIR studies. Natural polymers viz. gum kondagogu, gum karaya, *Aegle marmelos* gum were used as release retardant. Optimized batch of conventional tablets (F6) showed 99.8 % release in 35 min and optimized batch of PHC-SR tablets (F12) showed 99.9% release at 12th hr, both followed zero order kinetics and non-Fickian diffusion. These optimized formulations were subjected to stability studies and the similarity factors (f2) of the conventional and SR tablets were 88.75 and 66.76 respectively. Pharmacokinetic parameters of three formulations in rat plasma were analyzed by PK Solver 2.0. *In vitro-in vivo* correlation (IVIVC) of three different formulations showed Level A correlation in all cases.

Keywords: phytocomposite, microspheres, conventional, sustained release, phytoceutical, Level A correlation.

INTRODUCTION

Considering the multiple etiology of Type 2 diabetes, therapeutic strategies in treating Type 2 diabetes have undergone a radical change and focuses on multi dimensional aspects viz. hormonal effects, oxidative stress, cell signaling defects, hyper or hypo activities of enzymes etc[1,2]. Enzymes like alpha amylase, alpha glucosidase, aldose reductase, dipeptidyl peptidase 4 are considered to play a role in the pathogenesis of Type 2 diabetes[2]. Currently there has been a great resurgence of interest in phytomedicine in the treatment of chronic ailments. Pharmacologically active molecules from natural sources inhibiting such enzymes can serve as effective therapeutic entities in the management of Type 2 DM. Indian subcontinent is bestowed with natural phytomedicinal hub with several pharmacologically active phytochemicals that can serve as Natural enzyme inhibitors (NEIs) as well as active pharmaceutical ingredients (API) which can be implemented in the control of this chronic disease[2].

Combination therapy with poly herbals or phytoceuticals has gained popularity in terms of providing multiple and synergistic health benefits[1]. Oleanolic acid is found to provide a synergistic effect with first line antidiabetic metformin[3]. Sesame oil forms a synergistic antidiabetic combination with glibenclamide[4]. Research works of Mitra et al. have shown that Fenugreek-tulsi composite or composite prepared from the Tulsi leaves (*Ocimum sanctum*), Amla (*Emblica officinalis*), Bitter Gourd (*Momordica charantia*), Gurmur leaves (*Gymnema sylvestre*) and Jamun (*Syzygium cumini*) fruit and its seed help in controlling the blood gluco-lipid profile of Type 2 diabetics and is accepted by the indigenous or tribal populace of Bengal as surveyed in Binpur and Jhargram area of rural Bengal[5-7].

Ficus benghalensis (Indian Banyan tree, family *Moraceae*), *Syzigium cumini* (Jamun or Black pulm, family *Myrtaceae*) and *Ocimum sanctum* (Holy Basil or Tulsi, family *Lamiaceae*) have documented anti-diabetic potentials. A poly herbal product, named as phytocomposite (PHC), prepared from the leaf powders of Banyan, Jamun and Tulsi in varying weight ratios is found to show synergistic antioxidant and anti-diabetic actions in various *in vitro* enzyme inhibitory assays that are found to play a role in the pathogenesis of Type 2 diabetes[2].

Despite immense potentialities of the phytomedicines, the preparation and delivery pattern being traditional (either as whole extracts or individual herbs) problem arises due to patient noncompliance owing to organoleptic issues,

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Review Article

PBPK Modeling - A Predictive, Eco-Friendly, Bio-Waiver Tool for Drug Research

Author(s): Ba Bhanu De, Koushik Bhandari, Raman Mukherjee, Prakash Katakam, Shanta K. Adiki, Rohit Gundamaraju and Analava Mitra*

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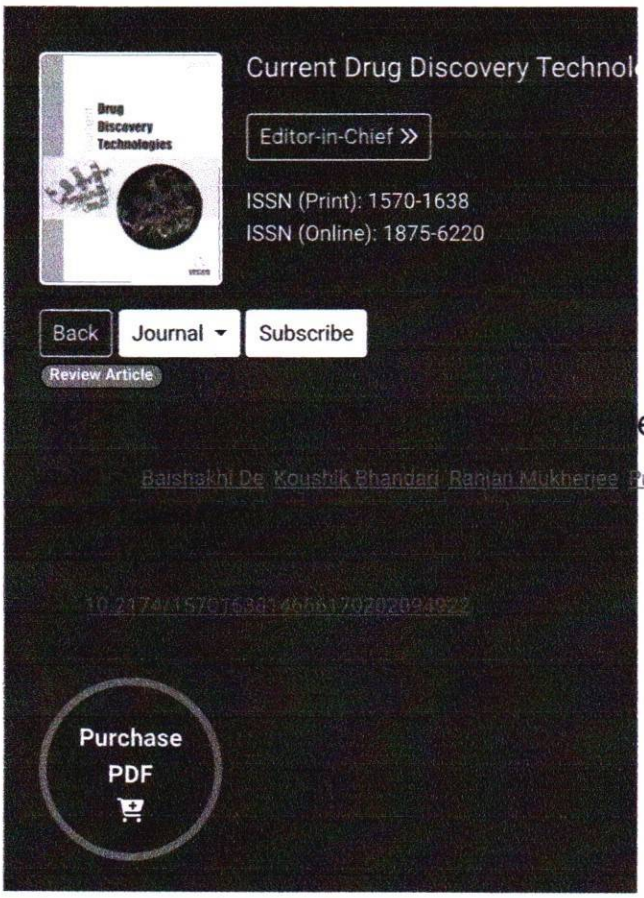
Abstract



Abstract

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Research article Open Access

Influence of guar gum, tragacanth and HPMC E-5 on fluconazole release from lozenzes

Bharkad V.B[1*], Jadhav Suvarna[2], Kadam Vaishali S[1], Suraj Sukare[1], Prakash Katakam[1], Deshmukh Kshitija[1], Shendarkar G.R[3], Kadam Sangita S[4]

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ABSTRACT

Topical application of drug prevents several drug interactions and lozenge is a better delivery system as the effective concentration of drug can be maintained in the oral cavity for a more prolonged period of time. The aim of study was to develop and evaluate fluconazole lozenges for topical therapy of oropharyngeal candidiasis. The current investigation was designed to improve patient compliance and its efficacy by delivering anti-fungal drug in the form of lozenges. Fluconazole is having poor flowing property it was decided to go for wet granulation in order to increase its ability to flow. For the formulation of compressed tablets lozenges guar gum, tragacanth and HPMC E-5 was used as drug release polymer. Other excipients used were gelatin 6% solution (as binder), sucrose (taste masking agent), methyl paraben (as preservative) and Magnesium stearate (lubricating agent). Among all the formulations F8 showed 98.33 % drug release at 35 min, thickness 4.0±0.1mm, hardness 3.3±0.3 kg/cm3, Friability 0.72±0.26%. F8 batch showed better drug release than other batches, hence F8 was the optimized batch from all formulations.

Keywords: Fluconazole lozenges, Guar gum, Tragacanth, HPMC E 5.

INRODUCTION

Oral drug delivery is the most preferred and simplest means as the oral route provides a maximum active surface area of all drug delivery system for administration of various drugs. The oral route of drug administration has been widely used for both conventional as well as novel drug delivery. The lozenges are solid medicated, flavored and sweetened base dosage forms intended to be sucked and hold in the mouth or pharynx to treat local irritation, mouth or pharynx infection. [1]

Lozenges should dissolve slowly in mouth and possess some degree of smoothness, with their shape being without corners. Lozenges may be formulated with various shapes, like flat, circular, octagonal, biconvex or bacilli, meaning short rods or cylinders. Lozenges are placed in oral cavity. Since the sublingual lozenges may be impractical due to their size, buccal lozenges are formulated and have been

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Original Article

Comparative *in-vivo* Evaluation of Anti-Cancer Drugs Loaded Nanospheres

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ABSTRACT

Objectives: objective of present research was to formulate and evaluate nanospheres of selected anticancer drugs, viz., Capecitabine (CPN), Tamoxifen (TAM) and Doxorubicin (DXO). The adverse effects associated with anticancer drugs which include are bone-marrow depression, cardio toxicity, diarrhoea, nausea and vomiting, stomatitis and dermatitis. **Materials and Methods:** Drug loaded nanospheres of polycaprolactone-chitosan in various drug: polymer ratios, cross linked with Tripolyphosphate were prepared by double emulsion solvent evaporation and solvent diffusion methods. Male white New Zeeland Rabbits(weighing about 2500 gm) were selected as the animalmodel. The rabbits selected for the study had no medicationfor two weeks prior to the study. **Results and Discussion:** The parameters like AUC(0-24) of DXO nanospheres 2362.0 ng.h/mL, whereas DXO pure drug was 1956.5 ng.h/mL. AUC (0-24) of TAM nanospheres 5646.00 ng.h/mL. Whereas TAM unadulterated medication was 4786.30ng.h/mL. AUC (0-24) of CPN nanospheres 4927.40 ng.h/mL. Whereas CPN pure drug was 4027.5ng.h/mL. **Conclusion:** *In vivo* results showed a significant increase in the bioavailability of drugs from DXO6, CPN6 and TAM6 nanospheres when compared to those of the standard drugs. This enhanced bioavailability could be helpful in reducing the dose of DXO, CPN and TAM and also reduce their toxicities. This enhanced bioavailability could be helpful in reducing the dose and also reduce the toxicities of the selected drugs.

Key words: Doxorubicin, Tamoxifen, Capecitabine, Nanospheres, *in vivo* studies.

INTRODUCTION

Tamoxifen (TAM) is a nonsteroidal specialist that ties to estrogen receptors (ER), propose a conformational change in the receptor. The outcome is a blockage or change in the indication of estrogen qualities.[1] TAM is utilized to treat a breast tumor that has reach out to different parts of the body, to treat breast growth in specific patients after surgery and radiation treatment. Doxorubicin (DXO) has antimitotic and cytotoxic activity through a numeral of future components of activity. DXO shapes edifices with DNA by intercalation between base sets, and it restrains topoisomerase II movement by settling the DNA-topoisomerase II complex. DXO is an anthracycline sort of chemotherapy that is utilized alone or with different medications to treat a few distinct sorts of breast tumor.[2] Capecitabine (CPN) is a prodrug that is specifically tumor-initiated to its cytotoxic moiety[3] fluorouracil, by thymidine phosphorylase.[4] CPN is utilized alone or with different medicines/drugs to take care of positive sorts of malignancy like colon, rectum.[5] The adverse effects associated with anticancer drugs which include are bone-marrow depression, cardio toxicity, diarrhoea, nausea and vomiting, stomatitis and dermatitis.[6] Therefore the objective of the present study was to evaluate the bioavailability studies of these drugs in order to eliminate its adverse effects.

Nanoparticles take an interest to a great degree basic obligation in tumor study. Because of a massively minimal size of nanoparticles they are basically and included

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RESEARCH ARTICLE ISSN: 2320 - 0782 V5-(I3) PG(34-57)

Study the enzyme inhibitory potentialities of a phytocomposite for Type 2 diabetes by *in silico* GRIP docking

Baishakhi De[1], Rajeev K Singla[2], Koushik Bhandari[1], Prakash Katakam[3], Shanta K Adiki[4], Analava Mitra[1*]

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ABSTRACT

This study reports the identification and characterization of pharmacologically active compounds present in a polyherbal product phytocomposite (PHC) prepared from the leaf powders of *Ficus benghalensis* (Banyan), *Syzigium cumini* (Jamun) and *Ocimum sanctum* (Tulsi) and explore the binding affinities of the compounds in PHC in inhibiting α-amylase and Dipeptidyl Peptidase 4 by *in silico* GRIP docking studies using V Life MDS software. These enzymes are found to play a role in the pathogenesis of Type 2 diabetes. MALDI-ToF spectra of the PHC showed compounds in the molecular range of 137-537g/mol. HPLC quantitation showed 0.22% w/w of lupeol, 1.24% w/w of rutin, 0.14% w/w of eugenol and 0.25% w/w of ursolic acid. Rutin showed highest negative dock score for inhibiting DPP4 and Eugenol in inhibiting α amylase. Lupeol, rutin, eugenol and ursolic acid all exhibit antidiabetic and antioxidant effect and their cumulative effect accounted for synergistic antidiabetic effect of PHC.

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Keywords:
Currency, Microbial contaminations, Cross-sectional study, Al-Kharj *spinachristi, Garcinia kola*

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Bacterial contamination of Saudi Arabian paper currency: A report from Al-Kharj

Mohammad Muqtader Ahmed*[,1], Farhat Fatima[1], Mohammad Javed Ansari[1], Ramadan Al-Shdefat[1], Mohammad Khalid Anwer[1], Shahid Jamil[1], Mutasim Osman Ahmed[1], Yonus Saeed[1], Mohammed Noor[1], Prakash Katakam[2], Aleemuddin M[3], Ayesha Farheen[4]

Abstract

Background: Currency is a public support tool for exchange of commodity and services. It's prevalent practice for acquiring bread to broast and bath to bed has connected all human being together irrespective of race and occupation. Currency notes along with their denomination values also carry pathogens if contaminated and will act as an agent for infection transference. Therefore the objective of this cross-sectional study was to assess the load microbial pathogens of paper currency collected in selected public places of Al-Kharj, Saudi Arabia.

Methods: Currency notes under study were assessed through microbiological culture, microscopic and biochemical visualization techniques.

Results: The results from this cross-sectional study suggested that lower the currency denominations higher was the microbial contaminations, frequency percentage was lower with higher isolations. Small eateries were the biggest source of contaminated currency from the ten selected centres. Percentage microorganism occurrence for *Bacillus* sp., *Staphylococcus* sp., *Klebsiella* sp. *and E. coli was* 56.84%, 25.03%, 13.40% and 04.71% respectively in all currency notes under study.

Conclusions: The outcomes of this study revealed that currency notes can be a source for microbe transmission causing infectious diseases represent public health hazards to the community and individuals.

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DEVELOPMENT AND EVALUATION OF ORAL MEDICATED JELLY OF ONDANSETRON HYDROCHLORIDE

Jadhav S. B.[1]*, Bharkad V. B.[1], Shinde M. K.[1], Kadam V. S.[1] and Katkam P.[2]

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ABSTRACT

The aim of present investigation was to formulate and evaluate the oral medicated jelly containing Ondansetron HCl for the treatment of nausea and vomiting. Jellies are semisolid to thick viscous fluids which is easily taken by patients of advanced age, patients with disability in ingestion of food and drink in other word those having difficulty in mastication and swallowing. The benefit of these prepared medicated jellies are increased bioavailability by passing first pass metabolism, easily taken without water and accepted by paediatrics easily. Jellies are prepared by heating and congealing method by dispersing gelling agents in water and evaluated for their physicochemical parameters like appearance, stickiness, pH, viscosity, spreadability, stability studies, drug release and content uniformity. All batches (F1-F12) of medicated jelly showed acceptable and comparable appearance, pH, viscosity, spreadability, stability studies, drug release and content uniformity. The viscosity range was found to be 619007 to 710077cps. The drug content of F1 to F12 formulations was found to be in the range of 95.21 to 103.76%. F8 batch prepared with xanthan gum shows 101.04%. drug release.

KEYWORDS: Oral medicated jelly, Heating and Congealing, Ondansetron HCl, Gelling agents, Nausea and Vomiting.

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Development and validation of RP-HPLC method for simultaneous estimation of paracetamol and chlorzoxazone in bulk form

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ABSTRACT

High performance liquid chromatography (HPLC) method was developed and validated for the analysis of Paracetamol and Chlorzoxazone. Chromatographic separation achieved isocretically on C-18 column Zorbax Eclipse XDB- C18 (4.6~250mm~5µ). Utilizing a mobile phase Acetonitrile: Water in the ratio 50:50v/v. with a flow rate of 1.5ml/min. UV detection was carried out at 274nm. The retention time of Paracetamol and Chlorzoxazone <10 min respectively. The developed method was validated in terms of recovery. precision..rggedness. robustness. linearity as per ICH guidelines. This study aimed at developing and validating an HPLC method.

Keywords: RP-HPLC. Paracetamol. Chlorzoxazone. Validation.

INTRODUCTION

Paracetamol (PCM) chemically is 4-hydroxyacetanilide [1]. Paracetamol acts by complex and includes the effects of both the peripheral (COX inhibition) and central (COX serotonergic descending neuronal pathway. L-arginine/NO Pathway. cannabinoid system) antinociception processes and redox mechanism. [2] Paracetamol is well tolerated drug and produces few side effects from the gastrointestinal tract. Chemical structure of PCM in given fig.1. Chlorzoxazone(CHZ) Chemically is 2(3H)-Benzoxazolone.5-chloro-5-chloro-2 benzoxazolinone.[3]

Chlorzoxazone acts by inhibiting multi synaptic reflexes involved in producing and maintaining skeletal muscle spasm of varied aetiology. It acts on the spinal cord by depressing reflexes. CHN a synthetic compound inhibits antigen-induced bronco spasms. CHN inhibits degranulation of mast cells. Subsequently preventing the release of histamine and slow-reacting substance of anaphylaxis (SRS-A). mediators of type-1 allergic reactions. CHZ also may reduce the release of inflammatory leukotrienes.[4] in given in CHZ in fig.2.

Literature survey revealed that various analytical technique such as spectrophotometric

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DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF METHYLDOPA AND HYDROCHLOROTHIAZIDE IN BULK FORM

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ABSTRACT

Present work concerns with development of high performance liquid chromatographic (HPLC) method development for simultaneous determination of Methyldopa and Hydrochlorothiazide in combined dosage form. Chromatographic separation was achieved isocratically on C18 Column Zorbax Eclipse XDB(4.6×250mm×5µ) utilizing Mobile phases consists of Methanol: Water (30:70 v/v) with flow rate of 1ml/min, with detection of 267nm. The Retention Time for Methyldoa & Hydrochlorothiazide was found to be 2.420min and 3.220 min respectively. The developed method was validated in terms of recovery, precision, Ruggedness, Robustness, linearity. This study aimed at developing and validating an HPLC method.

KEYWORDS: Methyldopa, Hydrochlorothiazide, RP- HPLC, Validation.

INTRODUCTION

Methyldopa (MD) (Fig.1) is 3-(3, 4dihydrophenyl)-2-Methyl-L-alanine sequihydrate is Chemical name of methyldopa.[1] It is White to yellowish white, Fine powder which may contain friable lumps it is slightly soluble in water, very slightly soluble in Ethanol (95%), practically insoluble in chloroform and in ether. It is freely soluble in dilute hydrochloric acid.[2]

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INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

STABILITY INDICATING VALIDATED DISSOLUTION METHOD FOR DETERMINATION OF PROPRANALOL AND HYDRALAZINE BY MULTICOMPONENTMODE METHOD AND SECOND ORDER DERIVATIVE METHOD

***Hajera Khan, DhotreLaxmi, A. G Mangulkar., MD Zameeruddin**

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Dissolution, Spectroscopy,
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Stability, Validation.

ABSTRACT

The aim of this work was development and validation of a dissolutionmethod for Propranolol and Hydralazine (Carbetazine Tablets). The dissolution established conditions were 900 mL of 0.1M HCl (pH 1.0) as dissolution medium, using a paddle apparatus at a stirring rate of 50 rpm. The drug release was evaluated by UV spectrophotometric method the absorbance of solution were recorded at288.20nm and 259.20nm for Propranolol and Hydralazinemixture for Multicomponent Mode methodand at 221.8nmand 243.36nm for Propranolol and Hydralazine respectively for Second order derivative method .Ahead of the results it can be concluded that the method developed consists in an efficient alternative for assays of dissolution for tablets.

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INTRODUCTION

Propranolol hydrochloride (PRP)chemically is (RS)-1-[(1-methylethyl) amino]-3-(naphthalene-1-yloxy) propan-2-olhydrochioride [Barar, 2009] and chemical structure of PRP is given in the Fig. 1.The exact mode of hypertensive action is including an effect on the CNS, an adrenergic neuron blocking effect, an antirenin effect and the resetting of the baroreceptors. The cardiac output falls, and on prolonged use an initial rise in TPR is followed by a fall. Propranolol has appreciable antirenin activity and its response is good in moderate hypertensive with normal or high Propranolol, whereas it is poor if the is low [Indian Pharmacopeia, 1996]. Propranolol has been lately employed in the management of malignant hypertensive emergencies. Hydralazine (HCZ) chemically is phthalazin-1-ylhydrazine hydrochloride [Barar, 2009]. Chemical structure of HCZ is given in the fig. 2.Hydralazine directly dilates the arteriole, reducing the TPR. It seems to exert a more favorable effect on the diastolic BP than on the systolic BP, as it affects the precapillary resistance vessels much more than the post capillary capacitance vessels. Hydralazine reflex stimulates the heart, causing tachycardia, increased cardiac output and blood flow[Indian Pharmacopeia, 1996]. Literature survey revealed that various analytical technique such as spectrophotometric technique[Chapke and Game, 2013; Hapse et al., 2012; Sahu and Patel, 2006; Adegoke, 2008; de AssisGonsalves, 2011]. Several methods based on separation technique including HPTLC[Bhavar and Chatpalliwar, 2008; Patilet al., 2012; Shahet al., 2007], and HPLC[Srikanthet al., 2012; El-Saharty, 2003; Tulja Rani et al., 2011] have been reported. No single method is available for this combination by using mobile phase as methanol: ortho phosphoric acid (60:40v/v). The present work therefore emphasizes on the quantitative estimation of PRP and HCZ in synthetic mixture by HPLC. This method was validated as per the International Conference on Harmonization (ICH) guidelines [ICH, Q2A1994; ICH, Q2B1996].

MATERIALS AND METHODS

Gift sample of Propranolol was obtained from Flamigo Private Ltd., Nanded. And Gift sample of Hydralazine was obtained from Alkem laboratories limited, taloja MIDC, Navi Mumbai. Formulations of Propranolol and Hydralazine are purchased from local market (Carbetazine).

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Research Article

STABITY INDICATING DISSOLUTION METHOD DEVELOPMENT FOR ESTIMATION OF PARACETAMOL AND CHLORZOXAZONE IN COMBINE DOSAGE FORM

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ABSTRACT

The aim of this work was to develop dissolution test method for Paracetamol and Chlorzoxazone in combination tablet. The dissolution established conditions were 900 mL of 0.1M HCl pH 1.0 as dissolution medium, using a paddle apparatus at a stirring rate of 50 rpm. The assay was performed by spectrophotometry for the better conditions stirring speed of 50 rpm, is used .Ahead of results it can be concluded that the method developed consists in an efficient alternative for assay of dissolution for tablets. The method was validated to meet requirements for a global regulatory filing which includes linearity, precision, accuracy robustness and ruggedness. In addition, filter suitability and drug stability in medium were demonstrated.

KEYWORDS:*Dissolution study of Paracetamol and Chlorzoxazone, In vitro release, Spectrophotometry, Q-Analysis Method, Validation.*

INTRODUCTION

Paracetamol (PCM) chemically is 4-hydroxyacetanilide[1]. Paracetamol acts by complex and includes the effects of both the peripheral (COX inhibition) and central (COX serotonergic descending neuronal pathway, L-arginine/NO Pathway, cannabinoid system) antinociception processes and redox mechanism [2]. Paracetamol is well tolerated drug and produces few side effects from the gastrointestinal tract. Chemical structure of PCM is given fig .1.

Chlorzoxazone Chemically is 2(3H)-Benzoxazolone,5-chloro-5-chloro-2 benzoxazolinone[3].

Chlorzoxazone acts by inhibiting multi synaptic reflexes involved in producing and maintaining skeletal muscle spasm of varied aetiology.It acts on the spinal cord by depressing reflexes. CHN a synthetic compound, inhibits antigen-induced bronco spasms.CHN inhibits degranulation of mast cells. Subsequently preventing the release of histamine and slow-reacting substance of anaphylaxis(SRS-A), mediators of type-1 allergic reactions. CHZ also may reduce the release of inflammatory leukotrienes[4]. CHZ is given fig.2.

Literature survey revealed that various analytical technique such as spectrophotometric technique [5-8]. Several method based on separation technique including HPLC[9-11], have been reported. The method was validated as per the International Conference on Harmonization (ICH) guidelines [12,13].

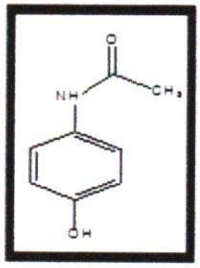

Fig. 1: chemical structure of Paracetamol

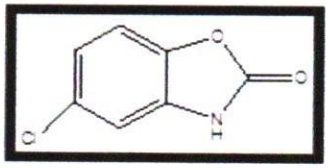

Fig. 2: chemical structure of Chlorzoxazone

MATERIALS AND METHODS

Materials:

Paracetamol was received as a gift samples from Glenmark Pharmaceuticals Ltd. (Goa, India) and Chlorzoxazone was received as a gift samples from Flemingo Pharmaceuticals Nanded, India.

Instrumentation:

Dissolution test was performed in a ELECTROLAB (VK7025) Model(TDT-06L)[14]dissolution apparatus, multi-bath (n=6), in accordance to USP Pharmacopoeia generalmethod. The medium were vacuum degassed under in house vacuum and weremaintained at 37.0 ± 0.5°C by using a thermostatic bath. A double-beam UV-Visiblespectrophotometer (Model:UV 1800,Shimadzu] with a fixed slit width (2 nm)using1.0 cm quartz cell was used for all absorbance measurements. Elico pH analyzer(Model: Elico 11610) was used to determine the pH of all solutions.

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ABSTRACT

The aim of this work was to develop dissolution test method for Paracetamol and Chlorzoxazone in combination tablet. The dissolution established conditions were 900 mL of 0.1M HCl pH 1.0 as dissolution medium, using a paddle apparatus at a stirring rate of 50 rpm. The assay was performed by spectrophotometry for the better conditions stirring speed of 50 rpm, is used .Ahead of results it can be concluded that the method developed consists in an efficient alternative for assay of dissolution for tablets. The method was validated to meet requirements for a global regulatory filing which includes linearity, precision, accuracy robustness and ruggedness. In addition, filter suitability and drug stability in medium were demonstrated.

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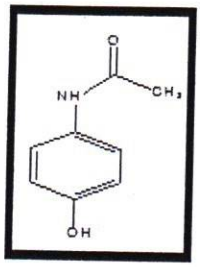
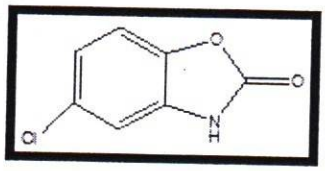


Fig. 1: chemical structure of Paracetamol



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STABITY INDICATING DISSOLUTION METHOD DEVELOPMENT FOR ESTIMATION OF METHYLDOPA AND HYDROCHLOROTHIAZIDE IN COMBINE DOSAGE FORM

H.N Khan*, Kodli Puja, Sana Javeria, MD Zameeruddin, A. G Mangulkar, V.B Bharkad

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Abstract:

The aim of this work was to develop validate a dissolution test for Methyldopa and Hydrochlorothiazide in combination tablets using spectrophotometric method. The dissolution established conditions were 900 mL of 0.1M HCl pH 1.0 as dissolution medium, using a paddle apparatus at a stirring rate of 50 rpm. The drug release was evaluated by UV spectrophotometric method the areas of solution were recorded at 274-284 nm and266-276 nm for Methyldopa *and Hydrochlorothiazide respectively. It can be concluded that the method developed consists in an efficient alternative for assay of dissolution for tablets. The method was validated to meet requirements for a global regulatory filing which includes linearity, precision, accuracy robustness and ruggedness. In addition, filter suitability and drug stability in medium were demonstrated*

Keywords: *In vitro release, Stability, Dissolution study of methyldopa and Hydrochlorothiazide, Spectrophotometry, Area under curve method, Validation.*

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Area Under Curve Spectrophotometric Method for Determination of Finasteride in Pharmaceutical Formulation

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(www.jpsbr.org)

ABSTRACT:

A simple, accurate and precise Area Under Curve spectrophotometric method was developed for determination of Finasteride in pharmaceutical dosage form. This method involves the calculation of integrated value of absorbance with respect to the wave-length between two selected wavelengths. The area selected between 210-220 nm for the determination of Finasteride. The drug follows Beer-Lambert's law over the concentration range of 2-10 µg/ml for Finasteride. The % estimation of the drug 99.546% representing the accuracy of the method. The recovery of Finasteride found near to 99.68. The validation of the proposed method was carried out for its accuracy, precision, limit of detection and limit of quantitation according to ICH guidelines. The proposed methods can be successfully applied in routine work for the determination of Finasteride in its pharmaceutical dosage form.

KEY WORDS: Spectroscopy, Area under curve,Methanol, Dimethyl Sulfoxide (DMSO), Finasteride, validation.

INTRODUCTION:

Finasteridechemically is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-en-3-one (Figure. 1).It is white in colour and crystalline powder. The molecular weight of Finasteride is 372.6g/ml and molecular formula is $C_{23}H_{36}N_2O_2$.[1]. It is competitive inhibitor of enzyme 5α-reductase which converts testosterone responsible for androgen action in tissues including prostate gland and hair follicles. Finasteride is antiandrogenicdrug and also found effectively in male baldness. It is effective orally,metabolized in liver and excreted in urine faeces.[2]Literature survey revealed UV ,HPLC and UPLC analytical methods for its estimation.[3-17] The validation of the proposedmethod was carried out by ICH guidelines.[18]

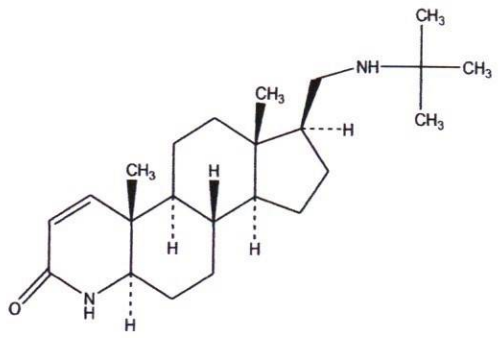

Figure 1: Chemical structure of Finasteride

MATERIAL AND METHODS:

Chemical:

A standard sample ofFinasteride was obtained as gift from Cipla Ltd. Mumbai, Maharashtra. FINAST 5mg tablet was

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Research article *Open Access*

Simultaneous spectrophotometric determination of methyldopa and hydrochlorothiazide in pharmaceutical dosage form by AUC and first order derivative method

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ABSTRACT

A New, Simple, Accurate And Sensitive UV-Spectrophotometric Method has been developed for simultaneous determination of Methyldopa And Hydrochlorothiazide(HCTZ) in bulk And combined dosage form .Method A is AUC method, which involved measurement of area between 276-286nm and 266-276nm for the estimation of MD and HCTZ respectively. Method B Applied first order derivative Spectrophotometry, which involved measuring the absorbance values at 271.40nm and 251.20nm of first derivative spectrum. Beer's law obeyed in concentration range of 10-60µg/ml and 2-14µg/ml for MD & HCTZ respectively by both Methods. Results of analysis were statistically reported & were found to be satisfactory.

Keywords: Methyldopa, Hydrochlorothiazide, Spectroscopy, AUC Method, First order derivative method.

INTRODUCTION

Methyldopa [3, 4] (MD) (Fig 1)is 3-(3, is Chemical name of methyldopa. It isWhite to yellowish white, Fine powder which may contain friable lumps it is slightly soluble in water, very slightly soluble in Ethanol (95%), practically insoluble in chloroform and in ether. It is freely soluble in dilute hydrochloric acid.

Hydrochlorothiazide [5, 6] (HCTZ)(Fig2) is 6-chloro-3, 4dihydro-2H-1, 2, 4, benzathiadiazine-7-sulphonamide. It is White or almost white, sparingly soluble in ethanol (95%).Very slightly soluble in water, it dissolves in dilute solution of alkali hydroxides Literature survey revealed UV-Visible spectrophotometric methods such as simultaneous equation method [7], Dual Wavelength method [8] and RP-HPLC [9, 10] for

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Research article Open Access

Development and validation of RP-HPLC method for simultaneous estimation of paracetamol and chlorzoxazone in bulk form

Hajera N. Khan*, Mahajan Swarali, Chopde Asha, Mohammad Zameeruddin, Vishvanath B. Bharkad.

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ABSTRACT

High performance liquid chromatography (HPLC) method was developed and validated for the analysis of Paracetamol and Chlorzoxazone. Chromatographic separation achieved isocretically on C-18 column Zorbax Eclipse XDB- C18 (4.6~250mm~5µ). Utilizing a mobile phase Acetonitrile: Water in the ratio 50:50v v. with a flow rate of 1.5ml/min. UV detection was carried out at 274nm. The retention time of Paracetamol and Chlorzoxazone <10 min respectively. The developed method was validated in terms of recovery, precision..rggedness, robustness, linearity as per ICH guidelines. This study aimed at developing and validating an HPLC method.

Keywords: RP-HPLC, Paracetamol, Chlorzoxazone, Validation.

INTRODUCTION

Paracetamol (PCM) chemically is 4-hydroxyacetanilide [1]. Paracetamol acts by complex and includes the effects of both the peripheral (COX inhibition) and central (COX serotonergic descending neuronal pathway, L-arginine NO Pathway, cannabinoid system) antinociception processes and redox mechanism. [2] Paracetamol is well tolerated drug and produces few side effects from the gastrointestinal tract. Chemical structure of PCM in given fig.1. Chlorzoxazone(CHZ) Chemically is 2(3H)-Benzoxazolone.5-chloro-5-chloro-2 benzoxazolinone.[3]

Chlorzoxazone acts by inhibiting multi synaptic reflexes involved in producing and maintaining skeletal muscle spasm of varied aetiology. It acts on the spinal cord by depressing reflexes. CHN a synthetic compound inhibits antigen-induced bronco spasms. CHN inhibits degranulation of mast cells. Subsequently preventing the release of histamine and slow-reacting substance of anaphylaxis (SRS-A), mediators of type-1 allergic reactions. CHZ also may reduce the release of inflammatory leukotrienes.[4] in given in CHZ in fig.2.

Literature survey revealed that various analytical technique such as spectrophotometric

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STABITY INDICATING DISSOLUTION METHOD DEVELOPMENT FOR ESTIMATION OF METHYLDOPA AND HYDROCHLOROTHIAZIDE IN COMBINE DOSAGE FORM

H.N Khan*, Kodli Puja, Sana Javeria, MD Zameeruddin, A. G Mangulkar, V.B Bharkad

SSS Indira College of Pharmacy, Vishnupuri, Nanded-431606. Maharastra, India.
Nanded Pharmacy College, Nanded-431606, Maharastra, India.

Abstract:

The aim of this work was to develop validate a dissolution test for Methyldopa and Hydrochlorothiazide in combination tablets using spectrophotometric method. The dissolution established conditions were 900 mL of 0.1M HCl pH 1.0 as dissolution medium, using a paddle apparatus at a stirring rate of 50 rpm. The drug release was evaluated by UV spectrophotometric method the areas of solution were recorded at 274-284 nm and266-276 nm for Methyldopa *and Hydrochlorothiazide respectively. It can be concluded that the method developed consists in an efficient alternative for assay of dissolution for tablets. The method was validated to meet requirements for a global regulatory filing which includes linearity, precision, accuracy robustness and ruggedness. In addition, filter suitability and drug stability in medium were demonstrated*

Keywords: *In vitro release, Stability, Dissolution study of methyldopa and Hydrochlorothiazide, Spectrophotometry, Area under curve method, Validation.*

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INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

STABILITY INDICATING VALIDATED DISSOLUTION METHOD FOR DETERMINATION OF PROPRANALOL AND HYDRALAZINE BY MULTICOMPONENTMODE METHOD AND SECOND ORDER DERIVATIVE METHOD

***Hajera Khan, DhotreLaxmi, A. G Mangulkar., MD Zameeruddin**

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Dissolution, Spectroscopy,
Multicomponent Mode method,
Second order derivative method,
Stability, Validation.

ABSTRACT

The aim of this work was development and validation of a dissolutionmethod for Propranolol and Hydralazine (Carbetazine Tablets). The dissolution established conditions were 900 mL of 0.1M HCl (pH 1.0) as dissolution medium, using a paddle apparatus at a stirring rate of 50 rpm. The drug release was evaluated by UV spectrophotometric method the absorbance of solution were recorded at288.20nm and 259.20nm for Propranolol and Hydralazinemixture for Multicomponent Mode methodand at 221.8nmand 243.36nm for Propranolol and Hydralazine respectively for Second order derivative method .Ahead of the results it can be concluded that the method developed consists in an efficient alternative for assays of dissolution for tablets.

Citation: Hajera Khan, Dhotre Laxmi, mangulkar, A. G. and Zameeruddin, 2017. "Stability indicating validated dissolution method for determination of propranalol and hydralazine by multi component mode method and second order derivative method", *International Journal of Current Research*, 9, (11), 60355-60360.

INTRODUCTION

Propranolol hydrochloride (PRP)chemically is (RS)-1-[(1-methylethyl) amino]-3-(naphthalene-1-yloxy) propan-2-olhydrochioride [Barar, 2009] and chemical structure of PRP is given in the Fig. 1.The exact mode of hypertensive action is including an effect on the CNS, an adrenergic neuron blocking effect, an antirenin effect and the resetting of the baroreceptors. The cardiac output falls, and on prolonged use an initial rise in TPR is followed by a fall. Propranolol has appreciable antirenin activity and its response is good in moderate hypertensive with normal or high Propranolol, whereas it is poor if the is low [Indian Pharmacopeia, 1996]. Propranolol has been lately employed in the management of malignant hypertensive emergencies. Hydralazine (HCZ) chemically is phthalazin-1-ylhydrazine hydrochloride [Barar, 2009]. Chemical structure of HCZ is given in the fig. 2.Hydralazine directly dilates the arteriole, reducing the TPR. It seems to exert a more favorable effect on the diastolic BP than on the systolic BP, as it affects the precapillary resistance vessels much more than the post capillary capacitance vessels. Hydralazine reflex stimulates the heart, causing tachycardia, increased cardiac output and blood flow[Indian Pharmacopeia, 1996]. Literature survey revealed that various analytical technique such as spectrophotometric technique[Chapke and Game, 2013; Hapse et al., 2012; Sahu and Patel, 2006; Adegoke, 2008; de AssisGonsalves, 2011]. Several methods based on separation technique including HPTLC[Bhavar and Chatpalliwar, 2008; Patilet al., 2012; Shahet al., 2007], and HPLC[Srikanthet al., 2012; El-Saharty, 2003; Tulja Rani et al., 2011] have been reported. No single method is available for this combination by using mobile phase as methanol: ortho phosphoric acid (60:40v/v). The present work therefore emphasizes on the quantitative estimation of PRP and HCZ in synthetic mixture by HPLC. This method was validated as per the International Conference on Harmonization (ICH) guidelines [ICH, Q2A1994; ICH, Q2B1996].

MATERIALS AND METHODS

Gift sample of Propranolol was obtained from Flamigo Private Ltd., Nanded. And Gift sample of Hydralazine was obtained from Alkem laboratories limited, taloja MIDC, Navi Mumbai. Formulations of Propranolol and Hydralazine are purchased from local market (Carbetazine).

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JOURNAL OF PHARMACEUTICAL SCIENCE AND BIOSCIENTIFIC RESEARCH (JPSBR)

(An International Peer Reviewed Pharmaceutical Journal that Encourages Innovation and Creativities)

Area Under Curve Spectrophotometric Method for Determination of Finasteride in Pharmaceutical Formulation

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(www.jpsbr.org)

ABSTRACT:

A simple, accurate and precise Area Under Curve spectrophotometric method was developed for determination of Finasteride in pharmaceutical dosage form. This method involves the calculation of integrated value of absorbance with respect to the wave-length between two selected wavelengths. The area selected between 210-220 nm for the determination of Finasteride. The drug follows Beer-Lambert's law over the concentration range of 2-10 µg/ml for Finasteride. The % estimation of the drug 99.546% representing the accuracy of the method. The recovery of Finasteride found near to 99.68. The validation of the proposed method was carried out for its accuracy, precision, limit of detection and limit of quantitation according to ICH guidelines. The proposed methods can be successfully applied in routine work for the determination of Finasteride in its pharmaceutical dosage form.

KEY WORDS: Spectroscopy, Area under curve,Methanol, Dimethyl Sulfoxide (DMSO), Finasteride, validation.

INTRODUCTION:

Finasteridechemically is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-en-3-one (Figure. 1).It is white in colour and crystalline powder. The molecular weight of Finasteride is 372.6g/ml and molecular formula is $C_{23}H_{36}N_2O_2$.[1]. It is competitive inhibitor of enzyme 5α-reductase which converts testosterone responsible for androgen action in tissues including prostate gland and hair follicles. Finasteride is antiandrogenicdrug and also found effectively in male baldness. It is effective orally,metabolized in liver and excreted in urine faeces.[2]Literature survey revealed UV ,HPLC and UPLC analytical methods for its estimation.[3-17] The validation of the proposedmethod was carried out by ICH guidelines.[18]

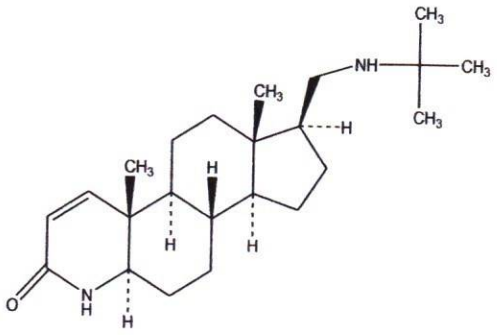

Figure 1: Chemical structure of Finasteride

MATERIAL AND METHODS:

Chemical:

A standard sample ofFinasteride was obtained as gift from Cipla Ltd. Mumbai, Maharashtra. FINAST 5mg tablet was

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SJIF Impact Factor 6.647
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FORMULATION AND EVALUATION OF FAST DISSOLVING ORAL FILM OF METOCLOPRAMIDE HCL

Kadam V. S.*[1], Bharkad V. B.[1], Shete G. A.[1], Jameel A.[1], Shendarkar G. R.[2] and Jadhav S. V.[3]

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Indira College of Pharmacy, Vishnupuri, Nanded, Maharashtra, India.

ABSTRACT

Oral films dissolve rapidly along with drug in mouth and majority of the drug is absorbed through buccal/oral mucosa in to systemic circulation avoiding first pass metabolism. The aim of present investigation was to formulate and evaluate the Fast dissolving oral films (FDOF) of Metoclopramide HCl (anti-emetic drug). Metoclopramide HCl film formulations were prepared by solvent casting technique using HPMC E5, E15, K4M, K15 as film forming polymer and PEG-400 as plasticizer. The prepared films were evaluated for their appearance, thickness, folding endurance, weight uniformity, % drug content, surface pH, tack test, disintegration time and in-vitro dissolution studies.

KEYWORDS: Metoclopramide HCl; fast dissolving oral films; Solvent casting method; In vitro dissolution.

INTRODUCTION

There are many different routes by which a medicinal agent can be placed for the convenient and efficacious treatment of a disease. Amongst all the routes of administration, oral route is most preferred route receiving more attention in the pharmaceutical field because of flexibility in the designing of dosage form than drug delivery design of other routes.[1]

A vast variety of pharmaceutical research is directed at developing new dosage forms. Most of these efforts have focused on either increasing the patient compliance or formulating novel

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Development and Validation of Area under curve Method for the Estimation of Clonidine HCl in Bulk and Pharmaceutical dosage form

H.N. Khan*,Chopde Asha, Mahajan Swarali, Md Zameeruddin, V.B. Bharkad

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*Corresponding Author E-mail: **khan.hajera@rediff.com**

ABSTRACT:

A simple, rapid, economical, precise and accurate Area under curve method was developed for determination of Clonidine HCl in bulk and pharmaceutical dosage form. The ethanol was used as solvent. The wavelength ranges selected for the analysis was 201-211nm. The Linearity was found to be between 1-5µg/ml. The % assay for commercial formulation was found to be in the range 99.93% – 100.03 %. Recovery was found in the range of 99.94 –99.97%. The results of analysis have been validated statistically and recovery studies confirmed the accuracy and reproducibility of the proposed methods which were carried out by following ICH guidelines.

KEYWORDS: Clonidine HCl, Area Under Curve Method, Validation.

INTRODUCTION:

Chlorthalidone(CHR) is Chemically is 2-chloro-5[(1RS)-1-hydroxy-3-oxo-2, 3-dihydro- 1H-isoindol-1yl) benzene-1-sulfonamide[1]. Chemical structure of chlorthalidone is shown in figure 1. Chlorthalidone is a diuretic drug used to treat hypertension and fluid retention caused by various conditions, including heart diseases. Chlorthalidone is very similar to hydrochlorothiazide and is used as an independent drug or in combination with other antihypertensive agents for lowering arterial blood pressure[2]. Diuretics lower blood pressure by decreasing cardiac output and reducing plasma and extracellular fluid volume[3]

Chemically clonidine HCl (CLD) is chemically ((2-[2, 6-dichlorophenyl] amino)-2-imidazoline) [4] preferentially stimulates central alpha (2)-adrenoceptors. Chemical structure of clonidine is shown in figure 2 which leads to inhibition of sympathetic tone, resulting in a lowering of arterial pressure and of heart rate[5].

Clonidine HCl is a centrally acting alpha agonist hypotensive agent used to treat hypertension (high blood pressure), attention deficit hyperactivity disorder, migraine etc. Clonidine HCl used to treat psychiatric disorders including stress, sleep disorders, other anxiety disorders. Mild sedative nature of Clonidine HCl implies its use as premedication before surgery or procedures[6].

Literature survey revealed UV-Visible spectrophotometric methods [7, 8] RP-HPLC [9, 10], HPTLC[11] and UPLC[12] Methods for the estimation of CHR and CLD alone or in combination with other drugs. The validation of methods was carried out as per ICH guidelines [13,14]

Figure 1.Chlorthalidone

Figure 2. Clonidine Hydrochloride

MATERIALS AND METHODS:

Instrument [15]:

The Present Work Was Carried out on Shimadzu UV 1800 Double Beam Visible Spectrophotometer Wave length range 190-1100Band Width 2nmm, with a pair of 1 cm matched quartz cells.

Reagents and Materials:

Pure samples of Clonidine HCl and chlorthalidone were provided as gift sample from Neon Lab. Ltd. Mumbai. Tablet Catapres (100mg) purchase from local market.

Clonidine standard stock solution:

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STABITY INDICATING DISSOLUTION METHOD DEVELOPMENT FOR ESTIMATION OF METHYLDOPA AND HYDROCHLOROTHIAZIDE IN COMBINE DOSAGE FORM

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Keywords: *In vitro release. Stability, Dissolution study of methyldopa and Hydrochlorothiazide, Spectrophotometry, Area under curve method, Validation.*

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Development and Validation of RP-HPLC Method for Simultaneous Determination of Aspirin and Omeprazole

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ABSTRACT

In this study, reverse phase high performance liquid chromatographic method have been developed and validated for the simultaneous determination of aspirin and omeprazole. The chromatographic separation was achieved in a Zorbax Eclipse XDB- C18 (4.6 × 250 mm × 5 µ) as a stationary phase Acetonitrile: Water (50:50, v/v) as mobile phase at a flow rate of 1 ml/min. UV detection was performed at 293 nm. The retention time of aspirin and omeprazole was found to be 3.260 and 1.787 min respectively. The results of analysis were validated statistically and by recovery studies. Linearity, accuracy and precision were acceptable in the ranges (2-14 µg/ml) for aspirin and (2-18 µg/ml) for omeprazole. The % recovery for aspirin and omeprazole was 99.79 and 99.61, respectively. The results of the studies showed that the proposed Reverse Phase High Performance Liquid Chromatography (RP-HPLC) method was simple, rapid, precise and accurate, which can be used for the routine determination of aspirin and omeprazole.

Keywords: Aspirin, Omeprazole, Liquid chromatography, Validation

INTRODUCTION

Aspirin (ASP) was Nonsteroidal anti-inflammatory, antirheumatic, antithrombic and chemically it was 2-Acetoxy benzoic acid. Chemical Structure of Aspirin was given in Figure 1, molecular formula was $C_9H_8O_4$, molecular weight is 180.16 g/mol [1].
Omeprazole (OME) was proton pump inhibitors chemically it was 5-Methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methy]sulfinyl]-1H-benzimidazole, chemical structure of omeprazole was given in Figure 2, molecular formula was $C_{17}H_{19}N_3O_3S$, molecular weight is 345.42 g/mol [2].

Literature survey revealed that there are various methods have been reported for estimation of ASP and OME by High Performance Liquid Chromatography (HPLC) method [3-7], UV-spectroscopic methods [8-10], Liquid Chromatography-Mass Spectrometry (LC-MS) [11-13] and High-performance Thin-Layer Chromatography (HPTLC) method [14] individually and in combined dosage form with other drugs. But no single method is available in combination by using this mobile phase. The present work therefore emphasizes on the quantitative estimation of ASP and OMP in synthetic mixture by HPLC. The proposed method was validated as per the International Conference on Harmonization (ICH) analytical method validation guidelines [15].

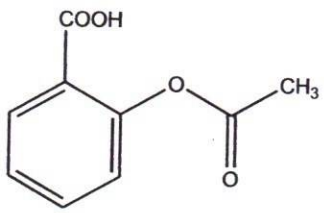

Figure 1: Aspirin

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(http://www.derpharmachemica.com/archive.html)

Development and Validation of RP-HPLC Method for Simultaneous Determination of Aspirin and Omeprazole

Hajera N Khan*, Swapna S Bandewar, Mohammad Zameeruddin, Vishvanath B Bharkad

SSS Indira College of Pharmacy, Vishnupuri, Nanded-431606, India

ABSTRACT

In this study, reverse phase high performance liquid chromatographic method have been developed and validated for the simultaneous determination of aspirin and omeprazole. The chromatographic separation was achieved in a Zorbax Eclipse XDB- C18 (4.6 × 250 mm × 5 μ) as a stationary phase Acetonitrile: Water (50:50, v/v) as mobile phase at a flow rate of 1 ml/min. UV detection was performed at 293 nm. The retention time of aspirin and omeprazole was found to be 3.260 and 1.787 min respectively. The results of analysis were validated statistically and by recovery studies. Linearity, accuracy and precision were acceptable in the ranges (2-14 μg/ml) for aspirin and (2-18 μg/ml) for omeprazole. The % recovery for aspirin and omeprazole was 99.79 and 99.61, respectively. The results of the studies showed that the proposed Reverse Phase High Performance Liquid Chromatography (RP-HPLC) method was simple, rapid, precise and accurate, which can be used for the routine determination of aspirin and omeprazole.

Keywords: Aspirin, Omeprazole, Liquid chromatography, Validation

INTRODUCTION

Aspirin (ASP) was Nonsteroidal anti-inflammatory, antirheumatic, antithrombic and chemically it was 2-Acetoxy benzoic acid. Chemical Structure of Aspirin was given in Figure 1, molecular formula was $C_9H_8O_4$, molecular weight is 180.16 g/mol [1].
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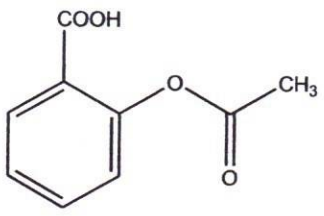

Figure 1: Aspirin

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Research Paper

Spectroscopic Determination of Aspirin and Omeprazole by Absorbance Ratio and Multicomponent Mode Method

Hajera Khan*, Swapna S. Bandewar, Mohammad Zameeruddin and Vishvanath B. Bharkad

SSS Indira College of Pharmacy, Vishnupuri, Nanded-431606, Maharastra, India.

Received July 21, 2017; accepted August 30, 2017

ABSTRACT

Here we describe a simple, rapid and accurate method for simultaneous assay of aspirin and omeprazole. The first method was Absorbance ratio method (Method 1) and second method was multi component mode method of analysis (Method 2). Methanol: water (8:2) was used as solvent for both methods, using 293 nm as isobestic point for absorbance ratio method. The wavelength ranges 275.80 nm for aspiring and 302.20 nm for omeprazole for method 2, which represents the absorbance maxima of both drugs respectively. Beer's law was applied in the concentration ranges of 2-14µg/mL and 2-18 µg/mL for aspiring and omeprazole, respectively, in absorbance ratio methods. The percentage assay was found to be in the range 99.74 to 100 % for aspiring and 99.69 to 99.9 % for omeprazole for both the methods. Recovery was found in the range of 99.74 –100.14 % for aspirin and omeprazole for both methods. The analysis data has been validated statistically and recovery studies confirmed the accuracy and reproducibility of the proposed methods, which were carried out according to the ICH guidelines.

KEYWORDS: Aspirin; Omeprazole; Absorbance ratio; Multicomponent; stability.

Introduction

Aspirin (ASP) is non- steroidal anti-inflammatory, antirheumatic, antithrombic and chemically it was 2-Acetoxy benzoic acid. Chemical structure of aspirin is given in Figure 1 (mass 180.16g/mol) (IP, 2010)). Omeprazole (OME) is a proton pump inhibitor. Chemically it is 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methy]sulfinyl]-1H-benzimidazole. Structure of omeprazole is shown in Figure 2 (mass 345.42 g/mol) (IP, 2010).

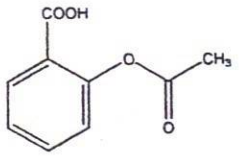

Fig. 1. Structure of Aspirin.

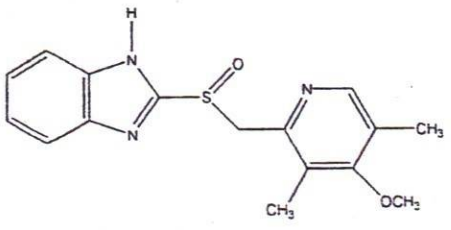

Fig. 2. Structure of omeprazole.

Recently, fixed dose combination of aspirin (ASP) and omeprazole (OME) has been approved as an initial once a day therapy for Ischemic stroke-prophylaxis, gastric ulcer prophylaxis, cardiovascular disease. ASP is an antiplatelet, Non-steroidal anti-inflammatory, antirheumatic drug. Literature survey revealed that there are various methods have been reported for estimation of ASP and OME by UV spectrophotometry[3-7] and HPLC Methods[8-10], LC-MS[11-13], HPTLC[14] individually or in combined form with other drugs (Rajput and Fanse, 2015; Chodvadiya et al., 2015; Jain et al., 2012; Godavariya et al., 2012; Solanki and Patel, 2012; Kumaraswamy et al., 2016; Patel et al., 2012; Purkar et al., 2012; Wickremsinhe et al., 2007; Farid et al., 2007; Lukram et al., 2012; Borole et al., 2010).We found no alternative method for this combination by absorbance ratio method and multicomponent mode method. Therefore, the present work emphasizes on the quantitative estimation of ASP and OMP in synthetic mixture by UV spectroscopy. The proposed methods were carried out and validated as per the International Conference on Harmonization (ICH) analytical method validation guidelines (ICH, 2005).

Materials and Methods

Apparatus

This method was carried as per the published paper (Kamal et al., 2016). Instrument used was an UV-Visible double beam spectrophotometer, make: SHIMADZU (model UV-1800) with a pair of 1 cm matched quartz cells. With spectral bandwidth of 1 nm, wavelength accuracy of ± 0.3 nm and 1.0 cm matched quartz cells

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Research Paper

Spectroscopic Determination of Aspirin and Omeprazole by Absorbance Ratio and Multicomponent Mode Method

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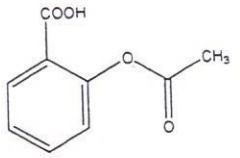

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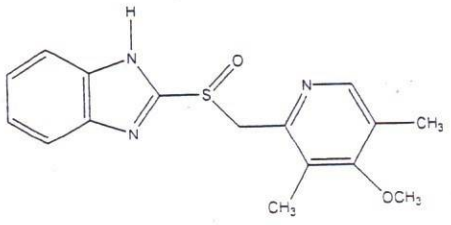

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Development and Validation of RP-HPLC Method for Simultaneous Estimation of Clonidine HCl and Chlorthalidone in Bulk Form

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HUMAN

Hajera N. Khan*, Chopde Asha, Mohammad Zameeruddin, Vishvanath B. Bharkad

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Keywords: Clonidine HCl, Chlorthalidone, RP-HPLC, Validation.

ABSTRACT

A Reverse phase High-Performance Liquid Chromatography method (HPLC) was developed for the simultaneous estimation of Clonidine HCl and Chlorthalidone in laboratory mixture. The chromatographic separation was achieved by Zorbax Eclipse XDB-C18 (4.6x250mmx5µ) column and Methanol-Ortho Phosphoric Acid (50:50 V/V) was used as mobile phase at a flow rate of 1ml/min. Detection was carried out at 236nm. The retention time of Clonidine HCl and Chlorthalidone were found to be 2.510 min and 3.403 min respectively. The method has been validated for linearity, accuracy, and precision. Linearity observed was 5-25 µg/ml for both drugs. The developed method was found to be accurate, precise and rapid for Simultaneous estimation of Clonidine HCl and Chlorthalidone in laboratory mixture.

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Stability Indicating Validated Dissolution Method for Determination of Propranalol and Hydralazine by Simultaneous equation method and Q-Analysis method.

H.N. Khan*, Dhotre Laxmi

Department of Quality Assurance SSS Indira College of Pharmacy, Vishnupuri, Nanded-431606.Maharashtra India.

Abstract : The aim of this work was development and validation of a dissolution method for Propranolol and Hydralazine(Carbetazine Tablets). The dissolution established conditions were 900 mL of 0.1M HCl (pH 1.0) as dissolution medium, using a paddle apparatus at a stirring rate of 50 rpm. The drug release was evaluated by UV spectrophotometric method the area of solution were recorded at288.20nm and 259.20nm for Propranolol and Hydralazine respectively for Simultaneous equation method and at 288.20nm(PRP) and 236.00nm(Isobestic point) for Q-Analysis method. Ahead of the results it can be concluded that the method developed consists in an efficient alternative for assays of dissolution for tablets.

Key Words : Dissolution, Spectroscopy, Simultaneous equation method, Q-Analysis method, Stability, alidation.

Introduction

Propranolol hydrochloride (PRP)chemically is (RS)-1-[(1-methylethyl) amino]-3-(naphthalene-1-yloxy) propan-2-olhydrochioride [1]and chemical structure of PRP is given in the fig. 1.

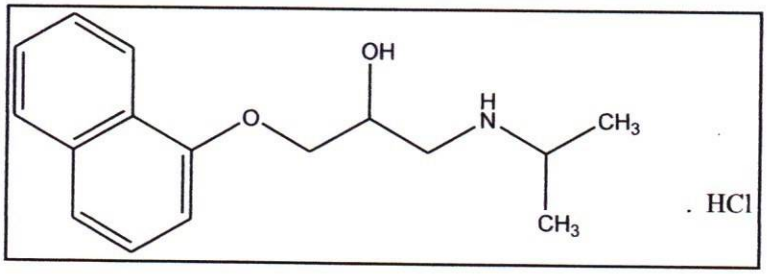

Figure I:Propranolol

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Original Article **CODEN: IJPNL6**

Stabity indicating Dissolution Method Development for Estimation of Paracetamol & Chlorzoxazone in Combine Dosage form

H.N khan[1*], M D Zameeruddin[2], Mirza Shahed Baig[2], Mahajan Swarali[2], V.B Bharkad[2]

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ABSTRACT

The present work concerns with development and validation of dissolution test for Paracetamol and Chlorzoxazone in combine tablets dosage form using spectrophotometric method. 0.1M HCl (pH 1.0, 900 mL) was used as dissolution medium, using a paddle apparatus, stirring rate was 50 rpm. The percent drug release was determined by UV spectrophotometric method the wavelength selected for analysis are 242.80 nm for Paracetamol and 279.80 nm for Chlorzoxazone from results it can be concluded that the method developed consists in an efficient alternative for assay of this tablets combination. The method was validated to meet requirements for a global regulatory filing which includes validation parameters as linearity, accuracy, precision, ruggedness and robustness which are as per ICH guidelines. In addition, filter suitability and drug stability in medium were demonstrated.

Keywords: Dissolution, Paracetamol, Chlorzoxazone, *In vitro* drug release, Spectrophotometry, Simultaneous equation method, Validation

INTRODUCTION

Paracetamol (PCM) is 4-hydroxyacetanilide it is official in Indian Pharmacopoeia [1]. Paracetamol is centrally and peripherally acting non opioid analgesic and antipyretic property overdose of Paracetamol can lead to hepatic necrosis or renal failure [2]. Chemical structure of PCM is given in Figure 1.

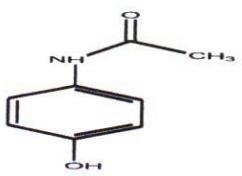

Figure 1: Chemical structure of Paracetamol

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Research Article

STABITY INDICATING DISSOLUTION METHOD DEVELOPMENT FOR ESTIMATION OF PARACETAMOL AND CHLORZOXAZONE IN COMBINE DOSAGE FORM

Hajera Khan *, Mohammad Zameerodin

Department of Quality Assurance, SSS Indira College of Pharmacy, Vishnupuri, Nanded-431606, Maharashtra, INDIA.

Received on: 13-11-2017; Revised and Accepted on: 24-11-2017

ABSTRACT

The aim of this work was to develop dissolution test method for Paracetamol and Chlorzoxazone in combination tablet. The dissolution established conditions were 900 mL of 0.1M HCl pH 1.0 as dissolution medium, using a paddle apparatus at a stirring rate of 50 rpm. The assay was performed by spectrophotometry for the better conditions stirring speed of 50 rpm, is used .Ahead of results it can be concluded that the method developed consists in an efficient alternative for assay of dissolution for tablets. The method was validated to meet requirements for a global regulatory filing which includes linearity, precision, accuracy robustness and ruggedness. In addition, filter suitability and drug stability in medium were demonstrated.

KEYWORDS:*Dissolution study of Paracetamol and Chlorzoxazone, In vitro release, Spectrophotometry, Q-Analysis Method, Validation.*

INTRODUCTION

Paracetamol (PCM) chemically is 4-hydroxyacetanilide[1]. Paracetamol acts by complex and includes the effects of both the peripheral (COX inhibition) and central (COX serotonergic descending neuronal pathway, L-arginine/NO Pathway, cannabinoid system) antinociception processes and redox mechanism [2]. Paracetamol is well tolerated drug and produces few side effects from the gastrointestinal tract. Chemical structure of PCM is given fig .1.

Chlorzoxazone Chemically is 2(3H)-Benzoxazolone,5-chloro-5-chloro-2 benzoxazolinone[3].

Chlorzoxazone acts by inhibiting multi synaptic reflexes involved in producing and maintaining skeletal muscle spasm of varied aetiology.It acts on the spinal cord by depressing reflexes. CHN a synthetic compound, inhibits antigen-induced bronco spasms.CHN inhibits degranulation of mast cells. Subsequently preventing the release of histamine and slow-reacting substance of anaphylaxis(SRS-A), mediators of type-1 allergic reactions. CHZ also may reduce the release of inflammatory leukotrienes[4]. CHZ is given fig.2.

Literature survey revealed that various analytical technique such as spectrophotometric technique [5-8]. Several method based on separation technique including HPLC[9-11], have been reported. The method was validated as per the International Conference on Harmonization (ICH) guidelines [12,13].

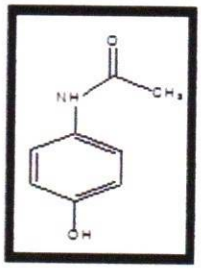

Fig. 1: chemical structure of Paracetamol

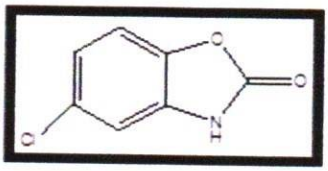

Fig. 2: chemical structure of Chlorzoxazone

MATERIALS AND METHODS

Materials:

Paracetamol was received as a gift samples from Glenmark Pharmaceuticals Ltd. (Goa, India) and Chlorzoxazone was received as a gift samples from Flemingo Pharmaceuticals Nanded, India.

Instrumentation:

Dissolution test was performed in a ELECTROLAB (VK7025) Model(TDT-06L)[14]dissolution apparatus, multi-bath (n=6), in accordance to USP Pharmacopoeia generalmethod. The medium were vacuum degassed under in house vacuum and weremaintained at 37.0 ± 0.5°C by using a thermostatic bath. A double-beam UV-Visiblespectrophotometer (Model:UV 1800,Shimadzu] with a fixed slit width (2 nm)using1.0 cm quartz cell was used for all absorbance measurements. Elico pH analyzer(Model: Elico 11610) was used to determine the pH of all solutions.

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Second Derivative Spectrophotometric Method For Determination Of Minoxidil And Finasteride In Bulk And Pharmaceutical Formulation

Smruti S. Gaikwad
Indira College of Pharmacy Vishnupuri, Nanded, Maharashtra

Miss. H. N. Khan
Guide

Abstract: ***Simple and reliable second derivative spectrophotometric method was developed and validated for simultaneous estimation of Minoxidil and Finasteride in bulk and Pharmaceutical formulation. The quantitative determination of second derivative were carried out using second derivative values measured at 228 nm 236 nm for Minoxidil and Finasteride respectively. The solution of standard and sample were prepared in DMSO: Methanol (1:9 v/v) and Potassium Phosphate buffer (PH7.2) respectively. The calibration graphs constructed at their wavelengths of determination were linear in concentration range of 15-65 µg/ml and 0.5-2.5 µg/ml for Minoxidil and Finasteride respectively. The developed second derivative spectrophotometric method validated according to ICH guideline.***

Keywords: Minoxidil, Finasteride, Dimethyl Sulfoxide (DMSO), Methanol, Potassium Phosphate buffer (PH 7.2).

I. INTRODUCTION

Minoxidil (MINO) chemically is 2,4-diamino-6-piperidinopyrimiddine-3-oxide (Figure 1) is act by relaxing arteriolar smooth muscle with little effect on venous capacitance. It increased rennin release and proximal tubular Na^+ reabsorbing and water retention. Minoxidil also increase hair growth by acting on alteration of androgenic effect on genetically programmed hair follicles and direct stimulation of resting hair follicles.

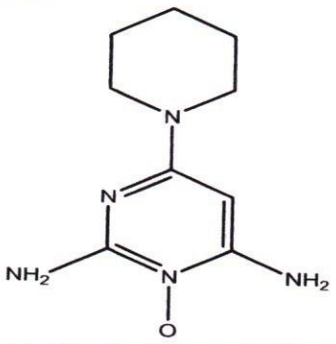

Figure 1: Chemical structure of Minoxidil

Finasteride (FNS) chemically is 17β-(N-tert-butyl carbamoyl)-4-aza-5α-androst-1-en-3-one (Figure.1). It is competitive inhibitor of enzyme 5α-reductase which converts testosterone responsible for androgen action in tissues including prostate gland and hair follicles. Finasteride is antiandrogenic drug and also found effectively in male baldness. It is effective orally, metabolized in liver and excreted in urine faeces.

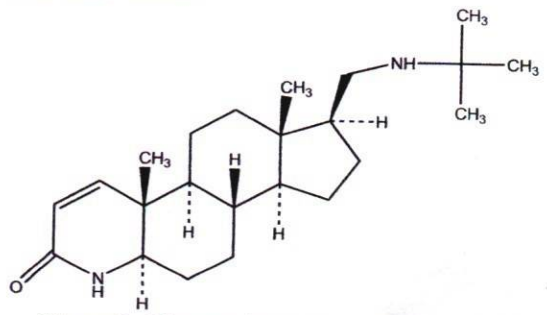

Figure 2: Chemical structure of Finasteride

Litrature survey revealed UV, HPLC and UPLC analytical methods for Minoxidil and Finasteride estimation.

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Research Article

STABITY INDICATING DISSOLUTION METHOD DEVELOPMENT FOR ESTIMATION OF PARACETAMOL AND CHLORZOXAZONE IN COMBINE DOSAGE FORM

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ABSTRACT

The aim of this work was to develop dissolution test method for Paracetamol and Chlorzoxazone in combination tablet. The dissolution established conditions were 900 mL of 0.1M HCl pH 1.0 as dissolution medium, using a paddle apparatus at a stirring rate of 50 rpm. The assay was performed by spectrophotometry for the better conditions stirring speed of 50 rpm, is used .Ahead of results it can be concluded that the method developed consists in an efficient alternative for assay of dissolution for tablets. The method was validated to meet requirements for a global regulatory filing which includes linearity, precision, accuracy robustness and ruggedness. In addition, filter suitability and drug stability in medium were demonstrated.

KEYWORDS:*Dissolution study of Paracetamol and Chlorzoxazone, In vitro release, Spectrophotometry, Q-Analysis Method, Validation.*

INTRODUCTION

Paracetamol (PCM) chemically is 4-hydroxyacetanilide[1]. Paracetamol acts by complex and includes the effects of both the peripheral (COX inhibition) and central (COX serotonergic descending neuronal pathway, L-arginine/NO Pathway, cannabinoid system) antinociception processes and redox mechanism [2]. Paracetamol is well tolerated drug and produces few side effects from the gastrointestinal tract. Chemical structure of PCM is given fig .1.

Chlorzoxazone Chemically is 2(3H)-Benzoxazolone,5-chloro-5-chloro-2 benzoxazolinone[3].

Chlorzoxazone acts by inhibiting multi synaptic reflexes involved in producing and maintaining skeletal muscle spasm of varied aetiology.It acts on the spinal cord by depressing reflexes. CHN a synthetic compound, inhibits antigen-induced bronco spasms.CHN inhibits degranulation of mast cells. Subsequently preventing the release of histamine and slow-reacting substance of anaphylaxis(SRS-A), mediators of type-1 allergic reactions. CHZ also may reduce the release of inflammatory leukotrienes[4]. CHZ is given fig.2.

Literature survey revealed that various analytical technique such as spectrophotometric technique [5-8]. Several method based on separation technique including HPLC[9-11], have been reported. The method was validated as per the International Conference on Harmonization (ICH) guidelines [12,13].

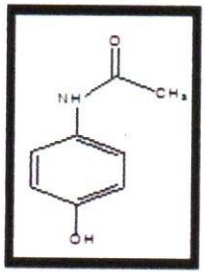

Fig. 1: chemical structure of Paracetamol

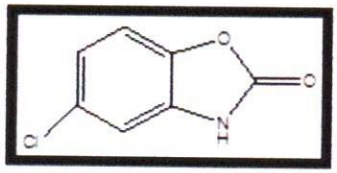

Fig. 2: chemical structure of Chlorzoxazone

MATERIALS AND METHODS

Materials:

Paracetamol was received as a gift samples from Glenmark Pharmaceuticals Ltd. (Goa, India) and Chlorzoxazone was received as a gift samples from Flemingo Pharmaceuticals Nanded, India.

Instrumentation:

Dissolution test was performed in a ELECTROLAB (VK7025) Model(TDT-06L)[14]dissolution apparatus, multi-bath (n=6), in accordance to USP Pharmacopoeia generalmethod. The medium were vacuum degassed under in house vacuum and weremaintained at 37.0 ± 0.5°C by using a thermostatic bath. A double-beam UV-Visiblespectrophotometer (Model:UV 1800,Shimadzu] with a fixed slit width (2 nm)using1.0 cm quartz cell was used for all absorbance measurements. Elico pH analyzer(Model: Elico 11610) was used to determine the pH of all solutions.

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IN-SILICO SCREENING OF FLAVONOLS AGAINST *BRUGIA MALAYI* ASPARAGINYL tRNA SYNTHETASE

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Keywords:

Flavonoids, Molecular Docking, *Brugia malayi*, Anti-filarial leads, Asparaginyl tRNA synthetase

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ABSTRACT: Lymphatic Filariasis is one of the most abandoned tropical diseases caused by the parasite, *Brugia malayi*. The existing conventional drugs act generally on the larval stages of the parasite. The enzyme asparaginyl tRNA synthetase is an excellent molecular target as it plays a crucial role in protein synthesis. Evidences based on the literature presented clues to discover the flavonoids as potential anti-filarial leads, which led to the scope for this computational study. The computational parameters such as docking score, binding energy, intermolecular hydrogen bond interaction and the identical amino acids confirm that flavonoids could serve as prospective anti-filarial agents. The outcomes prove that they can be further explored in *in-vitro* and *in-vivo* studies to authenticate their claim as potential anti-filarial agents.

INTRODUCTION: Lymphatic Filariasis (LF) is one of the most abandoned tropical diseases in several countries. It leads to major health problems such as physical disability, chronic morbidity and disfiguring [1]. It is included in the top 10-neglected tropical diseases by World Health Organization (WHO) [2]. According to a WHO report, about 70% of the infection worldwide is contributed alone by India, Bangladesh and Indonesia. Along with these countries, there are other endemic countries, like Nepal, Maldives, Sri Lanka, Myanmar, Timor-Leste and Thailand, having more number of LF patients. There are two main causative organism for LF, *Brugia malayi* and *Wuchereria bancrofti*, which signify a global health disaster with over 20% of the worldwide population at risk for infection.

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The most widespread causative organism for the filarial infection *B. malayi*, is transmitted by the mosquitoes (vector) like Culex, Anopheles, Mansonia and Aedes. The development and replication of *B. malayi* takes place in two different stages: in the mosquito vector and in the human. Both stages are necessary to the life cycle of the parasite. The male and female adult worms mate and the females produce an average of 10,000 sheathed eggs (microfilaria) daily. The micro-filariae enter the blood stream and exhibit the classic nocturnal periodicity and super periodicity[3]. In humans, the adult worms can stay alive in the lymphatic system for 5 - 15 years, resulting in swelling of the affected limbs.

Since the past 20 years, three conventional drugs namely diethylcarbamazine, ivermectin and albendazole are in practice to treat this disease. These drugs are effective against the larval stages of the parasite, but are inefficient to kill the adult filarial worms [4]. Currently these drugs are being used in the Global Programme to Eliminate Lymphatic Filariasis (GPELF) program, which has

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Research Article

SYNTHESIS, *IN VITRO* ANTIOXIDANT AND ANTIMICROBIAL EVALUATION OF 3-HYDROXY CHROMONE DERIVATIVES

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ABSTRACT

Objective: The objective of the present study was to synthesize a series of 3-hydroxychromone derivatives and to evaluate its *in vitro* antioxidant and antimicrobial activities.

Methods: 3-hydroxy chromones were synthesized using an algar flynn oyamada method which includes oxidative cyclization of 2-hydroxy chalcones in basic solution by hydrogen peroxide. 2-hydroxy chalcones were synthesized by Claisen-Schmidt condensation of substituted 2-hydroxy acetophenones with substituted aromatic aldehydes using polyethylene glycol-400 as a recyclable solvent. The synthesized compounds were evaluated for *in vitro* antioxidant activity by 1,1-diphenyl-2-picrylhydrazyl radical scavenging assay. In addition, these compounds were also screened for *in vitro* antibacterial and antifungal activity by agar cup method and Poison plate method, respectively.

Results: The structures of the synthesized compounds were characterized by infrared, ^{1}H nuclear magnetic resonance and mass spectroscopy. The antioxidant activity data revealed that all the synthesized derivatives exhibited good activity due to the presence of phenolic hydroxyl group, 4-oxo group and 2,3-double bond. Further, the activity increased with the introduction of a more phenolic hydroxyl group and adjacent methoxy group in the structure. The antimicrobial activity data showed that the compounds possess better antibacterial and antifungal activity which is attributed to the presence of phenolic hydroxyl group and 4-oxo group in the structure.

Conclusions: The use of inexpensive, eco-friendly and readily available reagents, easy work-up and high purity of products makes the procedure a convenient and robust method for the synthesis of title compounds. The presence of phenolic hydroxyl group, 4-oxo group, and 2,3-double bond in the structure is responsible for their good antioxidant and antimicrobial activities.

Keywords: Chromone, Chalcone, Claisen-Schmidt condensation, Algar Flynn Oyamada method, Antioxidant, Antibacterial, Antifungal.

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INTRODUCTION

Chromones are a group of naturally occurring compounds that are ubiquitous in nature, especially in plants. The word chromone is derived from the Greek word chroma, meaning "color," which indicates that many chromone derivatives can exhibit a diversity of colors [1].

Chromones are oxygen-containing heterocyclic compounds with a benzoannelated γ-pyrone ring being chromone (4H-chromen-4-one, 4H-1-benzopyran-4-one) the parent compound (Fig. 1). 3-hydroxy chromone is the class of flavonoids structurally related to flavonols (Fig. 1) [2].

Chromones are used as scaffolds for the development of bioactive compounds. These frameworks are naturally occurring derivatives containing anoxa-pyran ring [3]. The most frequently found chromone-based natural products are the 2-arylsubstituted chromones (flavonoids) carrying hydroxy and/or methoxy groups on the aromatic rings [4]. The substitution pattern of the chromone scaffolds determines their different biological effects. Known effects of these types of compounds are antioxidant [5], antiviral [6], antibacterial [7], antifungal, anti-inflammatory [8], antiobesity [9], immunomodulatoty [10], and kinase inhibition [11]. Hence, chromones can be considered privileged structures, defined as "a single molecular framework able to provide ligands for diverse receptors" [12].

Prompted by all these observations, we report herein the synthesis, *in vitro* antioxidant and antimicrobial activities of 3-hydroxy chromone derivatives.

EXPERIMENTAL

Aldehydes and acetophenones were procured from Sigma-Aldrich and SD fine chemicals. All other chemicals are of AR grade. Melting points were determined in open capillaries on a Metal Toledo digital melting point apparatus and are uncorrected. The purity of the compounds was checked by thin-layer chromatography (TLC) using TLC Silica gel 60 F_{254} aluminum sheets procured from Merck and spots were detected in ultra violet fluorescence analysis cabinet. The infrared (IR) spectra were recorded using potassium bromide (KBr) pellets on Shimadzu IR Affinity-1 Fourier transform IR spectrophotometer (cm^{-1}). ^{1}H nuclear magnetic resonance (NMR) spectra were recorded on Bruker AVANCE III 500 MHz NMR spectrometer using tetramethylsilane as internal standard (chemical shifts in δ ppm) and mass spectra recorded were on JEOL GC MATE II GC-MS system.

General procedure for synthesis of 2-hydroxy chalcone derivatives (Fig. 2)

An equimolar mixture of substituted acetophenone (1 mmol), aromatic aldehyde (1 mmol) and potassium hydroxide (2 mmol) was stirred in polyethylene glycol-400 (PEG-400) (15 ml) at 40°C for 1 h. After completion of the reaction (monitored by TLC), the crude mixture was worked up in ice-cold water (100 ml). The separated product was filtered, washed with water and recrystallized with suitable solvent. The filtrate was evaporated to remove water, leaving PEG behind. The same PEG was utilized to synthesize further chalcones [13].

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RESEARCH ARTICLE

ROLE OF FUNCTIONALIZED GUAR GUM IN SOLID DISPERSION OF NON-STEOIDAL ANTI-INFIAMMATORY DRUG

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Key words:-
Ibuprofen, Guargum, Aminated, Solubility, Solid Dispersion

Abstract

The current investigation was developed to study the role of functionalized guar gum as carrier in solid dispersion of iboprofen. The solid dispersion technique using aminated guar gum would be an effective approach for increasing the solubility and increasing dissolution behaviour of ill fathomable medicament than the native guar gum. The results of FTIR and DSC studies confirmed that there is no chemical interaction or no incompatability between the drug and excipients. The invitro dissolution study was performed for the the prepared formulations. Based on the results SD3 was shown highest drug release 99.41% within 24hrs. Stabiliy study was conducted as per ICH guidelines and the falloutsrevealed that there is no physical or chemical change.it may be concluded that solubility of ibuprofen can br improved by using functionalized guar gum in the solid dispersion, which provides a wide scope for the therapeutic efficiency.

Introduction:-

SolidDispersion: The term strong scattering alludes to a gathering of strong items comprising of somewhere around two parts, by and large a hydrophilic grid and a hydrophobic medication. The lattice can be either glasslike or nebulous. The medication can be scattered microscopically, in nebulous particlesorincrystallineparticles.[1]

Oral availability of medication relies upon its solvency or potentially disintegration rate, in this way serious issues related with these medications was its very dissolvability in natural liquids, which results into helpless bioavailability after oral organization. Numerous techniques are accessible to further develop disintegration rate, dissolvability attributes, including salt arrangement, micronization and expansion of dissolvable or surface dynamic specialists. The term strong scattering alludes to a gathering of strong items comprising of somewhere around two parts, by and large a hydrophilic network and a hydrophobic medication. The lattice can be either glasslike or nebulous. The medication can be scattered microscopically, in formless particlesorincrystallineparticles.2Strong scattering is one othese strategies, which was most broadly and effectively applied to work on the solvency, disintegration rates and thus the bioavailability of inadequately solvent medications. The idea of strong scatterings (SDS) was presented in 1961 by Sekiguchi and Obi, in which the medication is scattered in inactive water-dissolvable transporter at strong state. Several water soluble carriers such ashydroxyl propyl methyl cellulose, ethyl cellulose, beta cyclodextrin, urea, lactose,citric acid, poly vinyl pyrrolidone(PVP) and poly ethylene glycols such as carriersforSolid dispersion

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PHYTOCHEMICAL AND PHARMACOLOGICAL EVALUATION OF *VIGNA RADIATA* STEM BARK EXTRACTS FOR ANTIAMNETIC ACTIVITY

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ABSTRACT

The present study reports physicochemical characterization, antioxidant and Antiamnetic activity of extracts from *vigna radiata* stem bark collected from local region of Nanded, Maharashtra, India. Different physical parameters like ash values, extractive value, Loss on drying, solubility etc were evaluated for powdered drug. The extracts were obtained from Soxhlet method by using ethyl acetate and methanol as solvents for extraction and subjected for preliminary physicochemical evaluation and antioxidant studies. Total phenolic and flavonoids content were also analyzed. The presence of primary and secondary metabolites such as carbohydrate, proteins, alkaloids, phenolic compounds, saponins was confirmed through preliminary phyto-chemical analysis. DPPH free radical scavenging assays showed strong antioxidant activities with increase in concentration of ethyl acetate and methanol stem bark extracts. Maximum percentage inhibition i.e. 80.97% was shown by ethyl acetate extract at concentration of 150 µg/ml and was compared with Ascorbic acid as reference standard. The *In-Vivo* Antiamnetic activity of *vigna radiata stem* bark was evaluated by radial arm maze model in rats using Piracetam as a standard. Scopalamine (1mg/kg) used as inducing agent. Both the extracts at 200mg/kg concentrations showed significant to highly significant number of entries & time spent in P zone (from $P < 0.05$ to $P < 0.001$). The result suggests that *vigna ridiata* stem bark extracts possess Antiamnetic avtivity and this might be due to flavonids. Phenolic compound, steroid and proteins present in extract.

Keywords: *Vigna radiata,* ethyl acetate and Methanolic extract, Phytochemical screening, Antioxidant effect, Antiamnetic activity.

I. INTRODUCTION:

Amnesia is when a person can no longer memorize or recall information that is stored in memory. It is very rare, despite being a popular theme for movies and books. Being a little forgetful is completely different to having amnesia. Amnesia refers to a large-scale loss of memories that should not have been forgotten.These may include important milestones in life, memorable events, key people in our lives and vital facts we have been told or taught. A French psychologist Theodule-Armand Ribot was among the first scientists to study amnesia. Because of this, medical experts started to call the gradients of memory loss as Ribot gradients.

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PHYTOCHEMICAL, PHARMACOGNOSTICAL AND QUANTITATIVE ESTIMATION OF *PONGAMIA PINNATA* LEAVES EXTRACT-A PRELIMINARY STUDY TO IDENTIFIED PHYTOCONSTITUENTS

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ABSTRACT

Objective: The objective of this study was to carry out phytochemical and pharmacognostic and quantitative evaluation of leaves of *Pongamia pinnata* L. (Fabacea). **Method:** The present study provides pharmacognostic, phytochemical and quantitative details of the leaves of *P. pinnata.* **Results:** The macroscopic study showed that the leaf was ovate or elliptic with smooth margins, short petiole, alternate imparipinnate, hairless, acuminate at apex, rounded to cuneate at base and slightly thickened. Microscopic study revealed collateral, closed vascular bundles, trichomes, paracytic stomata, xylem vessels and prismatic calcium oxalate crystals. Qualitative Phytochemical screening showed the presence of alkaloids, glycosides, carbohydrates, steroids and flavonoids and phenolic compounds in both the extracts. Total Poly phenol content & total flavonoid content was determined by Folin Ciocaltue & Aluminium trichloride method respectively by using UV-Visible spectrophotometer. DPPH scavenging assay were performed to evaluate the antioxidant activity which was found maximum at 125 µg/ml concentration for both the extracts. **Conclusions:** The results of this study can serve as valuable source of information for identification of this plant for future investigation and applications.

INTRODUCTION

Plants have been the foundation of traditional medicine system throughout the world and continue to nurture mankind with new remedies. The research pertaining to medicinal plants is rapidly increasing at national and international levels.[1] Further investigation of traditional systems of medicine with emphasis on safety, efficacy and quality will help to rationalize the

PHYTOCHEMICAL INVESTIGATION AND PHARMACOLOGICAL EVALUATION OF *TRIGONELLA FOENUM-GRAECUM* LEAVES EXTRACTS FOR ITS WOUND HEALING ACTIVITY

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Abstract: **The present study reports physicochemical characterization, antioxidant, antimicrobial and Wound Healing activity of extracts from *Trigonella Foenum-graecum* leaves collected from local region of Nanded, Maharashtra, India. The extracts were obtained from Soxhlet method by using ethyl acetate and methanol as solvents for extraction and subjected for preliminary physicochemical evaluation and antioxidant studies. Total phenolic and flavonoids content were also analyzed.**

The presence of primary and secondary metabolites such as carbohydrate, amino acids, tannins, alkaloids, phenolic compounds, saponins were confirmed through preliminary phyto-chemical analysis. DPPH free radical scavenging assays showed strong antioxidant activities with increase in concentration of Ethyl acetate and methanol leaves extracts. Maximum percentage inhibition i.e. 80.97% was shown by Ethyl acetate extract at concentration of 150 µg/ml and was compared with Ascorbic acid as reference standard.

The *in vitro* Antibacterial property of *Trigonella Foenum-graecum* leaves was carried out by using agar cup and plate method. In this method, increase in zone of inhibition was Ethyl acetate extract having better antibacterial activity on *Baccilus substillus* than *Staphylococcus aureus* & *E.coli.* Methanol extract having better antibacterial activity against *Baccilus substillus* & *Staphylococcus aureus* than *E.coli*

Antifungal property of *Trigonella Foenum-graecum* leaves was carried out by using poison plate method. In this method, reducing growth of fungi (moderate antifungal activity) and no growth of fungi of test sample was calculated and compared with standard i.e. (*Griseofulvin*). Both extract showed the reduced growth (more than 50% and less than 90% reduction in growth) at 100 mg/ml.

The *In-Vivo* Wound Healing activity of *Trigonella Foenum-graecum* leaves was evaluated by excision wound model in rats using Soframycin as standard. Both the extracts at 5 % conc^{n} showed significant reduction in wound size.

The result suggest that *Trigonella Foenum-graecum* leaves extracts possess wound healing activity and this might be due to flavonoids, Phenolic compound, coumarin, tannin and saponins present in extract.

Keywords: ***Trigonella Foenum-graecum,* Ethyl acetate and Methanolic extract, Phytochemical screening, Antioxidant effect, Anti-microbial activity, Wound healing activity.**

Introduction

Wound may be defined as a disruption of the cellular and anatomic continuity of a tissue, with or without microbial infection and is produced due to any accident or cut with sharp edged things. It may be produced due to physical, chemical, thermal, microbial or immunological exploitation to the tissues. Wound healing is a process of restoring normal structure and functions of damaged tissue. Healing is a natural phenomenon by which body itself overcome the damage to the tissue but the rate of healing is very slow and chance of microbial infection is high. This creates demand of a substance that speeds up the rate of healing.

Wound healers are one of the most critical requirement in the essential medicaments for soldier and may help in putting injured soldier back on the war field as quickly as possible. A wound healer also minimizes demand of other drugs like antibiotics and also their probable side effects by their use. India has a rich tradition of plant-based knowledge on healthcare. A large number of plants/plant extracts/decoctions or pastes are equally used by tribal and folklore traditions in India for treatment of cuts, wounds, and burns. Besides this, there is not a single synthetic drug formulation in the market which can claims for its wound healing properties. The drugs available are either bacteriostatic or bactericidal and in these cases healing is by a natural phenomenon only.

1. The inflammatory phase: The inflammatory phase starts immediately after the injury that usually last between 24 and 48 hrs may persist for up to two weeks in some cases. The inflammatory phase launches haemostatic mechanisms to immediately stop blood loss from the wound site.

2. The fibro plastic phase: The second phase of wound healing is the fibro plastic that last up to two days to three weeks after the inflammatory phase. The phase comprises of three steps viz., granulation, contraction and epithelialization.

3. Remodeling phase: This phase last for 3 weeks to 2 years. Tissue tensile strength is increased due to intermolecular cross linking of collagen via vitamin c dependent hydroxylation.

The rapidity of wound healing depends to a considerable extent on the contraction that begins a few days after injury and continuous for several weeks.

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Pharmacognostic evaluation of *trigonella foenum-graecum linn* leaves

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Abstract
Trigonella Foenum-graecum Linn., is an annual herb of bean family, reaching 30-60 cm and largely cultivated in India, Egypt and Morocco. It is commonly known as 'Fenugreek', which belongs to the family *Fabaceae*. The present study attempts to evaluate Pharmacognostic studies including examination of macroscopic and microscopic character and powder analysis of Fenugreek leaves. The detailed Pharmacognostic studies have given a clear idea regarding the different cell characters and various constants. The physicochemical parameters such as total ash value, acid insoluble ash value, water soluble ash value, loss on drying and extractive values were also determined. These Physicochemical parameters have given standard numerical values for comparison and detection of adulterants. The results of this study will possibly prove useful for establishing pharmacognostic standards for the identification, purity and quality of drug.

Keywords: *trigonella foenum-graecum linn.*, leaves, pharmacognostic studies, physicochemical parameters

1. Introduction

In recent times, there is a renewed interest in drugs of natural origin simply because they are considered as green medicine and green medicine is always supposed to be the safe. The advantage of natural drugs is their easy availability, economic and less or no side effects but the disadvantage is that they are the victims of adulteration. The more effective the natural drug, more is its demand and the chances of non-availability increases. To meet the growing demand, the natural drug is easily adulterated with low grade material. Pharmacognosy is the study of medicines derived from natural sources, mainly from plants. It basically deals with standardization, authentication and study of natural drugs. Pharmacognostic study includes parameters which help in identifying adulteration in dry powder form also. This is again necessary because once the plant is dried and made into powder form, it loses its morphological identity and becomes easily prone to adulteration. Such studies will help in authentication of the plants and ensure reproducible quality of herbal products which will lead to safety and efficacy of natural products.

Fenugreek, *Trigonella Foenum-graecum Linn.*, is an annual herb of bean family, reaching 30-60 cm and largely cultivated in India, Egypt and Morocco. The name fenugreek comes from *foenum-graecum*, meaning 'Greek hay', as the plant was traditionally used to scent inferior hay and the name of the *Trigonella* is derived from the old Greek name, denoting 'three angled', probably referring to the triangular shape of flowers. Fenugreek has strong flavor and aroma. The plants leaves and seeds are widely consumed in Indo-Pak subcontinent as well as in other oriented countries as a spice in food preparations and as a ingredient in traditional medicine. Medicinally it was used for the treatment of wound abscesses, arthritis, bronchitis, ulcer and digestive problems. The plant grows to height of about 3 feet. *Trigonella Foenum-graecum Linn* has long stalked leaves up to 5cm long stipules triangular; lanceolate leaflets about 2.5 cm long. The root mass of fingery structure. Flowers are white and pale yellow. The plant radiates spicy odor which persist on the hands after touching. Fenugreek is best grown as a annual crop from seeds by the line sowing method. The leaves contain 7 saponins, known as *graecunins*. These compounds are glycosides of diosgenin. Leaves contain moisture 86.1%, protein 4.4%, fat 0.9%, minerals 1.5%, fiber 1.1% and carbohydrate 6% & the vitamins (calcium, iron, phosphorous, carotene, thiamine, riboflavin, niacin and vitamin c).

Fabaceae: A large family that comprises the peas, beans and related herbaceous or woody plants with pea like flowers and a legume as fruit and that is now usually included in the family Leguminosae.

Fig 1: Trigonella Foenum-graecum leaves

2. Plant Profile

It is a biennial plant, but is usually grown as an annual. Modern varieties typically grow to a height of 15 to 45 cm (6 to 18 in). The leaves are yellowish to bluish green and grow alternately in a flattened, fan-shaped swathe. They are

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ANTI-INFLAMATORY ACTIVITY OF *ACACIA NILOTICA* PODS EXTRACTS IN EXPERIMENTAL RATS

S. K. Sarje*, Swati Tekale, Thakur Adhika, Tiwari Nikita and Yengload Sharda

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ABSTRACT

Inflammation is body's response to disturbed homeostasis occurs mainly due to infection, injury or trauma resulting in systemic and local effects. The Roman writer Celsus in1st Century AD named the four Cardinal Signs of inflammation as Rubor (redness), Tumor (swelling), Calor (heat) and Dolor (pain). *Acacia nilotica* has long been used in folk medicine in treatment of diarrhoea, snake bite, malaria, smallpox, fever, scabies; ulcer, and stomach disorders. [Prajapti *et al* 2003]. Although a lot of work has been done on the pharmacological activities and phytoconstituents isolation of seed and leaves of *A. nilotica* but no work has been done on anti-inflammatory activity of pods extract of *A. nilotica.* Therefore, the aim of the present work is "Evaluation of anti-inflammatory activity of pods extracts of *Acacia nilotica*." The work was initiated with authentication of plant *Acacia nilotica*. Morphological, Acute toxicity study aims at establishing the therapeutic index. Extracts were found safe up to 2000 mg/kg. *In-vitro* and in-*vivo* anti-inflammatory activity of ethyl acetate, ethanolic extract of *Acacia nilotica* was evaluated by using hyaluronidase inhibition assay and the carrageenan induced paw edema models.

INTRODUCTION

Inflammation associated with many diseases. The drug which are available presently in market itself cause ulcer, hence currently search for new anti-inflammatory agents that have few side effect is undertaken by many researchers. Many medicines of plant origin had been used since ages without any adverse effects. It is therefore essential that efforts should be made to introduce new medicinal plants to develop more effective and cheaper drugs. Plants

ORIGINAL ARTICLE

Development and Evaluation of Silver Nanoparticles and its Applications in Topical Drug Delivery Systems

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Abstract

Background: Nanotechnology is finding new applications in the field of pharmaceuticals and various other fields. Increase of the surface area of a drug by reaching to the nano size offers more than one beneficial effects and applications. The same drug molecule in the nano size can work more efficiently, reach the target organ in the desired concentration but in lowered therapeutic dose, with less side effects and thus can give better treatment. This science is explored in wound healing process using silver nanoparticles (SNPs). Silver in its nano size shows better wound healing effect. Nano size sliver can be synthesized by various reduction methods in which silver nitrate is reduced to give silver atoms. Atomic silver enters into wound healing process more efficiently than silver sulfadiazine a well-known silver compound for wound healing. Various reducing agents from chemical origin have been successfully tried for synthesis of SNPs, but these tend to leave their traces behind, and could be toxic in wound healing process. Many phytochemicals have redox potential and are successfully used in creation of metal nanoparticles. In this project SNPs are developed using phytochemicals of turmeric, which is not reported as yet. The in-vitro and in-vivo evaluation of SNPs developed in this project show promising results. **Aim:** To develop Silver Nanoparticles using phytochemicals from turmeric and evaluate these using in-vitro and in-vivo methods. **Method:** In this project, a new method is explored for synthesis of SNPs using hydroalcoholic turmeric exctract and curcumin as reducing agents. Curcumin and other ingredients of turmeric called curcuminoids, owing to their structures (Keto enol moieties) can act as reducing agents. 1 mM $AgNO_3$ was incubated with turmeric extract and curcumin separately for various time intervals. The temperature , time and proportion of reagents was optimized to gets maximum concentration of SNPs.SNP production using glucose as reducing agent was used as standard.Extract of turmeric proved better redox reagent than curcumin alone may be due to presence of other curcuminoids in the extract apart from curcumin. SNPs prepared using turmeric extract were evaluated by physical methods of characterizations such as scanning electron microscopy, Zeta potential, and particle size analysis. 0.02 % SNPs were loaded in 1% carbopol 934p gel and were evaluated for wound healing activity using burn wound model. **Results:** SNPs prepared using turmeric extract were evaluated for particle size analysis, PDI-Polydispersibility index, Zeta potential, SEM . All results indicated formation of SNPs (average particle size 235nm) compared with standard glucose reduction method (average particle size 895nm). Stability study showed no aggregation of SNPs. The in vivo study showed better wound healing activity than standard used namely silver sulphadiazine marketed cream. **Conclusion:** Synthesis of SNPs using turmeric extract and curcumin is a new, green method and not reported yet, as per literature survey done for this project. Successful synthesis and evaluation of SNPs was proved by the in vivo and in-vitro study.

Key words: Curcumin, curcuminoids, silver nanoparticles, turmeric extract, wound healing

INTRODUCTION

Nanotechnology is gaining tremendous impetus in the present century due to its capability of modulating metals into their nano size, which drastically changes the chemical, physical, and optical properties of metals. Nanoparticles are the clusters of atoms in the size range of 1-100 nm. Metallic

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Formulation and Evaluation of Chronomodulated Drug delivery System

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Abstract

The aim of the study is to develop chronomodulated floating drug delivery system for Famotidine to release the drug in the stomach after a predetermined time period. It is widely prescribed in gastric ulcers, duodenal ulcer, zolingerellison syndrome and gastroesophageal reflux disease. Nocturnal acid breakthrough typically appears in the second 6- hour period (2 to 4 am) after the evening dose of a PPI when patients are sleeping. Famotidine is a histamine H2 receptor antagonist with elimination half life 3 hours. Taking conventional tablets of Famotidine after evening meal cannot able to overcome nocturnal acid break through effectively. Chronomodulated tablets of Famotidine with local delivery to stomach, having ability for off release followed by burst release, can effectively suppress nocturnal histamine level and hence suppress high nocturnal acid release. Different levels of percentage weight ratio of ethyl cellulose to hydroxypropyl cellulose and different coating level were successfully optimized by using statistically analysis. For the present study of formulating chronomodulated floating drug delivery system optimized coating level / % weight gain was 7.56 % and percentage weight ratio of ethyl cellulose to hydroxypropyl cellulose was 78.50% that can give observed lag time of 218 minute and percentage cumulative drug release 88.210 % with minimum percentage error with predicted values from software. Developed Chronomodulated floating Drug delivery of Famotidine may effectively give night time relief from nocturnal acid breakthrough (pH < 4 at 2-4 am) in patients with peptic ulcer, duodenum ulcer and Gastro esophageal reflux disease.

Keywords: *chronomodulated drug, Famotidine, Control release*

INTRODUCTION

The oral route of drug administration is the most important method of administering drugs for systemic effects. The parenteral route is not routinely used for self

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Review Article

PBPK Modeling - A Predictive, Eco-Friendly, Bio-Waiver Tool for Drug Research

Author(s): Baishakhi De, Koushik Bhandari, Ranjan Mukherjee, Prakash Katakam, Shanta K. Adiki, Rohit Gundamaraju and Analava Mitra*

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Abstract

Background: The world has witnessed growing complexities in disease scenario influenced by the drastic changes in host-pathogen- environment triadic relation. Pharmaceutical R&Ds are in constant search of novel therapeutic entities to hasten transition of drug molecules from lab bench to patient bedside. Extensive animal studies and human pharmacokinetics are still the "gold standard" in investigational new drug research and bio-equivalency studies. Apart from cost, time and ethical issues on animal experimentation, burning questions arise relating to ecological disturbances, environmental hazards and biodiversity issues. Grave concerns arises when the adverse outcomes of continued studies on one particular disease on environment gives rise to several other pathogenic agents finally complicating the total scenario. Thus Pharma R&Ds face a challenge to develop bio-waiver protocols. Lead optimization, drug candidate selection with favorable pharmacokinetics and pharmacodynamics, toxicity assessment are vital steps in drug development.

Methods: Simulation tools like Gastro Plus™, PK Sim®, SimCyp find applications for the purpose. Advanced technologies like organ-on-a chip or human-on-a chip where a 3D representation of human organs and systems can mimic the related processes and activities, thereby linking them to major features of human biology can be successfully incorporated in the drug development tool box.

Results: PBPK provides the State of Art to serve as an optional of animal experimentation. PBPK models can successfully bypass bio-equivalency studies, predict bioavailability, drug interactions and on hyphenation with *in vitro-in vivo* correlation can be extrapolated to humans thus serving as bio-waiver.

Conclusion: PBPK can serve as an eco-friendly bio-waiver predictive tool in drug development.

Keywords: Therapeutic entities, Lead optimization, bio-equivalency, bio-waiver, biodiversity pharmacokinetics, pharmacodynamics, human-on-a chip.

Principal
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Tue, 12/26/2017 - 09:44 | Anonymous

‹ Matrix Tablet Containing Quaternary Inclusion Complex of Domperidone for Treatment of Diabetic Gastroparesis up Evaluation of Antiurolithiatic Potentials of Hydro-Alcoholic Extract of Cucumis sativus L. ›

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Comparative in-vivo Evaluation of Anti-Cancer Drugs Loaded Nanospheres

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[2]Department of pharmaceutics Jyothismathi college of Pharmacy, Turkapally(V), Shameerpet(M), Medchal-Dist. Telangana-500078, INDIA.

Abstract:

Objectives: objective of present research was to formulate and evaluate nanospheres of selected anticancer drugs, viz., Capecitabine (CPN), Tamoxifen (TAM) and Doxorubicin (DXO). The adverse effects associated with anticancer drugs which include are bonemarrow depression, cardio toxicity, diarrhoea, nausea and vomiting, stomatitis and dermatitis. **Materials and Methods:** Drug loaded nanospheres of polycaprolactone-chitosan in various drug: polymer ratios, cross linked with Tripolyphosphate were prepared by double emulsion solvent evaporation and solvent diffusion methods. Male white New Zeeland Rabbits(weighing about 2500 gm) were selected as the animalmodel. The rabbits selected for the study had no medicationfor two weeks prior to the study. **Results and Discussion:** The parameters like AUC(0-24) of DXO nanospheres 2362.0 ng.h/mL, whereas DXO pure drug was 1956.5 ng.h/mL. AUC (0-24) of TAM nanospheres 5646.00 ng.h/mL. Whereas TAM unadulterated medication was 4786.30ng.h/mL. AUC (0-24) of CPN nanospheres 4927.40 ng.h/mL. Whereas CPN pure drug was 4027.5ng.h/mL. **Conclusion:** *In vivo* results showed a significant increase in the bioavailability of drugs from DXO6, CPN6 and TAM6 nanospheres when compared to those of the standard drugs. This enhanced bioavailability could be helpful in reducing the dose of DXO, CPN and TAM and also reduce their toxicities. This enhanced bioavailability could be helpful in reducing the dose and also reduce the toxicities of the selected drugs.

Key words: Doxorubicin, Tamoxifen, Capecitabine, Nanospheres, *in vivo* studies.

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Comparative in-vivo Evaluation of Anti-Cancer Drugs Loaded Nanospheres

Authors and affiliation (s):

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[2]Department of pharmaceutics Jyothismathi college of Pharmacy, Turkapally(V), Shameerpet(M), Medchal-Dist. Telangana-500078, INDIA.

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Research Article

Development of An Antidiabetic Phytocomposite Loaded Phytoceutical Formulation, Its Quality Control and Pharmacokinetic Studies and Establishing *In Vitro- In Vivo* Correlation

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ABSTRACT

This study reports the development of solid oral phytoceutical formulations with Phytocomposite (PHC), an antidiabetic poly herbal preparation as the active core material. Spherical, monolithic PHC microspheres of size range (10 -100 µm) were obtained with Hausner ratio, Carr's index and angle of repose of 1.141± 0.010, 12.418±0.769 and 25.17±0.96 respectively. Encapsulation efficiency amongst different batches (F1-F5) ranged from 96.8- 100.7, with 99% release profile up to 12h. Conventional and sustained release tablets were prepared by direct compression and compatibility amongst polymers and the PHC checked by FTIR studies. Natural polymers viz. gum kondagogu, gum karaya, *Aegle marmelos* gum were used as release retardant. Optimized batch of conventional tablets (F6) showed 99.8 % release in 35 min and optimized batch of PHC-SR tablets (F12) showed 99.9% release at 12th hr, both followed zero order kinetics and non-Fickian diffusion. These optimized formulations were subjected to stability studies and the similarity factors (f2) of the conventional and SR tablets were 88.75 and 66.76 respectively. Pharmacokinetic parameters of three formulations in rat plasma were analyzed by PK Solver 2.0. *In vitro-in vivo* correlation (IVIVC) of three different formulations showed Level A correlation in all cases.

Keywords: phytocomposite, microspheres, conventional, sustained release, phytoceutical, Level A correlation.

INTRODUCTION

Considering the multiple etiology of Type 2 diabetes, therapeutic strategies in treating Type 2 diabetes have undergone a radical change and focuses on multi dimensional aspects viz. hormonal effects, oxidative stress, cell signaling defects, hyper or hypo activities of enzymes etc[1,2]. Enzymes like alpha amylase, alpha glucosidase, aldose reductase, dipeptidyl peptidase 4 are considered to play a role in the pathogenesis of Type 2 diabetes[2]. Currently there has been a great resurgence of interest in phytomedicine in the treatment of chronic ailments. Pharmacologically active molecules from natural sources inhibiting such enzymes can serve as effective therapeutic entities in the management of Type 2 DM. Indian subcontinent is bestowed with natural phytomedicinal hub with several pharmacologically active phytochemicals that can serve as Natural enzyme inhibitors (NEIs) as well as active pharmaceutical ingredients (API) which can be implemented in the control of this chronic disease[2].

Combination therapy with poly herbals or phytoceuticals has gained popularity in terms of providing multiple and synergistic health benefits[1]. Oleanolic acid is found to provide a synergistic effect with first line antidiabetic metformin[3]. Sesame oil forms a synergistic antidiabetic combination with glibenclamide[4]. Research works of Mitra et al. have shown that Fenugreek-tulsi composite or composite prepared from the Tulsi leaves (*Ocimum sanctum*), Amla (*Emblica officinalis*), Bitter Gourd (*Momordica charantia*), Gurmur leaves (*Gymnema sylvestre*) and Jamun (*Syzygium cumini*) fruit and its seed help in controlling the blood gluco-lipid profile of Type 2 diabetics and is accepted by the indigenous or tribal populace of Bengal as surveyed in Binpur and Jhargram area of rural Bengal[5-7].

Ficus benghalensis (Indian Banyan tree, family *Moraceae*), *Syzigium cumini* (Jamun or Black pulm, family *Myrtaceae*) and *Ocimum sanctum* (Holy Basil or Tulsi, family *Lamiaceae*) have documented anti-diabetic potentials. A poly herbal product, named as phytocomposite (PHC), prepared from the leaf powders of Banyan, Jamun and Tulsi in varying weight ratios is found to show synergistic antioxidant and anti-diabetic actions in various *in vitro* enzyme inhibitory assays that are found to play a role in the pathogenesis of Type 2 diabetes[2].

Despite immense potentialities of the phytomedicines, the preparation and delivery pattern being traditional (either as whole extracts or individual herbs) problem arises due to patient noncompliance owing to organoleptic issues,

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Prakash Katakam **Narendra CharyT**

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Formulation and Evaluation of Mucoadhesive Microspheres of Pioglitazone Hydrochloride Prepared by Ionotropic External Gelation Technique

Nagarajan Sriram (articles.aspx?searchcode=Nagarajan++Sriram&searchfield=authors&page=1)[1], Prakash Katakam (articles.aspx?searchcode=Prakash++Katakam&searchfield=authors&page=1)[2*]

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DOI: 10.4236/jeas.2016.61003 (http://dx.doi.org/10.4236/jeas.2016.61003) **PDF (//www.scirp.org/pdf/JEAS_2016031514322251.pdf) HTML (//www.scirp.org/journal/paperinformation.aspx?paperid=64518) XML (//www.scirp.org/xml/64518.xml)** **3,131** Downloads **5,380** Views Citations (papercitationdetails.aspx?paperid=64518&JournalID=531)

Abstract

Microspheres containing Pioglitazone hydrochloride were prepared by the ionotropic external gelation method, using sodium alginate with four mucoadhesive polymers namely sodium carboxy methyl cellulose, hydroxy propyl methyl cellulose, carbopol 934 P and cellulose acetate phthalate as coat materials. Ionotropic gelation is a method to prepare microspheres using combination of Ca^{2+} as cationic components and alginate as anion. The practical yield of prepared microspheres using the ionotropic gelation technique was between 172 mg and 604 mg. The result of the Chi-squared test carried out between the actual (practical) and expected (theoretical) yields showed no significant difference ($P < 0.05$) which indicated that the ionotropic gelation technique could be successfully employed to prepare pioglitazone microspheres using sodium alginate, sodium carboxy methyl cellulose, carbopol 934 P, HPMC, cellulose acetate butyrate polymers. The drug entrapment efficiency of prepared microspheres showed between 56.12% ± 3.86% to 84.68% ± 2.93% which was significantly higher for ionotropic gelation technique. The highest drug entrapment was found in formulation PMI 8. Swelling index is the capability of a polymer to swell before the drug is released which influences the rate and mechanism of drug release from the polymer matrix. The swelling index of prepared microspheres was in the range of 68% ± 4.52% to 87% ± 0.98%. Pioglitazone HCl microspheres showed controlled release of drug without initial peak level achieving. This type of properties in Pioglitazone HCl microspheres used to decrease side effects, reduce dosing frequency and improve patient compliances. From the all batches PMI 8 is considered the best formulation, because among all other formulations, it shows better extent of drug release up to 82.12% (18 h), good entrapment efficiency (84.68%) and the *ex-vivo* wash-off test shows the best mucoadhesive property. The *in vitro* drug release studies do up to 18 h. As observed from the various plots, most of the formulations followed the Korsmeyer-Peppas model.

Keywords

Diabetes Mellitus (articles.aspx?searchcode=Diabetes+Mellitus&searchfield=keyword&page=1&skid=0), Mucoadhesive Microspheres (articles.aspx?searchcode=+Mucoadhesive+Microspheres&searchfield=keyword&page=1&skid=0), Mucoadhesive Polymers (articles.aspx?searchcode=+Mucoadhesive+Polymers&searchfield=keyword&page=1&skid=0), Mucoadhesion (articles.aspx?searchcode=+Mucoadhesion&searchfield=keyword&page=1&skid=0), Sustained Release (articles.aspx?searchcode=+Sustained+Release&searchfield=keyword&page=1&skid=0), Ionotropic External Gelation Technique (articles.aspx?searchcode=+Ionotropic+External+Gelation+Technique&searchfield=keyword&page=1&skid=0)

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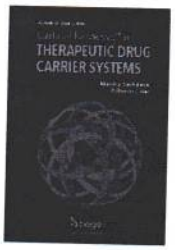

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Top-Down and Bottom-Up Approaches in 3D Printing Technologies for Drug Delivery Challenges

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ABSTRACT

3-Dimensional printing (3DP) constitutes a raft of technologies, based on different physical mechanisms, that generate a 3-dimensional physical object from a digital model. Because of its rapid fabrication and precise geometry, 3DP has gained a prominent focus in biomedical and nanobiomaterials research. Despite advancements in targeted, controlled, and pulsatile drug delivery, the achievement of site-specific and disease-responsive drug release and stringent control over in vivo biodistribution, are still some of the important, challenging areas for pharmaceutical research and development and existing drug delivery techniques. Microelectronic industries are capable of generating nano-/microdrug delivery devices at high throughputs with a highly precise control over design. Successful miniaturizations of micro-pumps with multireservoir architectures for delivery of pharmaceuticals developed by micro-electromechanical systems technology were more acceptable than implantable devices. Inkjet printing technologies, which dispense a precise amount of polymer ink solutions, find applications in controlled drug delivery. Bioelectronic products have revolutionized drug delivery technologies. Designing nanoparticles by nanoimprint lithography showed a controlled drug release pattern, biodistribution, and in vivo transport. This review highlights the "top-down" and "bottom-up" approaches of the most promising 3DP technologies and their broader applications in biomedical and therapeutic drug delivery, with critical assessment of its merits, demerits, and intellectual property rights challenges.

KEY WORDS: 3D printing, biomedical, drug delivery, MEMS technology, inkjet printing, top-down, bottom-up, IPR challenges

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Original Article

In vitro–in vivo studies of the quantitative effect of calcium, multivitamins and milk on single dose ciprofloxacin bioavailability ☆

Baishakhi Dey [a], Prakash Katakam [b], Fathi H. Assaleh [b], Babu Rao Chandu [b], Shanta Kumari Adiki [c], Analava Mitra [a]

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https://doi.org/10.1016/j.jpha.2015.02.003

Abstract

Ciprofloxacin, commonly used in India as an anti-microbial for prolonged use in chronic and non-specific indications, may affect the bioavailability of the drug. The drug prescribed is commonly taken with multivitamins, calcium and milk. A simple and reliable analytical methodology obtaining a correlation with *in vivo* urinary excretion studies using UV and HPLC and *in vitro* dissolution studies (IVIVC) has shown a significant increase in elimination rate of ciprofloxacin co-administered with multivitamins, calcium and milk. Appreciable IVIVC results proved that dissolution studies could serve as an alternative to *in vivo* bioavailability and also support bio-waivers.

Previous

Next

Keywords

Ciprofloxacin; Analytical methodology; Bioavailability; Bio-waiver; Dissolution study

1. Introduction

Development of antimicrobial resistance is a challenging problem in world health scenario, despite the increasing demand for antimicrobials in global pharmaceutical market worths a current value of about $66.5 billions [1]. However, antibiotics are one of the most widely used and frequently misused drugs. Due to wide predominance of infectious diseases and emergence of resistant strains, there is an increased inclination among clinicians to prefer newer-generation antibiotics as one of the first-line therapeutic regimens. However, prolonged antibiotic therapy may give rise to some side effects like anemia, dyspepsia, hyperacidity, gastritis, hepatotoxicity and nephrotoxicity, which necessitate co-medications. Such co-medications include common antacids or multivitamins (MVs) which are either prescribed by physicians or self-advised and that may adversely affect the bioavailability of the antibiotic prescribed. Thus, the anti-microbial effect of the drug is compromised, leading to prolonged consumption of the antibiotic and development of antimicrobial resistance against that particular antibiotic [2], [3], [4].

Editorial

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Computational pharmacokinetics and in *vitro-in vivo* correlation of anti-diabetic synergistic phyto-composite blend

Baishakhi De, Koushik Bhandari, Nishant Chakravorty, Ranjan Mukherjee, Rohit Gundamaraju, Rajeev K Singla, Prakash Katakam, Shanta K Adiki, Biswajoy Ghosh, Analava Mitra

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Author contributions: De B developed the central theme of the manuscript under the guidance of Chakravorty N, Katakam P and Mitra A; Bhandari K, Mukherjee R, Gundamaraju R and Singla RK contributed in literature review, and provided their valuable suggestions; De B developed the manuscript under the guidances of Chakravorty N, Shanta KA and Mitra A; Ghosh B prepared the pictorial presentations of receptor pathways and gave his suggestions.

Conflict-of-interest statement: All authors declare that the conflict of interest is nil.

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Chemometrics Based Extraction of Polyphenolics from Fresh Tea Leaves and Processed Tea Showing *In- Silico* Docking and Anti-oxidative Theronostic Dietary Adjuvant in Alzheimer

Koushik Bhandari [1], Rajeev K Singla [2], Baishakhi De [1], Bijoy Chandra Ghosh [3], Prakash Katakam [4], Dilip Kumar Khushwaha [3], Rohit Gundamaraju [5], Gargi Sen [6], Gargi Saha [7], Anirban Mitra [8], Analava Mitra [1*]

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Keywords
Chemometrics; Tea polyphenolics; Antioxidant; GRIP docking studies; Alzheimer.

ABSTRACT: Aim of the study is to chemometrically optimize the extraction procedure of tea polyphenolics, evaluate antioxidant potentials of fresh tea leaves and made tea grown in the non-traditional tea zone of IIT Kharagpur by in vitro assays, in silico docking studies and in vitro AChE inhibitory assays. Total tea polyphenolics, flavonoids and volatile contents of aqueous and methanolic extracts of fresh tea leaves and made tea were estimated by UV, HPLC and GC-MS analysis. The extraction process parameters were optimized by central composite design of chemometrics to maximize polyphenol yield. Antioxidant properties were studied by in vitro DPPH radical scavenging, FRAP, ABTS and Dot Blot Assay. In silico GRIP docking studies were done to evaluate the effectivity of tea catechins as antioxidants against the targeted proteins. In vitro AChE inhibitory assay was done to see its anti-Alzheimer effect. Basing on desirability function, 3.75±0.04 g of sample weight and 207.32±0.01 mL of methanol of TV fresh leaf varieties gave percent yield of poly phenols in range of 31.35 ± 2.78 - 25.14 ± 1.74 and for aqueous extract the polyphenol yield range was from 21.94 ± 2.06 - 20.13 ± 2.78. Both fresh leaf and made tea of TV 25 variety gave highest polyphenol yields of 31.35±2.78% (methanol) and 9.84±0.79% (aqueous) respectively. In silico GRIP docking studies showed epi-catechin gallate as the most potent antioxidant. The IC50 values for AChE inhibitory assay of black tea (CTC) was found to be 34.18µg/mL. Amongst three varieties (TV 25, TV 26 and TV 23), both fresh leaf and made tea of TV 25 variety showed maximal poly phenol content with highest antioxidant potential and were found to be comparable to Assam clones in this respect. The same fact is also reflected in the AChE inhibitory assay. Considering the significant polyphenol content and anti-oxidant capacity it can be concluded that these tea polyphenols can serve the purpose of adjuvant therapy in Alzheimer.

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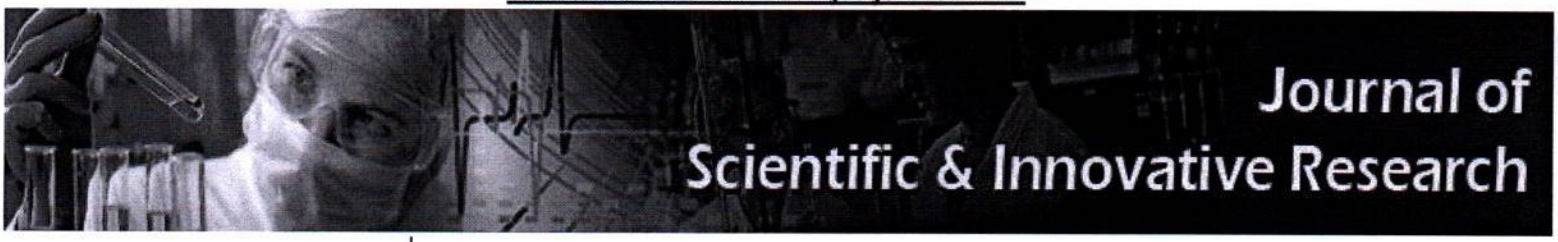

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Formulation and evaluation of sustained release venlafaxine tablets using hydrophilic-hydrophobic polymer combinations by melt granulation

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Abstract

The current research aims to formulate Venlafaxine Sustained Release (VHL-SR) tablets using hydrophilic-hydrophobic polymers combination blends by melt granulation technique which highlights the novelty. The polymers selected for the present study have matrix forming properties. Results of FTIR studies have shown that there were no interactions between the polymers used and the drug VHL. Various formulations of VHL- SR tablets (F1-F16) using different combinations of hydrophilic and hydrophobic polymers viz. Carbopol 71G, HPMC K15M, PEO, sodium CMC, Eudragit RS100 and precirol were formulated. Prior pre-formulation studies carried out on powder blend showed good flow properties.

Routine quality evaluations of the VHL-SR tablets showed the diameter of the tablets of all formulations were found to be 9.0±0.0 mm and thickness ranged between 2.08±0.08 to 2.25±0.14 mm, hardness 4.08±0.20 - 5.50±0.31 kg/cm^2, percentage friability 0.24±0.03 - 0.45±0.01%, weight variation from 0-1.15%, drug content uniformity from 98.17±0.68 to 101.89±0.73%, all within Pharmacoepial limits. Results of *in-vitro* drug release study indicated that the formulation containing Carbopol 71G (50 mg), Xanthan gum (75 mg) and MCC (50 mg) extended the release of the VHL. Formulation F15 was the optimized one which gave satisfactory release (95.2%) for 16 hr and with a similarity factor (f2) 68.46, the release kinetics best explained by the Korsmeyer-peppas and Higuchi diffusion models. The "N" values between 0.5-1.0 in all the formulations exhibiting a non-Fickian release behavior controlled by a combination of diffusion and chain relaxation mechanism. The formulation showed appreciable stability under accelerated conditions after 2 m.

Keywords: Melt granulation technique, Polymers, Pre-formulation, FTIR, Higuchi diffusion models, Non-Fickian.

Introduction

Oral route is the most commonly adapted and convenient route for drug delivery because of flexibility in the formulation, patient compliance and physician's convenience for dose adjustment. Most of the conventional dosage formulations are immediate-release systems where there is no stringent control over drug release and often results in multiple dosing, leads to fluctuations in plasma drug concentration.[1-6] Moreover to achieve effective concentration at the targeted site of action, intermittent drug intake becomes necessary and often sub or supra therapeutic drug concentrations results in unpredicted side effects. To overcome all these, Sustained Release Dosage

Formulation development and evaluation of novel oral jellies of carbamazepine using pectin, guar gum, and gellan gum

PDF (https://www.asiapharmaceutics.info/index.php/ajp/article/view/450/389)

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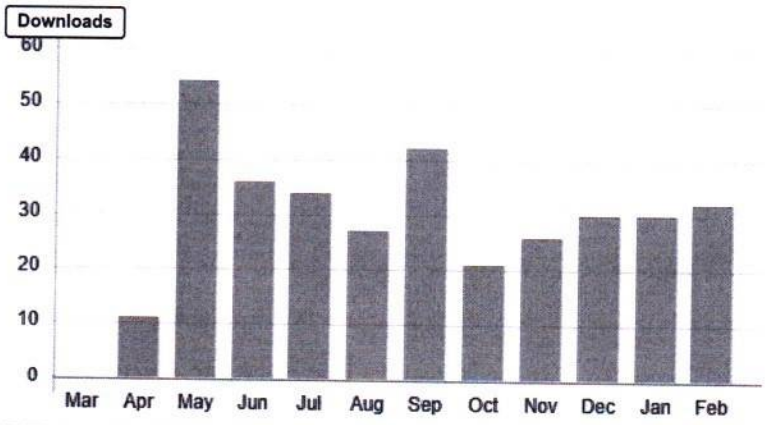
Dr. Katakam Prakash

Abstract

Medicated jelly formulations are more suitable for pediatric, geriatric and dysphagic patients, which offer rapid dissolution and absorption of drugs thereby early onset of action. The aim was to develop and evaluate oral jellyÂ formulations of carbamazepine (CBZ). Carbamazepine oral jellies were prepared to employ pectin, guar gum and gellanÂ gum alone and pectinâ€guar gum combination. Preformulation studies, organoleptic, physical characteristics, drug content,Â pH, spreadability, rheological properties, syneresis, taste masking, in vitro dissolution testing, drug release kinetics andÂ stability studies were conducted. The Fourier transform infrared and differential scanning calorimeter studies showed thatÂ there was no interaction between drug and excipients. The pH of all the formulations was found between pH 6.37 Â± 0.03Â and 6.83 Â± 0.04. The concentration of gelling agents influenced the spreadability. Syneresis was observed in jellies madeÂ from guar gum alone, whereas those made from pectin and guar gum it was absent. The optimized formulations (F3, F11Â and F15) masked the bitter taste of CBZ and demonstrated acceptable flavor and mouth feel. All formulations showed moreÂ than 50% drug release in 15 min except those made of gellan gum alone. The formulations F3, F11 and F15, were foundÂ stable for 90 days as per International Conference on Harmonization stability protocol. Carbamazepine jellies made from pectin (F3, 1.2%), gellan gum (F11, 1.5%) and pectinâ€guar gum (F15, 1:0.4%) were found more successful and could be employed to improve the palatability and acceptability by pediatric, geriatric and dysphagic patients. The jellies could be useful to overcome the problems of poorly soluble CBZ.

Key words: Carbamazepine, dysphagic patients, medicated jelly, natural polymers



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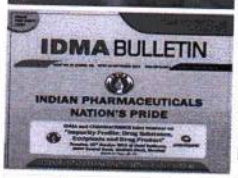

Article Details

DOXORUBICIN LOADED POLYCAPROLACTONE-CHITOSAN NANOSPHERES: FORMULATION, CHARACTERISATION AND IN VITRO EVALUATION

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ABSTRACT

The present study was aimed to develop and evaluate polycaprolactone–chitosan nanospheres of doxorubicin hydrochloride (DXO) in different drug to polymer ratios using double-emulsion solvent evaporation and solvent diffusion methods. FTIR studies showed that there was no chemical interaction between the drug and polymers. Scanning electron microscopy showed the nanospheres having a discrete spherical structure without aggregation. Prepared nanospheres were characterized for particle size, zeta potential, entrapment efficiency and in-vitro drug release kinetics. Nanospheres showed the particle size of 700±105to770±115 nm with an entrapment efficiency of 66.23±0.11% to 93.62±0.17%. The DXO content was found 76±0.12% to 91±0.36% in several batches. In-vitro drug release studies were performed using the dialysis membrane method. All the drug loaded batches were rendered sustained release over a period of 24 h.

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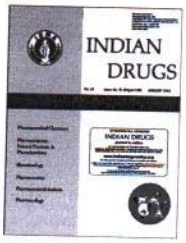

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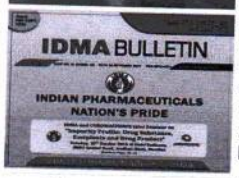

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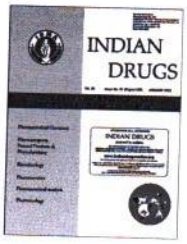

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Full Length Research Paper

A Comparative Evaluation of Drug Release and Permeability of Ethylcellulose, Cellulose Acetate and Eudragit RS100 Microspheres

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Abstract. Present study aims at comparative evaluation of drug release and permeability of diclofenac sodium loaded ethylcellulose (EC), cellulose acetate (CA) and eudragit (EU) microspheres. Microspheres of EC, CA and EU containing diclofenac sodium were prepared by an emulsification-solvent evaporation (oil-in-oil, o/o) method and were investigated for a comparative evaluation of various parameters. The microspheres were found discrete, free flowing, multinucleate, monolithic and spherical. About 55–60% of all microspheres prepared were in the size range of –20+30 (715 μm) mesh size. The encapsulation efficiency was in the range of 97.1–106.4% with various polymers. The wall thickness of microspheres was in the range of 13.69-74.97μm which depended on polymer employed and was directly proportional to polymer concentration. Diclofenac release from the microspheres was slow over longer periods of time and depended on the polymer used and coat:core ratio. Release was diffusion controlled and followed first order kinetics. Good linear relationships were observed between percent coat, wall thickness and release rate constant with all the three polymers. The slopes of percent coat vs release rate (k_1) plots were found to be 0.4117, 0.2351 and 0.9762; and those of wall thickness (h) vs drug release rate (k_1) plots were found 0.2549, 0.1863 and 0.7850 respectively for EC, CA and EU microspheres. The lower the slope the better is the controlling effect. Cellulose acetate exhibited better release-controlling effect than that of ethylcellulose and eudragit. The increasing order of diclofenac release rate and permeability observed with various microspheres was, cellulose acetate < ethylcellulose < eudragit RS100. The possible permeability of drug from the prepared porous micrsopheres could be due to osmotic pressure generated by diclofenac.

Keywords: Diclofenac sodium, Microspheres, Ethylcellulose, Cellulose acetate, Eudragit RS100 Release kinetics

1. INTRODUCTION

Microspheres are solid, approximately 1 to 1000 μm in size and are made of synthetic and natural polymeric, waxy or other protective materials both biodegradable and non-biodegradable (Vyas and Khar, 2002). The internal structure of microspheres varies as a function of polymer and the process employed to prepare them (Brannon-Peppas, 1992). Reservoir microcapsules have a core of drug coated with a polymer. Whereas in monolithic microspheres, the drug is distributed homogeneously throughout the polymeric matrix. Microspheres have been widely accepted as a means to achieve oral and parenteral controlled release (Sau-hung et al., 1987). Microspheres provide several advantages over other sustained release systems, especially matrix type gastrointestinal tract, improve drug absorption and minimize side effects due to localized buildup of irritating drugs against the gastrointestinal mucosa (Li et al., 1988).

The rate of drug release from microspheres dictates their therapeutic action. Release is governed by the molecular structure of the drug and polymer, the resistance of the polymer to degradation and the surface area and porosity of microspheres (Izumikawa et al., 1991; Pitt and Schindler, 1983). Drug release from polymeric systems with a variety of geometries has been described (Cheung et al., 1988). Zero order release kinetics may be more easily achieved with slab or rod geometries than spheres. The rate of release from spheres may result from polymer diffusion or erosion (Cartensen, 1984; Crank, 1975).

Ethylcellulose, cellulose acetate and eudragit

Starch - Stärke / Volume 66, Issue 3-4 / p. 409-417

Research Article

Synthesis and characterisation of starch tartrate and its application as novel disintegrant in telmisartan tablets

Fathi H. Assaleh, Prakash Katakam ✉, Ramesh Botcha, Babu Rao Chandu, Shanta Kumari Adiki

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Abstract

The aim of the present study was to synthesize potato starch (PS) derivatives of tartaric acid (TA) under semi-dry conditions and to evaluate the physicochemical properties as per official compendia requirements. Starch tartrate (ST) was synthesized by reacting PS (St–OH) and TA in semi-dry condition using sodium hypophosphite (SHP) as a catalyst. Further we have applied its use as disintegrant in directly compressed telmisartan tablets. The microscopic, spectroscopic (FTIR), thermal (DSC) and crystallographic (XRD) studies confirmed the formation of ST. No gelling was observed at 100°C but it was converted to a clear solution with a swelling index of 1.666 times. ST was found to have suitable compression properties required for directly compressible tablets. The tablets formulated employing ST (5–15% w/w) as disintegrant gave rapid disintegration and dissolution rates compared to those prepared using commercial superdisintegrants (sodium starch glycolate and crosscarmellose sodium). The optimized formulation showed disintegration time of 31 ± 3 s which is found superior to that of others. It is concluded that the synthesized ST could be employed as a promising disintegrant in dispersible tablet formulations.

World Journal of Diabetes

(/1948-9358/index.htm)

Original Article

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Exploration of natural enzyme inhibitors with hypoglycemic potentials amongst *Eucalyptus* Spp. by *in vitro* assays

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Abstract

AIM: To investigate the presence and potency of natural enzyme inhibitors with hypoglycemic potentials amongst *Eucalyptus Spp*. by *in vitro* assays.

METHODS: The leaf extracts of the three different *Eucalyptus* species [E. *globulus* (EG), E. *citriodora* (EC), E. *camaldulensis* (ECA)] were subjected to *in vitro* assay procedures to explore the prevalence of natural enzyme inhibitors (NEIs) after preliminary qualitative and quantitative phytochemical evaluations, to study their inhibitory actions against the enzymes like α-amylase, α-glucosidase, aldose reductase, angiotensin converting enzyme and dipeptidyl peptidase 4 playing pathogenic roles in type 2 diabetes. The antioxidant potential and total antioxidant capacity of the species were also evaluated.

Article

Comparative Evaluation of Hypoglycemic Potentials of Eucalyptus Spp. Leaf Extracts and their Encapsulations for Controlled Delivery

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Abstract

Eucalyptus is well represented in different Pharmacopeias for its variant pharmacology and depicts a wide range of photochemicals like triterpenoids, flavonoids, polyphenols, gallotannins and macrocarpals both in its volatile and nonvolatile fractions. Hot aqueous leaf decoctions of Eucalyptus have been recommended as 'herbal tea' in different regions of world for its hypoglycemic potentials. However lack of definitive dosage formulations of Eucalyptus bioactive, side effects like nausea, vomiting, gastric irritation, organoleptic unacceptability have limited its application; besides data on toxicology and posology being inconsistent and variant. In the current research work firstly comparative evaluations of hypoglycemic potentials amongst three Eucalyptus spp. E. globulus, E. citriodora, E. camaldulensishave been done by in vitro α-glucosidase assay. E. globulus showed maximal inhibitory effect in a concentration dependent manner (IC50 = 2.0829±0.001 µg/ml) followed by E. citriodora (IC 50 = 2.11117±0.011 µg/ml) and E. camaldulensis (IC50 = 2.68395±0.005 µg/ml). Next, leaf extract concentrate of E. globulus (EGLE) was bio-fabricated to microcapsules by a combined liquid orifice-emulsification-ionic gelation method where active extract is embedded in inner alginate gel matrix with an outer chitosan coating. Mucoadhesivity of the microcapsules were tested on rat intestinal tissues by an in vitro adhesion testing called wash-off test. Microencapsulation efficiency was 97.9±0.001-98.3±0.001% and exhibited good mucoadhesivity in wash-off test. Initial EGLE release was slow but a controlled release of 12-14 hr was achieved in dissolution studies in vitro. Kinetic release data of EGLE fits well with first order and Higuchi Model however there is a predominance of first order release kinetics and the EGLE release pattern was primarily diffusion controlled. Further "n" value of KorsmeyerPeppas equation showed that mechanisms of EGLE release followed anomalous non-Fickian diffusion and also by erosion. The optimized microcapsules were found to be promising for oral controlled delivery of Eucalyptus extract.

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Research Article | Volume: 3, Issue: 8, August, 2013 Check for updates

Comparative in vivo evaluation of three types of honey on topical wound healing activity in rabbits

Nagiat T Hwisa, Prakash Katakam, Babu Rao Chandu, Einas Ghafar Abadi and Ebtihal Mosbah Shefha ⊕ Author Affiliations

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Abstract

The present investigation has focused on the comparative evaluation of topical wound healing activity in rabbits using three types of honeys such as Sidr (SDH), Thyme (TYH), Spring (SPH). The activity was compared with commercial wound healing formulations, Mebo (MBC) and Fusidin (FSC) creams. Among the different types of the honey SDH was found to possess higher healing rate of wounds induced either by thermal or chemical methods. Whereas, in thermal induced burns, both TYH and SPH have shown similar wound healing activity but better than that of standard drugs. The activity for thermal and chemical induced burns was found in the order of SDH > TYH/SPH > MBC > control and SDH > TYH > SPH > FSC > control respectively. Among the three tested honeys, the t-test data was compared to those of controls and it was found that there was a significant ($p<0.05$) reduction in the wound area. It was concluded that honey in general could be employed as natural topical wound healing agent comparable to commercial synthetic analogs tested in the study. Further the present investigation proves that SDH is possessing superior wound healing activity than that of TYH and SPH.

Keyword: **Honey** **Sidr** **Thyme** **Spring** **wound healing** **topical.**

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Simultaneous Quantification of Mesalamine and Its Metabolite N-Acetyl Mesalamine in Human Plasma by LC-MS/MS and Its Application to a Bioequivalence Study

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Abstract

Liquid chromatography–tandem mass spectrometry (LC–MS/MS) was used for simultaneous quantification of mesalamine and its metabolite N-acetyl mesalamine in human plasma with N-acetyl mesalamine D3 as an internal standard (IS). Chromatographic separation was performed on a Thermo, HyPURITY C18 (150 x 4.6 mm, 5 ïm) column with an isocratic mobile phase composed of 10 mM ammonium acetate and methanol in the ratio of 85:15 (%v/v), at the flowrate of 0.6 mL/min. The drug, metabolite and internal standard were extracted by liquid-liquid extraction. The method was validated over a linear concentration range of 2-1500 ng/mL for mesalamine and 10-2000 ng/ml for N-acetyl mesalamine, which demonstrated intra and inter-day precision ranging from 1.60 to 8.63% and 2.14 to 8.67% for mesalamine and 0.99 to 5.67% and 1.72 to 4.89% for N-acetyl mesalamine respectively. Similarly, the intra- and inter-day accuracy varied from 102.70 to 105.48% and 100.64 to 103.87% for mesalamine, 99.64 to 106.22% and 100.71 to 104.27% for N-acetyl mesalamine respectively. Both analytes were found to be stable throughout freeze–thawing cycles, bench top and postoperative stability studies. The method was successfully applied to support a bioequivalance study of healthy subjects.

Keywords: Mesalamine; N-Acetyl mesalamine; LC/MS/MS; bioequivalence; pharmacokinetics

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Research article **Open Access**

An Experimental Design Approach for Impurity Profiling of Valacyclovir-Related Products by RP-HPLC

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Abstract

Impurity profiling has become an important phase of pharmaceutical research where both spectroscopic and chromatographic methods find applications. The analytical methodology needs to be very sensitive, specific, and precise which will separate and determine the impurity of interest at the 0.1% level. Current research reports a validated RP-HPLC method to detect and separate valacyclovir-related impurities (Imp-E and Imp-G) using the Box-Behnken design approach of response surface methodology. A gradient mobile phase (buffer: acetonitrile as mobile phase A and acetonitrile: methanol as mobile phase B) was used. Linearity was found in the concentration range of 50–150 µg/mL. The mean recovery of impurities was 99.9% and 103.2%, respectively. The %RSD for the peak areas of Imp-E and Imp-G were 0.9 and 0.1, respectively. No blank interferences at the retention times of the impurities suggest the specificity of the method. The LOD values were 0.0024 µg/mL for Imp-E and 0.04 µg/mL for Imp-G and the LOQ values were obtained as 0.0082 µg/mL and 0.136 µg/mL, respectively, for the impurities. The S/N ratios in both cases were within the specification limits. Proper peak shapes and satisfactory resolution with good retention times suggested the suitability of the method for impurity profiling of valacyclovir-related drug substances.

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Research article **Open Access**

Development and Validation of a Liquid Chromatography-Mass Spectrometry Method for the Determination of Zileuton in Human Plasma

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Abstract

A selective and sensitive liquid chromatography-tandem mass spectrometric method (LC-MS/MS) has been developed and validated for the quantification of zileuton in human plasma. Deuterated internal standard (zileuton D4) was used as the internal standard (ISTD). Zileuton was extracted by liquid-liquid extraction using methyl *tert*-butyl ether and separated by isocratic elution on a C18 column (100 x 4.6 mm, 5 µm, Discovery C18) with the mobile phase consisting of 1 mM ammonium acetate buffer and methanol in the ratio of 10:90. A flow rate of 1.0 ml/min was used with isocratic elution. Multiple reaction monitoring transitions in positive mode for zileuton and the internal standard were 237.3/161.2 and 241.2/161.1, respectively. The method was validated within the linearity range of 50.5–10,012.7 ng/ml for the bioanalytical method validation parameters like selectivity, accuracy, precision, recovery, stability, and matrix effect.

Keywords

Zileuton • Plasma • LC-MS/MS • Validation

Intruduction

Zileuton is an asthma drug that differs chemically and pharmacologically from other antiasthmatic agents. Zileuton is chemically known as 1-[1-(1-benzothiophen-2-yl)ethyl]-1-hydroxyurea (Figure 1) and is an orally active inhibitor of 5-lipoxygenase, the enzyme that

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Research Article

DEVELOPMENT AND VALIDATION OF UV AND RP-HPLC METHODS FOR THE ESTIMATION OF CEFTRIAXONE SODIUM IN PHARMACEUTICAL FORMULATIONS

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ABSTRACT
The current research paper reports a validated UV and RP-HPLC method for routine estimations of CFTX in bulk and unit dosage formulations. For the UV estimation of CFTX, using ammonium acetate buffer as the solvent, λ_{max} was set at 241.5 nm and linearity range obtained in the concentration range of 2–10 µg/mL. The optimized RP-HPLC conditions for CFTX estimation were obtained with isocratic separation mode in a C_{18} inertsil column (150 mm × 4.6 mm, 3 µm) using a degassed mixture of buffer: methanol in the ratio of 74:26, injection volume (20 µL), flow rate (1 mL/min) and run time (20 minutes), at ambient column temperature with UV detector set at 254 nm. The linearity of the method was demonstrated over the concentration range of 80–120 µg/mL. The percent assay of CFTX determined by UV and RP-HPLC method were 99.8 ± 0.001 and 101.5 ± 0.001 respectively. The recovery CFTX determined by UV and RP-HPLC were 99.6–99.8 % and 101.1 % respectively with % RSD values of peak areas 0.2 and 0.3 respectively. Values of all other parameters of method validations in both methodologies were within the acceptance limits.
Keywords: Ceftriaxone, Dosage formulations, UV estimation, RP-HPLC method, validation.

INTRODUCTION

With the advancements in pharmaceutical researches, adoption of novel drug delivery technologies, development of both small and large scale pharmaceutical industries worldwide, the number of drugs and drug formulations are increasing in the market day by day which may be entire new entities or partial modifications of the existing drugs or novel dosage formulations[1–3]. Analytical method development plays a pivotal role in statuary certification of drugs and their formulations either by the industry or by the regulatory authorities and simultaneously an integral part of pre formulation and formulation development research. Quality assurance and quality control departments of Pharmaceutical industries are largely responsible in bringing out safe, effective dosage formulations. The current good manufacturing practices (CGMP) and the Food Drug Administration (FDA) guidelines insist for adoption of analytical methodologies which are simple, rapid, cost effective and robust and provide results with great accuracy and precision. Sophisticated hyphenated techniques are in vogue but they are relatively expensive; many methods necessitate analyte extraction from respective sample matrices and hence complicated sample preparation steps, become time consuming, difficult in operation and error in recovery. More rapid, robust and precise the developed analytical methodologies are, more are the chances to bring newer products to the international markets faster[4–8]. Ceftriaxone (CFTX), chemically known as disodium (6R, 7R) -3[(acetyl-oxy) methyl] -7-[(2Z) - (2-amino- 4- thiazolyl) (methoxy amino) - acetyl] amino] -8- oxo- 5-thia-1- azabicyclo [4.2.0.] Oct- 2- ene- 2- carboxylic acid, is a cephalosporin β-lactam antibiotic used in the treatment of bacterial infections caused by susceptible usually gram-positive organisms (Figure 1). Bactericidal activity of CFTX is mostly by inhibition of mucopeptide synthesis in the bacterial cell wall and by binding to one or more of the penicillin-binding proteins (PBPs) which in turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus hindering cell wall biosynthesis. Bacteria eventually lyse due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases) while cell wall assembly is arrested[9–11]. Literature surveys have shown that the UV and HPLC methods developed estimates CFTX mostly in combined formulations[1–8,12–21]. However the current research aims to develop a validated UV and RP-HPLC method for routine estimations of CFTX alone in bulk and unit dosage formulations.

MATERIALS AND METHODS

Chemicals and reagents

Pure ceftriaxone sodium was gratis sample from Medreich Ltd, Hyderabad, India. HPLC grade water, methanol, AR grade ammonium acetate, ortho-phosphoric acid were purchased from Merck, Mumbai, India.

Instrumentation

HPLC (Shimadzu model, LC 10 ADVp, Japan with UV detector); UV-visible spectrophotometer (Thermo Scientific, Aquamate Plus, India), Electronic balance (Shimadzu, Japan), Sonicator (Cyber labs, India), pH meter (Datla instruments, DI-45, India)

UV method development

For the UV estimation of CFTX, ammonium acetate buffer was used as the solvent for study. Standard and stock solutions of CFTX were prepared using ammonium acetate buffer as the solvent. A solution of 10 µg/mL concentration was scanned in 200–400 nm wavelength range and the λ_{max} was set at 241.5 nm. The standard calibration curve was prepared with aliquots in the concentration range of 2–10 µg/mL using buffer as the blank.

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Original Article

Simultaneous determination of ezetimibe and simvastatin in rat plasma by stable-isotope dilution LC-ESI–MS/MS and its application to a pharmacokinetic study

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Abstract

A simple, sensitive and specific liquid chromatography–tandem mass spectrometry method was developed for simultaneous quantification of ezetimibe and simvastatin in rat plasma. The deuterium isotopes: ezetimibe d_4 and simvastatin d_6 were used as internal standards for ezetimibe and simvastatin, respectively. MS/MS detection involved a switch of electron spray ionization mode from negative to positive at retention time 3.01 min. Samples were extracted from plasma by liquid–liquid extraction using tertiary butyl methyl ether. Chromatographic separation was achieved with Agilent Eclipse XBD-C_{18} column using mobile phase that consisted of a mixture of ammonium acetate (pH4.5; 10mM)–acetonitrile (25:75 v/v). The method was linear and validated over the concentration range of 0.2–40.0ng/mL for simvastatin and 0.05–15.0ng/mL for ezetimibe. The transitions selected were m/z 408.3→271.1 and m/z 412.0→275.10 for ezetimibe and ezetimibe d_4, and m/z 419.30→285.20 and m/z 425.40→199.20 for simvastatin and simvastatin d_6. Intra- and inter-batch precisions for ezetimibe were 1.6–14.8% and 2.1–13.4%; and for simvastatin 0.94–9.56% and 0.79–12%, respectively. The proposed method was sensitive, selective, precise and accurate for the quantification of ezetimibe and simvastatin simultaneously in rat plasma. The method was successfully applied to a pharmacokinetic study by oral co-administration of ezetimibe and simvastatin in SD rats.

Previous

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ARTICLE

A Retrospective Study on Antibiotic Use in Different Clinical Departments of a Teaching Hospital in Zawiya, Libya

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Abstract

A cross-sectional retrospective drug utilization study was conducted in different wards of the Zawiya teaching hospital, Libya, over a 15-month period. One hundred prescriptions were examined, of which 51% were for females. The World Health Organization (WHO) indicators (utilization in defined daily doses (DDD); DDD/1000inh/day) were used and the ATC/DDD method was implemented. The most frequently prescribed antibiotic (30 occurrences) was amoxicillin+clavulanic acid, while the least frequent (once) was neomycin or cloxacillin. The DDD/1000inh/day of amoxicillin+clavulanic acid was the highest (11.69) and that of ciprofloxacin was lowest (2.86). The ward with the highest number of prescribed antibiotics (35%) was surgery, while the ward with the lowest number (9%) was ENT. Average treatment period was found to be five days. In conclusion, our data showed an overuse of amoxicillin+clavulanic acid in contrast to other antibiotics. High pharmacological effectiveness against most local and systemic infections, low incidence of side effects, and the availability of many suitable dosage forms with different strengths was thought to be the reason that prescribers tended to prefer amoxicillin+clavulanic acid over other antibiotics. This study showed a need for microbiological investigation before treatment of infections. This also helps physicians to have a more precise idea about prescriptive patterns prevalent in the Libyan community.

Key words: Drug utilization research, cross-sectional, inpatient, defined daily dose, anatomical therapeutic chemical (ATC)

Introduction

Antibiotics are the most frequently prescribed group of drugs among hospitalized patients, especially in intensive care and surgical departments. Programs designed to encourage appropriate antibiotic prescriptions in health institutions are an important element in quality of care,

Pandemic influenza A (H1N1) vaccination among libyan health care personnel: A cross-sectional retrospective study

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ABSTRACT

Context: Vaccination rate among health-care personnel's (HCPs) are not promising notwithstanding the World Health Organization campaigns over three decades resulting in compromising patient safety. The H1N1 virus, which caused a world-wide pandemic earlier has now transformed into a seasonal flu virus. **Aims:** The aim of this study was to analyze the incidence of 2009-10 pandemic influenza A (H1N1) vaccination among Libyan HCPs in four hospitals of Al-Zawia, Libya. **Materials and Methods:** A questionnaire, which listed eight sections of parameters distributed among 310 HCPs to assess the vaccination rate and resulting adverse effects. **Statistical Analysis:** The data were analyzed using descriptive statistics, Pearson's χ^2-test and Student's *t*-test where appropriate. **Results:** The overall pandemic A (H1N1) vaccination among all HCPs was only 107 (39.9%) out of 268 respondents. The distribution of respondents based on physicians, other staff and sex were found significant ($P < 0.05$). The common barriers of H1N1 vaccination being lack of awareness fear of adverse effects, allergies and religious beliefs. The major adverse effect observed was erythema in 95.56% of physicians and 87.1% in other staff. About 2% of HCPs have reported arthralgia. No significant differences existed between the responses of general variables and adverse effects. The glycoprotein 120 and squalene were found responsible for the reported adverse effects. 37 (82.22%) vaccinated medical HCPs have advised their patients to get vaccinated. **Conclusions:** Due to recurrence of H1N1 influenza in recent times, vaccination campaigns should be promoted immediately to address the knowledge gap of HCPs for intervention by regulatory and health organizations in Libya. The health belief model could be applied to improve vaccination among HCPs.

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KEY WORDS: Cross-sectional, health care personnel's, H1N1, Libya, pandemic, retrospective study

Influenza A (H1N1) virus is the subtype of influenza A virus that was the most common cause of human influenza (flu) in 2009. As of May 30, 2010 global update by the World Health Organization (WHO) over 214 countries have reported cases of pandemic influenza H1N1 2009, including more than 18,138 deaths.[1] On August 10, 2010, the WHO had declared that the H1N1 influenza pandemic was ended, stating that the flu activity had returned to typical seasonal patterns. However, small regional outbreaks or epidemics that comprise serious disease in younger age groups were expected to continue during the post-pandemic phase.[2,3] Recently, five deaths have been reported among the 29 suspected cases of influenza A (H1N1) virus infections in Libya during the month of March 2013. The H1N1 virus, which caused a worldwide pandemic in 2009 and 2010, has now transformed into a seasonal flu virus, a "hybrid" of a number of swine and avian flu viruses.[4] The WHO does not list Libya among the countries displaying the infection. However, it cautions "member states to continue surveillance for severe acute respiratory infections and to carefully review any unusual patterns".[5] WHO recommends member states to report on post-pandemic surveillance and are encouraged to use standard WHO case definitions for surveillance.[6] The main purpose of vaccination is to reduce morbidity, mortality

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REVIEW

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Solvent Evaporation Techniques as Promising Advancement in Microencapsulation

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ABSTRACT

In recent times solvent evaporation techniques have gained prominence in microencapsulation process. Solvent evaporation techniques are broadly classified into emulsification solvent-evaporation and extraction methods. Several variations have been developed recently based on this technology. Using solvent evaporation methods we can regulate microsphere morphology and other characteristics to the desired level for the targeted delivery of bioactives like peptides and vaccines using various biomaterials as carriers. Several methods of solvent evaporation, core and coat materials used, emulsion stabilizers, and process variables were discussed in detail with due interest of recent advancements in this area of research. This technology is showing a promising future for drug targeting and throwing challenges to pharmaceutical scientist such as: scale-up problems, use of non-organic solvents, use of alternative biodegradable polymers, and the application of a viable hybrid technology by amalgamating various techniques of microencapsulation to overcome the problems of peptide degradation during the process and stability of microspheres after the process.

INTRODUCTION

Proteins and peptides delivery in the form of controlled release creates new challenges to pharmaceutical scientist. Investigators and pharmacologists have been trying to develop delivery systems that allow the fate of a drug to be controlled and the optimal drug dosage to arrive at the site of action in the body by means of novel microparticulate dosage forms. During the past two decades, researchers have succeeded in part in controlling the drug-absorption process to sustain adequate and effective plasma drug levels over a prolonged period of time by designing controlled release microspheres intended for either oral or parenteral administration. Targeted or site-specific microparticulate delivery systems were also developed to alter the pharmacokinetic profiles of various therapeutic classes of drugs resulting in maintaining effective drug concentration for a prolonged period and result in decreased side effects associated with lower plasma concentrations in the peripheral blood without attempting to modify the normal buffet of the active molecules in the body after administration and absorption.

Microspheres can be defined as solid, approximately spherical particles ranging in size from 1 to 1000 μm. They are made of polymeric, waxy, or other protective materials, that is, biodegradable synthetic polymers and modified natural products such as starches, gums, proteins, fats and waxes. The natural polymers include gelatin and albumin whereas the synthetic polymers include polylactic acid and polyglycolic acid [1-4]. The influence of hydrophilic protective colloids was studied by Lin *et al.* [5].

Microencapsulation is a process by which a drug substance is entrapped within discrete free-flowing polymeric particle microcapsule products [6-16]. Different types of coated particles can be obtained depending on coating process used. The particles can be embedded within a polymeric or proteinic matrix network in either a solid aggregated state or a molecular dispersion, resulting in the formulation of micromatrices. Alternatively, the particles can be coated by a solidified

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Full Length Original Research Paper

Formulation and Evaluation of sustained release Troxipide Matrix Tablets for Twice Daily

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Abstract: The main objective of the present work was to develop sustained release matrix tablets of troxipide using Hydroxy propyl methyl cellulose (HPMC) Varying ratios of drug and polymer like 1:0.5,1:1, 1:1.5, 1:2, 1:2.5 and 1:3 were selected for the study. After fixing the ratio of drug and polymer for control the release of drug up to desired time. After evaluation of physical properties of tablet, the *in vitro* release study was performed in 0.1N HCl pH 1.2 for 2 hrs and in phosphate buffer pH 6.8 up to 12 hrs. The effects of polymer concentration were studied. Dissolution data was analyzed by Korsmeyer-Peppas power law expression and modified power law expression. It was observed that matrix tablets contained drug : polymer ratio 1:2 was successfully sustained the release of drug upto 12 hrs. Among all the formulations, release the drug which follows Zero order kinetics via, swelling, diffusion and erosion and the release profile of formulation F4 was optimized. Stability studies (40±2°C/75±5%RH) for 3 months indicated that Troxipide was stable in the matrix tablets. The FTIR study revealed that there was no chemical interaction between drug and excipients.

Keywords: Troxipide, matrix tablets, anti-ulcer, twice daily, HPMC 15 LV.

INTRODUCTION:

Troxipide is a drug used in the treatment of gastro esophageal reflux disease. Troxipide is a novel systemic non-anti secretory gastric cytoprotective agent with anti-ulcer, anti-inflammatory and mucus secreting properties irrespective of pH of stomach or duodenum.

For many decades treatment of an acute disease or a chronic illness has been mostly accomplished by delivery of drug to patient using various conventional dosage forms like tablets, solutions and suspensions, and syrups. Even today these conventional drug delivery systems are the primary pharmaceutical products commonly seen in the prescription and over-the-counter drug market place. This type of drug delivery system is known to provide a prompt release of drug. To achieve therapeutic concentration and also maintain therapeutic concentration desired time done by using polymers. This results in a significant fluctuation in drug levels can be avoided. Novel techniques helpful for capable of controlling the rate of drug delivery, sustaining the duration of therapeutics activity Conventional oral dosage forms often produce fluctuation of drug plasma level that either exceed safe therapeutic level this problem can overcome by matrix tablets.[1] The composition of each tablet is shown in table(1).

Matrix tablet concept has long been utilized to develop sustained- release formulation. The most common method of modify drug release

ScienceDirect

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Original Article

Formulation and in-vitro evaluation of moxifloxacin loaded crosslinked chitosan films forthe treatment of periodontitis

Durga Praveena Chinta, Prakash Katakam, Varanasi Satya Narayana Murthy, Maria John Newton

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https://doi.org/10.1016/j.jopr.2013.06.019
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Abstract

Aim

The purpose of the present work was to develop a local drug delivery system of moxifloxacin loaded crosslinked chitosan films using sodium citrate as a crosslinking agent with different concentrations and crosslinking time.

Methods

The films were prepared using solvent casting technique. The formulated films were evaluated for physicochemical parameters like FT-IR, DSC, thickness, weight variation, content uniformity, surface pH and release kinetics.

Results

IR and DSC studies indicated that there is no interaction between the drug and excipients. The drug loaded chitosan films were flexible, possessed good tensile strength and demonstrated satisfactory physicochemical characteristics. Although the films showed an initial burst release of drug, the release was sustained for up to 15 days. From the obtained results F6 formulation is optimized one among all the formulations.

Conclusion

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Design of dissolution media for *in-vitro* bioequivalence testing of Lamivudine

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Lamivudine, Stability indicating, Bioequivalence studies, Dissolution media.

ABSTRACT

The present investigation is aimed at developing the stability indicating dissolution media for the determination of lamivudine (3TC) in pharmaceutical dosage forms. The stability of 3TC was tested in various dissolution media maintained at ambient temperature and 37 °C for 48 hrs. Stability studies of 3TC in various media indicated that the drug was stable in 0.1M HCl, pH 1.2 KCl-HCl buffer, pH 6.2 and pH 7.0 phosphate buffers. The λ_{max} were found to be 280.0, 278.8, 273.0 and 271.5nm for 0.1M HCl, pH 1.2 KCl-HCl buffer, pH 6.2 and pH 7.0 phosphate buffers respectively with low CV of <4.44%. The linearity of standard plots in optimized media was 0.5-40 µg/ml for 0.1M HCl and pH 1.2 KCl-HCl buffer. Similarly it was 0.5-60 µg/ml in pH 6.2 buffer and 0.2-40 µg/ml in pH 7.0 phosphate buffer. The validated methods were applied to determine 3TC concentration in formulations. In-vitro dissolution testing indicated that the 3TC was stable and drug release is uniform from tablet dosage forms. The optimized media could be employed to study the dissolution profiles of 3TC in bioequivalence studies.

INTRODUCTION

Dissolution of drugs from solid dosage forms is an important parameter in assessing the product quality and uniformity at the formulation stage and during the shelf-life of the product. The significance of a dissolution test is based on the fact that for a drug to be absorbed and available to the systemic circulation, it should be in solution form. Therefore, an *in vitro* dissolution test was introduced not only for quality control to assess batch-to-batch consistency of release from a drug product, but also in an attempt to identify potential problems of *in vivo* drug release and absorption (Qureshi and McGilveray, 1999), Dissolution medium is used for the regular *in-vitro* determination of various drugs. It is often desirable to have a dissolution medium that is stable and selective based on the formulation used. Dissolution media were usually developed in the past to improve the solubility in dissolution media for poorly water soluble drugs such as for nimodipine (Zhonggui *et al.*, 2004), cefixime trihydrate (Madhura *et al.*, 2009), rifampicin (Rao and Murthy, 2001) and valdecoxib (Subramanian *et al.*, 2006). In light of the FDA's recent guidance there is an increased awareness of the potential relevance of dissolution tests (Guidance, 1996; Guidance for Industry, 1997; Martin *et al.*, 2003). The FDA provides guidelines for dissolution tests for oral modified release dosage forms, but also realizes the need for individualizing the method on a case by case basis leaving the justification of a given methodology up to the scientist. As a result of patent expiry for many drugs, there is increase in rise of formulating the dosage forms from conventional to extended release products. The authorized USP pending monograph for lamivudine tablets specifies 0.1N HCl as dissolution medium (Lamivudine tablets, 2011). In our earlier works, we have developed stability indicating dissolution media of abacavir sulphate and didanosine and proposed their application for extended release formulations (Awen *et al.*, 2011; Prakash *et al.*, 2011). Therefore there is a tremendous scope for pharmaceutical scientists to develop suitable dissolution testing media for bioequivalence studies of newly developed formulations. Lamivudine is 4-amino-1-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-1H-pyrimidin-2-one (Fig. 1). Lamivudine is a synthetic nucleoside analogue and is phosphorylated intracellularly to its active 5'-triphosphate metabolite, lamivudine triphosphate (L-TP). This nucleoside analogue is incorporated into viral DNA by HIV reverse transcriptase and HBV polymerase, resulting in DNA chain termination (Lamivudine, 2006; Flexner, 2006; Steven *et al.*, 2009).

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Bioequivalance and pharmacokinetic study of febuxostat in human plasma by using LC-MS/MS with liquid liquid extraction method

Babu Rao Chandu, Kanchanamala Kanala ✉, Nagiat T Hwisa, Prakash Katakam & Mukkanti Khagga

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Abstract

A bioequivalence study was proved of generic Febuxostat 80 mg tablets (T) in healthy volunteers.For this purpose, Authors developed a simple, sensitive, selective, rapid, rugged and reproducible liquid chromatography–tandem mass spectrometry method for the quantification of Febuxostat (FB) in human plasma using Febuxostat D7 (FBD7) as an internal standard (IS) was used. Chromatographic separation was performed on Ascentis Express C18 (50x4.6 mm, 3.5 µ) column. Mobile phase composed of 10 mM Ammonium formate: Acetonitrile (20:80 v/v), with 0.8 mL/min flow-rate. Drug and IS were extracted by Liquid- liquid extraction. FB and FBD7 were detected with proton adducts at m/z 317.1→261.1 and 324.2→262.1 in multiple reaction monitoring (MRM) positive mode respectively. The method was validated with the correlation coefficients of (r^2) ≥ 0.9850 over a linear concentration range of 1.00-8000.00 ng/mL. This method demonstrated intra and inter-day precision within 2.64 to 3.88 and 2.76 to 8.44% and accuracy within 97.33 to 99.05 and 100.30 to

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Comparative *in vivo* evaluation of three types of honey on topical wound healing activity in rabbits

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Honey, Sidr, Thyme, Spring, wound healing, topical.

ABSTRACT

The present investigation has focused on the comparative evaluation of topical wound healing activity in rabbits using three types of honeys such as Sidr (SDH), Thyme (TYH), Spring (SPH). The activity was compared with commercial wound healing formulations, Mebo (MBC) and Fusidin (FSC) creams. Among the different types of the honey SDH was found to possess higher healing rate of wounds induced either by thermal or chemical methods. Whereas, in thermal induced burns, both TYH and SPH have shown similar wound healing activity but better than that of standard drugs. The activity for thermal and chemical induced burns was found in the order of SDH > TYH/SPH > MBC > control and SDH > TYH > SPH > FSC > control respectively. Among the three tested honeys, the t-test data was compared to those of controls and it was found that there was a significant ($p<0.05$) reduction in the wound area. It was concluded that honey in general could be employed as natural topical wound healing agent comparable to commercial synthetic analogs tested in the study. Further the present investigation proves that SDH is possessing superior wound healing activity than that of TYH and SPH.

INTRODUCTION

Honey is the sweet, viscous fluid produced by honey bees (the genus *Apis*) using the nectar of flowers. Historically, honey has been used by humans to treat a variety of ailments, from gastric disturbances to ulcers, wounds and burns, through ingestion or topical application, but only recently have the antiseptic and antibacterial properties of honey chemically explained (Drgrotte, 2013). Antibacterial properties of honey are the result of the low water activity causing osmosis, chelation of free iron, its slow release of hydrogen peroxide, low pH, and the antibacterial activity of methylglyoxal. Honey appears to be effective in killing drug-resistant biofilms which are implicated in chronic rhinosinusitis (Bansal *et al.*, 2005; Lusby *et al.*, 2002). It also possesses antiinflammatory activity by inhibiting prostaglandins (Al-Waili and Boni, 2003) and by thrombin-induced oxidative burst in phagocytes (Ahmad *et al.*, 2009). The most remarkable discovery was the antibacterial activity of honey that has been mentioned in numerous studies (Al-Waili and Haq, 2004). Natural honey exhibits bactericidal activity against many enteropathogenic organisms, including those of the *Salmonella* and *Shigella* species, and enteropathogenic *E. coli* and methicillin-resistant *S. aureus* strains (Jeffrey and Echazarreta, 1996; Alvarez-Suarez, 2010; Emsen, 2007).

On the other hand, honey is well known for its advantages within the wound environment from recent clinical studies (Visavadia *et al.*, 2008). It maintains a moist wound environment that promotes healing and its high viscosity helps to provide a protective barrier to prevent the infection. In addition, the mild acidity and low-level hydrogen peroxide release both aid tissue repair and contribute to the antibacterial activity of honey (Lusby *et al.*, 2005). Honey has been reported to have immunomodulatory activities of monocytic cells to repair the wounded tissue by releasing anti-inflammatory cytokines and growth factors (Henriques *et al.*, 2006; Tonks *et al.*, 2003). Its effectiveness in rapidly clearing up the infection and promoting healing is not surprising in light of the large number of research findings on its antibacterial activity. The precise composition of honey varies according to the plant origin on which the bee feeds. (Rakha *et al.*, 2008; Al-Mamary *et al.*, 2002). Sidr honey is most revered honey and expensive honey in the world. It is obtained from the flowers of the ancient Sidr tree (*Ziziphus spina-christi*). Sidr tree grows in coastal, desert, and semi-desert areas and found extensively in the eastern part of Yemen. (Sidr Honey[a, b], 2013).

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ScienceDirect

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Original Article

Development and validation of a liquid chromatography mass spectrometry method for the determination of donepezil in human plasma

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https://doi.org/10.1016/j.jopr.2013.08.021
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Abstract

Aim

A selective, and sensitive LC–MS/MS method has been developed and validated for quantification of donepezil in human plasma using donepezil D7 as an internal standard (IS).

Methods

The analyte and IS were extracted by liquid–liquid extraction using dichloromethane and hexane mixture and separated by isocratic elution on C18 analytical column with 0.1% formic acid and methanol in the ratio of 70:30 (flow rate of 1 ml/min) as the mobile phase in the positive ion mode. Multiple Reaction Monitoring transitions for donepezil and internal standard are 380.2/91.2 and 387.2/98.2 respectively.

Results

The lower limit of quantification was 50 pg/ml with the linearity range of 50 pg/ml–25,000 pg/ml and the method was validated as per international regulatory guidelines for its selectivity, stability, accuracy, precision, and recovery.

Conclusion

The method can be readily applicable to pharmacokinetic and bioequivalence studies to support different regulatory submissions.

Previous Next

Keywords

ScienceDirect

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Original Article

Quantification of Acamprosate in human plasma by LC-ESI-MS/MS with solid phase extraction: Application to a bioequivalence study

Kanchana Mala Kanala [a b], Babu Rao Chandu [c], Nagiat T. Hwisa [c], Mukkanti Khagga [d], Prakash Katakam [c], B.R. Challa [e]

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Abstract

Background

The purpose of this investigation was to explore high selective, sensitive, rapid, stable, reproducible extraction method in long run with broader linear range. At the same time, it could be expected that, this method would be efficient in analyzing large numbers of plasma samples obtained for pharmacokinetic, bioavailability or bioequivalence studies.

Methods

A simple, sensitive, selective and rapid high-performance liquid chromatography coupled with tandem mass spectrometry was developed and validated for quantification of Acamprosate in human plasma. The chromatography was performed by using waters atlantis HILIC, (2.1 mm×50mm, 3.0μm) column connected with guard column waters atlantis HILIC, (2.1 mm×10mm, 3.0μm). Acamprosate-d12 calcium trihydrate used as an IS. The extraction of drug and internal standard were obtained by solid phase extraction. The linearity was proved with concentration range 1.00–250.00ng/ml for Acamprosate in human plasma.

Results and discussion

The LOQ was demonstrated at 1.00ng/ml. The within-batch, between-batch precision was found to be 2.21–4.07% and 2.00–3.20%. The within-batch, between-batch accuracy was found to be 96.26–102.00% and 98.27–102.00% for Acamprosate. Drug and IS were eluted within 3.0min.

Conclusion

The developed LC-MS/MS assay for Acamprosate is rapid, simple, sensitive, selective and suitable for routine measurement of sample analysis. The validated method was successfully applied in pharmacokinetic study of human plasma.

ScienceDirect

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Original Article

Bioanalytical method development and validation of milnacipran in rat plasma by LC–MS/MS detection and its application to a pharmacokinetic study

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Abstract

A simple, sensitive and specific liquid chromatography–tandem mass spectrometry (LC–MS/MS) method was developed for the quantification of milnacipran (MC) in rat plasma by using the liquid–liquid extraction method. Milnacipran-d10 (MCD10) was used as an internal standard (IS). Chromatographic separation was achieved on Zorbax SB-CN (4.6mm×75mm, 3.5μm) column with an isocratic mobile phase composed of 10mM ammonium acetate (pH 4.0) and methanol in the ratio of 25:75(v/v), at a flow-rate of 0.7mL/min. MC and MCD10 were detected with proton adducts at m/z 247.2→230.3 and m/z 257.2→240.4 in multiple reaction monitoring (MRM) positive mode respectively. The method was validated over a linear concentration range of 1.00–400.00ng/mL with a correlation coefficient (r^2)≥0.9850. This method demonstrated intra- and inter-day precision within 5.40–10.85% and 4.40–8.29% and accuracy within 97.00–104.20% and 101.64–106.23%. MC was found to be stable throughout three freeze–thaw cycles, bench top and postoperative stability studies. This method was successfully applied to a pharmacokinetic study of rats through i.v. administration.

Previous Next

Keywords

Milnacipran; Pharmacokinetics; Rat plasma; LC–MS/MS

1. Introduction

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Full Length Research Paper

Pharmaco-epidemiological Studies on Self Medication and Drug Utilization Pattern in Chronic Diseases via Prescription Auditing

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Abstract. Prescription auditing, a sort of vigilance activity is an important tool in pharmaco-epidemiological studies to get a clear picture about rational usage of drug, widely prescribed drugs, extent of polypharmacy, and the most prevalent diseases in a particular area. With the changing dynamics of the lifestyle, behavioral pattern, socioeconomic and educational status an increasing trend of self medication observed in both rural and urban dwellers. Till yet there is no such report about the drug utilization pattern or extent of self medication practice in the Kharaghpur area. A study was conducted in Kharaghpur region of India (Block 1 and 2) to determine the drug utilization trend and practice of self medication in the prevailing disease conditions by prescription monitoring and exit interviews with pretested Performa on customers randomly visiting the pharmacies. Prescription auditing showed that disease prevalence was predominant in age group of 11.00±6.25–50.00±9.75 and comparatively less incidences in the pediatrics (1.00±1.05–5.00±0.79) and geriatrics (70.00±1.31–75.00±1.01). There was a predominance of infectious diseases like fever, cough and cold during the study period followed by asthmatic problems and gastrointestinal infections GIT infections in the surveyed area. Self-medication of asthma and GIT infections was more prevalent in urban population (60%, n=133) as compared to the rural population (33.89%, n=107). Easy availability of lifestyle drugs, enhanced education levels amongst urban population and economic hindrance to pay physicians fees, influences of peer groups, advices of pharmacists, difficulty to avail drugs from clinics in rural regions influenced self medication. Analgesics, antipyretics were the most widely used self medicating drugs in survey area.

Key words: Prescription auditing; vigilance activity; self medication; poly-pharmacy; drug utilization; asthma; GIT infections; analgesics; antipyretics

1. INTRODUCTION

Pharmaco-epidemiology refers to epidemiological studies of the clinical use of drugs, their effects and side effects in large population mass with the purpose of promoting cost-effective rational use of drugs so as to achieve better health outcomes of the common mass (Sjokvist and Birkett, 2003; Sills et al., 2009; Prasant et al., 2013). Prescription auditing or monitoring is an important mechanism to improve the quality of care afforded by the physicians both private practitioners and the public hospitals. It is a sort of vigilance activity which refers to the collection of prescriptions and gathering of information's relating to widely prescribed drugs, extent of poly-pharmacy and the existing drug utilization pattern (Aitken et al., 2009; Abidi et al., 2012; Bhattacharya et al., 2012; Potharaju et al., 2011; Ndungu et al., 2007; Jyoti et al., 2013). Drug worth crores of rupees are consumed every year but a substantial amount of such drugs is irrationally prescribed (Abidi et al., 2012). Recent trends have shown increasing incidences of self-medication in both rural and urban populations. Self medication is the "use of drugs or Pharmaceutical products by the consumer to treat self recognized disorders or symptoms or the intermittent or continued use of the medication prescribed by the physicians for a chronic or recurring diseases or symptoms" (Widayati et al., 2011). Self medication is multi-factorial (Chawla et al., 2013; Bimo et al., 1995; Chaudhuri et al., 2011; Krishnaswamy and Kumar, 2005; Patel et al., 2012; Pisarik, 2010; Pandey et al., 2010). Unintentional administration of xenobiotics including heavy metals also affects human health along with irrational use of drugs (Saedi et al., 2013).

Different socio-economic implications, unavailability of registered medical practitioners (RMPs) in remote areas, increasing cost of medical treatments, inability to pay physician's fees, long waiting hours in clinics or other medical facilities, advices from peer groups and pharmacists greatly promotes self medication in rural areas. In urban areas, ready access to drugs from several medical stores, rapid growth of mass medias, television and newspaper advertisements, internet facilities and easy availability of lifestyle drugs are important

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Scientific Research Publishing

Formulation and Evaluation of Mucoadhesive Microspheres of Pioglitazone Hydrochloride Prepared by Ionotropic External Gelation Technique

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Abstract

Microspheres containing Pioglitazone hydrochloride were prepared by the ionotropic external gelation method, using sodium alginate with four mucoadhesive polymers namely sodium carboxy methyl cellulose, hydroxy propyl methyl cellulose, carbopol 934 P and cellulose acetate phthalate as coat materials. Ionotropic gelation is a method to prepare microspheres using combination of Ca^{2+} as cationic components and alginate as anion. The practical yield of prepared microspheres using the ionotropic gelation technique was between 172 mg and 604 mg. The result of the Chi-squared test carried out between the actual (practical) and expected (theoretical) yields showed no significant difference ($P < 0.05$) which indicated that the ionotropic gelation technique could be successfully employed to prepare pioglitazone microspheres using sodium alginate, sodium carboxy methyl cellulose, carbopol 934 P, HPMC, cellulose acetate butyrate polymers. The drug entrapment efficiency of prepared microspheres showed between 56.12% ± 3.86% to 84.68% ± 2.93% which was significantly higher for ionotropic gelation technique. The highest drug entrapment was found in formulation PMI 8. Swelling index is the capability of a polymer to swell before the drug is released which influences the rate and mechanism of drug release from the polymer matrix. The swelling index of prepared microspheres was in the range of 68% ± 4.52% to 87% ± 0.98%. Pioglitazone HCl microspheres showed controlled release of drug without initial peak level achieving. This type of properties in Pioglitazone HCl microspheres used to decrease side effects, reduce dosing frequency and improve patient compliances. From the all batches PMI 8 is considered the best formulation, because among all other formulations, it shows better extent of drug

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Ars Pharmaceutica

Fabrication and in vitro evaluation of subgingival strips of calcium alginate for controlled delivery of ofloxacin and metronidazole

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Faculty of Pharmacy, 7th of April University, Al-Zawia (Libya).

Review Paper
Artículo de Revisión

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Competing interest / Conflicto de interes:
Los autores declaran que no hay ningún conflicto de interés.

Fundings / Financiación:
El estudio se ha realizado con los medios habituales de que dispone el Departamento de Nutrición y Bromatología y a través de los recursos aportados por el Máster Universitario en Atención Farmacéutica (EuropharmNES) de la Universidad de Granada.

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RESUMEN

Objetivos: Elaborar y evaluar tiras subgingivales combinadas compuestas por Ofloxacino y metronidazol in vitro con alginato de calcio biodegradable

Métodos: las tiras se prepararon utilizando el método de evaporación del disolvente. Se usó una concentración del 10% de $CaCl_2$ para la gelificación.de las tiras.

Resultados: el grosor de las tiras se encuentra dentro de las recomendaciones (>320 µm). In vitro, la liberación de la droga siguió una cinética bifásica que fue suficiente para alcanzar la CMI e inhibir el crecimiento de microorganismos durante 5 días. La "tasa de liberación de la droga" es inversamente proporcional a la concentración de polímero de la formulación. La liberación de la "droga" fue por difusión y en segunda fase por disolución

Discusión: Las preparaciones OM1 y OM2 que contienen un 90 y un 75% de polímero respectivamente, podrían ser empleadas en liberación controlada durante cinco días en infecciones sublinguales. Siendo el alginato cálcico biodegradable una buena elección como polímero retardante

PALABRAS CLAVE: Biodegradable, Liberador de droga bifásico, Alginato de calcio, Liberación controlada, Tiras subgingivales

ABSTRACT

Aim: Subgingival strips of combined ofloxacin (OFX) and metronidazole (MET) were fabricated and evaluated in vitro using biodegradable calcium alginate.

Methods: Strips of drug:polymer (10:90, 25:75, 50:50 and 75:25) were prepared using solvent casting method. A 10%w/v $CaCl_2$ solution was used for gelation of the strips.

Results: The thickness of strips were at par of recommended thickness (<320 µm). In vitro release of drugs followed a biphasic kinetics which was sufficient to maintain the minimum inhibitory concentrations (MIC) to inhibit the growth of the microorganisms for 5 days. The rate of drug release was inversely proportional to polymer concentration in the formulations. The drug release was by diffusion in second phase of dissolution.

Conclusions: The formulations OM1 and OM2 which contain 90 and 75%w/w of polymer could be employed for controlled delivery of combined OFX and MET for 5 days in subgingival infections. Calcium alginate, being a biodegradable is a good choice as drug retarding polymer.

KEY WORDS: Biodegradable, Polymer Biphasic drug release, Calcium Alginate, Controlled Release, Subgingival strips.

ARTICLE

A Retrospective Study on Antibiotic Use in Different Clinical Departments of a Teaching Hospital in Zawiya, Libya

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Abstract

A cross-sectional retrospective drug utilization study was conducted in different wards of the Zawiya teaching hospital, Libya, over a 15-month period. One hundred prescriptions were examined, of which 51% were for females. The World Health Organization (WHO) indicators (utilization in defined daily doses (DDD); DDD/1000inh/day) were used and the ATC/DDD method was implemented. The most frequently prescribed antibiotic (30 occurrences) was amoxicillin+clavulanic acid, while the least frequent (once) was neomycin or cloxacillin. The DDD/1000inh/day of amoxicillin+clavulanic acid was the highest (11.69) and that of ciprofloxacin was lowest (2.86). The ward with the highest number of prescribed antibiotics (35%) was surgery, while the ward with the lowest number (9%) was ENT. Average treatment period was found to be five days. In conclusion, our data showed an overuse of amoxicillin+clavulanic acid in contrast to other antibiotics. High pharmacological effectiveness against most local and systemic infections, low incidence of side effects, and the availability of many suitable dosage forms with different strengths was thought to be the reason that prescribers tended to prefer amoxicillin+clavulanic acid over other antibiotics. This study showed a need for microbiological investigation before treatment of infections. This also helps physicians to have a more precise idea about prescriptive patterns prevalent in the Libyan community.

Key words: Drug utilization research, cross-sectional, inpatient, defined daily dose, anatomical therapeutic chemical (ATC)

Introduction

Antibiotics are the most frequently prescribed group of drugs among hospitalized patients, especially in intensive care and surgical departments. Programs designed to encourage appropriate antibiotic prescriptions in health institutions are an important element in quality of care,

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Research Paper

Preparation of Zidovudine Extended Release Matrix Tablets with Various Controlled Release Polymers: A Feasibility Study of Granulation and Compression

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ABSTRACT: The matrix tablets were prepared by using Eudragit L 100, Poly ethylene oxide and Carbopol 971 P. The granules of Zidovudine using above polymers were prepared by direct mixing, wet granulation with water and wet granulation with IPA. The granules were characterized for the morphological study, bulk density, tapped density and particle size distribution. The granules were compressed in to tablets. The tablets were characterized for *in vitro* dissolution, DSC and FTIR. Different shapes of the granules were formed with the wet granulation process with different polymers. *In vitro* dissolution studies showed the prolonged release of the Zidovudine with these polymers. The drug release depended up on the type of polymer and granulation process. DSC and FTIR studies showed no drug polymer interaction. This study gives an idea about the feasibility of granulation process for the preparation of the Zidovudine matrix tablets with different polymers.

KEY WORDS: Zidovudine; PEO; Eudragit L100; Carbopol 971P; Granulation; Matrix tablets

Introduction

Acquired Immunodeficiency Syndrome (AIDS) was first identified in California in 1981. It is disease of which the body's immune system breaks down and is unable to fight of infections caused by human immunodeficiency virus (HIV). HIV infects human cells and utilizes the energy and nutrients provided by those cells for their replication. Drugs having shorter biological half-lives need to administer frequently to maintain constant therapeutic levels. It is crucial for the success of AIDS therapy to maintain systemic drug levels consistently above its target antiretroviral concentration throughout the course of the treatment (Chien et al., 1989; Jain et al., 2004)

Zidovudine is a synthetic nucleoside analogue of the naturally occurring nucleoside, thymidine, in which the 3′-hydroxy (-OH) group is replaced by an azido (-N3) group. Within cells, zidovudine is converted to the active metabolite, zidovudine 5′-triphosphate (AztTP), by the sequential action of the cellular enzymes (USFDA 2008). Zidovudine is rapidly absorbed and extensively distribute, the extent of Zidovudine absorption (AUC) was similar when a single dose of Zidovudine was administered with food. The drug is freely soluble at any pH and the absorption is rapid, judicious selection of release retarding excipients is necessary for achieving constant in vivo release.

The peak serum concentration of Zidovudine (Cmax) was 41.8 ± 7.7 ng/mL. The mean elimination half-life (t½) ranged from 0.5 to 3 hours thus necessitating frequent administration to maintain constant therapeutic drug levels.(Himadrisen etal., 2005) Thus the main object of the present invention is to provide a prolonged release composition containing Zidovudine, which is designed such that the resulting composition maintains the blood levels of the active ingredient for a prolonged period of time. The drug is freely soluble at any pH and the absorption is rapid, judicious selection of release retarding excipients is necessary for achieving constant in vivo release. A limited study has been done so far for preparing the Zidovudine extended release (Punna Rao et al., 2008; Malay kumar et al., 2006).

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Articles

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FORMULATION AND IN-VITRO EVALUATION OF OFLOXACIN EMBEDDED CONTROLLED RELEASE CALCIUM A

20-Jan-2011 *Research* *2011 : January - March2011 : January - March*

Z A Bahlul, K Prakash, C B Rao, A K Shanta, O Sarah, M Nora

The aim of the present investigation was to prepare and evaluate ofloxacin controlled release subgingival films using biodegradable calcium alginate the present investigation was fabricated and employed for casting of sodium alginate subgingival films. Subgingival films of drug:polymer (10:90, solvent casting method. A 10%w/v CaCl2 solution was used for converting sodium alginate into calcium alginate and gelation of the films. As polyı of the films increased. The thickness of films varied from 135±0.5 to 292±1.3µm which is well below the recommended thickness (<300 µm) of the films was found to be between 15.32±1.04 and 22.07 ±0.49 mg. The percentage of drug content ranged from 41.64±0.41to 58.22±0.41%. The l treatment with CaCl2 solution. In vitro release studies showed that all the films had an initial burst release for the first 8 h, followed by controlled which is sufficient to inhibit the growth of the micro-organisms. The rate of drug release was inversely proportional to polymer concentration in obtained may be due to biphasic drug release pattern. The formulations did not fit into Higuchi equation because of low values of <0.640846which diffusion only in second phase of dissolution. All the films have shown to have integrity even after 5 days of dissolution studies. The formulations polymer could be employed for controlled delivery of ofloxacin for 5 days in subgingival infections. Calcium alginate, being a biodegradable polyme

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Full Length Research Paper

Rapid and simultaneous determination of aspirin and dipyridamole in pharmaceutical formulations by reversed-phase high performance liquid chromatography (RP-HPLC) method

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The combination of Dipyridamole and Aspirin and is widely used to reduce thrombosis in patients with thrombotic diseases. A rapid, simple, precise and cost effective and reversed-phase high performance liquid chromatography (RP-HPLC) method has been developed and validated for the simultaneous determination of Aspirin and Dipyridamole in pharmaceutical formulations. Separation of both Aspirin and Dipyridamole was achieved within 5 min with required resolution, accuracy and precision thus enabling the utility of the method for routine analysis. Chromatographic separation was achieved on a waters symmetry C18 3.5 µm, 50 x 4.6 mm using a mobile phase consisting of 0.1% ortho phosphoric acid and acetonitrile in the ratio of 75:25 at a flow rate of 1.0 ml per minute. The detection was made at 227 nm and the retention time of Aspirin and Dipyridamole were1.5 and 2.8 minutes respectively. The method was found linear over the range of 4 to 80 µg/ml for Dipyridamole and 0.5 to 10 µg/ml for Aspirin.

Key words: Aspirin, Dipyridamole, high performance liquid chromatography.

INTRODUCTION

Aspirin (ASP) is 2- (Acetyloxy) benzoic acid, and is cyclo oxygenase inhibitor which is best known as an anti-platelet drug (Patel et al., 2010) and is one of the major antithrombogenic agent widely used for the treatment and prevention of cerebro and cardiovascular conditions such as stroke (Purushotam et al., 2009). Dipyridamole is a platelet inhibitor chemically described as 2,2',2",2"'-[(4,8-Dipiperidinopyrimido [5,4-d]pyrimidine-2,6-diyl)dinitrilo]-tetraethanol. Dipyridamole is widely used as a coronary vasodilator in patients with high blood pressure, a prophylactic agent in patients with angina pectoris and an inhibitor of platelet aggregation in various thromboembotic conditions (Davood et al., 1999).

The combination of Dipyridamole and Aspirin and is widely used to reduce thrombosis in patients with thrombotic diseases. This antithrombotic action results from additive antiplatelet effects of both drugs. Aspirin inhibits platelet aggregation by irreversible inhibition of platelet cyclooxygenase and thus inhibiting the generation of Thromboxane A2. Dipyridamole inhibits the uptake of adenosine into platelets and endothelial cells, thus decreasing the adhesion of platelets to thrombogenic surfaces (Hassan et al., 2008).

Analytical methods based on high performance liquid chromatography (HPLC), HPTLC, LC-MS (Kachhadia et al., 2008; Vora et al., 2008; Wada et al., 2007; William et al., 1983; Rajput et al., 2008; Mishra et al., 2006) and other methods were reported earlier for the determination of Aspirin individually and in combination with other drugs.

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Recent Research in Science and Technology

Design and In-vitro Evaluation of Controlled Release Cephalexin Subgingival Films Using Natural Biodegradable Polymer

Bahlul Z. Awen, Prakash Katakam*, Chandu Babu Rao, Soad Ali Mohammed and Turkiya Omer Alokbe

ABSTRACT

The aim of the present investigation was to prepare and evaluate cephalexin controlled release subgingival films using biodegradable sodium alginate. The equipment necessary for the present investigation was fabricated and employed for casting of sodium alginate subgingival films. Subgingival films of drug:polymer in various proportions (10:90, 25:75, 50:50 and 75:25) were prepared using solvent casting method. A 10%w/v $CaCl_2$ solution was used for gelation of the films. As polymer concentration is increased the smoothness of the films increased. The thickness of films varied from 146Ã‚Â±5 to 312Ã‚Â±15 ÃŽÂ¼m which is well below the recommended thickness (<300 ÃŽÂ¼m) of the subgingival films. The average weight of the films was found to be between 14.21Ã‚Â±0.18 and 20.42 Ã‚Â±0.49. The percentage of drug content ranged from 53.14 to 56.81%. The low values may be due to loss of drug during treatment of the films with $CaCl_2$ solution. In vitro release studies of all the films showed an initial burst release for the first 24 hrs, followed by controlled release of cephalexin (>0.24 ÃŽÂ¼g/ml) up to 120 hrs which is sufficient to inhibit the growth of the micro-organisms. The rate of drug release was inversely proportional to polymer concentration in the formulations. The low K_1 and Ã¢â‚¬ËœerÃ¢â‚¬â„¢ values obtained may be due to biphasic drug release pattern. The formulations did not fit into Higuchi equation because of low values of <0.788025 which indicate that the drug release might be due to diffusion only in second phase of dissolution. All the films have shown to have integrity even after 5 days of dissolution studies. The formulations C1 and C2 which contain 90 and 75%w/w of polymer could be employed for controlled delivery of cephalexin for 5 days in subgingival infections. Sodium alginate, being a biodegradable polymer is a good choice as drug carrier in the present study.

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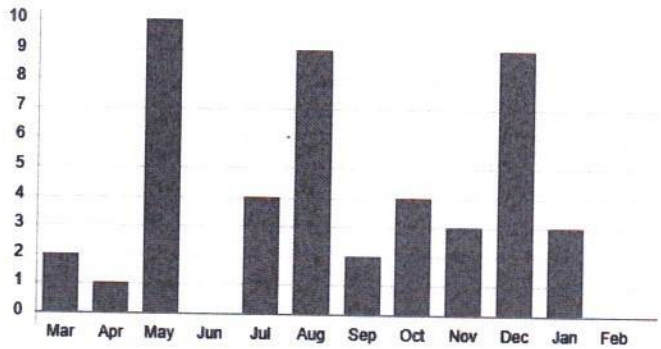

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Compatibility Study of Lamivudine with Various Cellulose Polymers

P. Narayana Raju[1], K. Prakash,[2] and M. Lakshmi Narasu[3]

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Abstract

For the development of any formulation, techniques such as thermal and isothermal stress testing were used to assess the compatibility of drug with excepients. Differential scanning calorimetry (DSC) and FTIR were the common methods for the study of compatibility. Isothermal stress testing (IST) is also a method for the compatibility study during proto type formulation. In the present study drug excepient compatibility study of lamivudine was conducted with different controlled release polymers. The drug and polymer mixtures were stored at 50 °C for 2 weeks. The samples were then characterized using DSC, FTIR and UV spectrophotometric methods. The results show that lamivudine was compatible with the all the polymers used in the study. The polymers used in the present study were definitely incorporated in the extended release lamivudine formulation.

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Solubility and Dissolution Rate Determination of Different Antiretroviral Drugs in Different pH Media Using UV Visible Spectrophotometer

K. Prakash,[1] **P. Narayana Raju**,[2] K. Shanta Kumari,[1] and M. Lakshmi Narasu[3]

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Abstract

Solubility and dissolution rate of three antiretroviral drugs such as lamivudine, zidovudine and stavudine was studied in four media having different pH. The samples were analyzed by using UV Visible spectrophotometer. lamivudine shows more solubility that is 276.08 mg/mL in 0.01 N HCl. Stavudine showing highest solubility that is 101.23 mg/mL in pH 4.5 acetate buffer. Zidovudine showing highest solubility that is 28.90 mg/mL in both water and 0.01 N HCl. All three drugs showing lower solubility in pH 6.8 phosphate buffer. Lamivudine and stavudine showing good dissolution rate in all media and showing similar release profiles and good correlation, whereas in zidovudine it was clearly observed a slower release at initial time points and then faster release profiles. The solubility and dissolution data in various media is helpful in predicting the bioavailability and also in dissolution method development.

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Research Article

Preparation and characterization of lamivudine microcapsules using various cellulose polymers

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Abstract

Purpose: *The objective of the present study was to prepare and evaluate microcapsules for the controlled release of lamivudine using various cellulose polymers*
Methods: *The microcapsules were prepared by the solvent evaporation method. The prepared microcapsules were characterized for the percent drug content, entrapment efficiency, FTIR, DSC, scanning electron microscopy (SEM) and in vitro dissolution studies. Accelerated stability studies were also carried out.*
Results: *The microcapsules were spherical and free flowing. The entrapment efficiency was 76-86%. The release of drug from the microcapsules extended up to 8 to 12 hours. FTIR and DSC thermograms showed the stable character of lamivudine in the microcapsules. SEM revealed that the microcapsules were porous in nature. The release kinetics study revealed that the prepared microcapsules were best fitted to the zero order for F-2, F-4 and F-5 formulations and Higuchi model, for F-1 and F-3 microcepsules*
Conclusion*: The release kinetics data and characteristion studies indicate that drug release from microcapsules was diffusion – controlled and that the micrapsules were stable..*

Keywords*: Lamivudine, cellulose polymers, microcapsules, controlled release, stability.*

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RESEARCH PAPER

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Effect of Some Hydrophilic Polymers on Dissolution Rate of Roxithromycin

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In the present investigation, the enhancement of dissolution rate of roxithromycin was carried out by preparing solid dispersions using hydrophilic polymers like polyethylene glycol 6000, hydroxypropylmethylcellulose K4M and hydroxypropylcellulose, each in the ratios of 1:1, 1:3 and 1:5. Physical mixing and coprecipitate techniques were employed to prepare formulations for increasing the solubility of roxithromycin. Formulations prepared by both physical mixing and coprecipitate methods have shown significant enhancement of dissolution rates compared to pure roxithromycin alone. All the solid dispersions obtained were fine and having good flow properties. The formulation, polyethylene glycol 6000:CP_5, containing roxithromycin:polyethylene glycol 6000 in 1:5 ratio has shown 99.4% drug release in 1h. The dissolution rate of roxithromycin was directly proportional to the increment in the drug to polymer ratios in the solid dispersions. Dispersions prepared by coprecipitate method have shown faster dissolution rate compared to physical mixing techniques. The dissolution efficiency of the formulation polyethylene glycol 6000:CP_5 was found to be highest compared to other formulations. The release profiles of roxithromycin from the dispersions have followed first order release kinetics and Hixson-Crowell's cube root law. It was concluded that hydrophilic polymers can be employed to prepare solid dispersions to enhance the solubility of roxithromycin.

The enhancement of oral bioavailability of drugs with poor water solubility remains one of the most challenging aspects of drug development. Although salt formation, solubilization and particle size reduction have commonly been used to increase dissolution rate and there by oral absorption and bioavailability of such drugs, there are some practical limitations of these techniques. In case of salts, the increased dissolution rate in the gastrointestinal tract may not be achieved because of the reconversion of salts into aggregates of their respective acid or base forms. Further, solubilization of drugs in organic solvents or in aqueous media by the use of surfactants and cosolvents leads to liquid formulations that are usually undesirable from patient acceptability and commercialization. Particle size reduction is commonly used to increase dissolution rate and there is a practical limit to how much size reduction can be achieved by such commonly used methods as controlled crystallization and grinding[1,2].

In 1961, Sekiguchi and Obi[3] developed a practical method whereby many of the limitations associated with the enhancement of bioavailability of poorly water soluble drugs can be over come. This method, which was later termed solid dispersion[4], involves the formation of eutectic mixtures of drugs with water soluble carriers by the melting of their physical mixtures. Sekiguchi and Obi[3] suggested that the drug has present as a eutectic mixture in a microcrystalline state. Later it was demonstrated that all the drug in a solid dispersion might not necessarily be present in a microcrystalline state; a certain fraction of the drug might be molecularly dispersed in the matrix, thereby forming a

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RESEARCH PAPER

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Influence of some Cellulose Ethers on the Release of Propranolol Hydrochloride from Guar Gum Matrix Tablets

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In the present research, an attempt has been made to develop controlled-release formulations of propranolol hydrochloride using guar gum as a carrier and also to study the influence of some cellulose ethers like sodium carboxymethylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose and ethylcellulose on the *in vitro* release of propranolol hydrochloride from guar gum matrix tablets. *In vitro* release studies indicated that 30 % of guar gum was the minimum concentration of guar gum that can be used to sustain the release for 12 h. Combination of guar gum and cellulose ethers were found to be effective in retarding the release of propranolol hydrochloride. The ratios of guar gum:cellulose ethers which showed better retarding of drug release were, 1:1 2:1, 2:1 and 5:1 for guar gum:sodium carboxymethylcellulose, guar gum:hydroxypropylmethylcellulose, guar gum:hydroxypropylcellulose and guar gum:ethylcellulose, respectively. *In vitro* dissolution kinetics followed a first order release via Fickian diffusion controlled mechanism. IR spectroscopy revealed that there was no interaction between the drug and the polymers used in the investigation.

Propranolol hydrochloride, a non-selective beta-adrenergic blocker, has been widely used in the treatment of hypertension, angina pectoris, pheochromocytoma and cardiac arrhythmias[1]. Because of its relatively short plasma half-life, patients are routinely asked to take propranolol HCl in divided daily doses once every 6 to 8 h. Such frequent drug administration may reduce patient compliance and therapeutic efficacy[2]. In recent years slow or sustained release formulations of propranolol HCl has become available with claims that these formulations maintain beta adrenoreceptor blockade throughout a 24 h period and enable the drug to be given once daily[3].

The present investigation is aimed at using the inexpensive, naturally and abundantly available guar gum for oral controlled delivery of propranolol HCl. Guar gum can be used as a carrier for controlled delivery[4-6]. In the present investigation matrix tablets of propranolol HCl were prepared using guar gum and the influence of some cellulose ethers like sodium carboxymethylcellulose (NaCMC), hydroxypropylmethylcellulose (HPMC), hydroxypropyl cellulose (HPC) and ethylcellulose (EC) on the release pattern of propranolol HCl from guar gum matrix tablets was studied.

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MATERIALS AND METHODS

Propranolol HCl, IP was obtained as a gift sample from Cipla Laboratories Ltd, Mumbai. Guar gum (3500 cps) was obtained from Roland Pharmaceuticals Limited, Berhampur. NaCMC, HPMC, HPC and EC were purchased from S. D. Fine Chemicals Ltd., Mumbai. Microcrystalline cellulose (MCC), starch, magnesium stearate and talc were obtained from Atlas chemical company, Mumbai. Methanol was obtained from E. Merck, Mumbai.

Preparation of matrix tablets:

All the formulations were prepared by wet granulation

RESEARCH PAPER

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Study of *Ocimum basilicum* and *Plantago ovata* as Disintegrants in the Formulation of Dispersible Tablets

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Ibuprofen dispersible tablets using *Plantago ovata* mucilage powder, *Ocimum basilicum* mucilage powder, *Plantago ovata* husk powder and *Ocimum basilicum* seed powder as disintegrants were prepared and disintegrating property was studied. The swelling index of the above disintegrants was studied. Disintegrating property of the above disintegrants were evaluated by comparing with the formulations of starch powder as standard disintegrant. The study revealed that *Plantago ovata* seed powder and mucilage powder were effective in low concentrations (5%) as disintegrants compared to others .The study further revealed a poor relation between the swelling index and disintegrating efficiency.

Ispaghula husk consists of dried seeds of *Plantago ovata* (Ispaghula). Epidermis of the seeds contains mucilage[1-5]. Both husk and mucilage is found to be good binding and disintegrating agent for the preparation of compressed tablets[6]. *Plantago ovata* seed husk is found to have high swellability[7] and it has been used in the formulation of nimesulide dispersible tablets[8]. *Ocimum basilicum* (Basil) seeds contain mucilage[9] and these seeds can be substituted for ispaghula husk for their bulk laxative effect to treat constipation[10,11].

The present work was carried out to study the disintegrating properties of *Plantago ovata* mucilage powder, *Plantago ovata* husk powder, *Ocimum basilicum* mucilage powder and *Ocimum basilicum* seed powder by formulating dispersible tablets of ibuprofen. Disintegrant property of above disintegrants were evaluated by comparing with the formulations of starch powder as standard disintegrant. The swelling index of the above disintegrants were carried out.

MATERIALS AND METHODS

Ibuprofen, lactose, talc and magnesium stearate was obtained from M/S Roland Pharmaceuticals, Berhampur as gift samples. Ispaghula husk was procured from local market. The husk was dried at 50°, powdered and passed through sieve No. 100. *Ocimum basilicum* seeds were obtained from local market. These seeds were dried at 50° for 24 h, powdered and passed through sieve No.100. This seed powder was again dried at 40° for 24 h and passed through sieve No. 100. Other materials used in the formulation and evaluation were of pharmaceutical grade.

Mucilage extraction:

The mucilages of both *Plantago ovata* and *Ocimum basilicum* were extracted and precipitated separately using previously reported methods[12,13]. The precipitates collected were dried in an oven at 40° for 24 h, finely powdered, passed through sieve No.120 and kept in a dessicator.

Swelling index studies:

The swelling index is the volume in ml occupied by 1 g of drug; including any adhering mucilage after it has swollen in an aqueous liquid for 4 h[14]. Swelling index of *Plantago ovata* mucilage powder, *Plantago ovata* husk powder, *Ocimum basilicum* mucilage powder, and *Ocimum basilicum* seed powder were carried out using BP method[14]. One gram of each disintegrant was taken in a 25-ml ground glass stoppered cylinder graduated over a height of 120 to 130 mm in 0.5 ml divisions. About 25 ml of water was added and shaken vigorously every 10 min for 1 h and then allowed to stand for

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RESEARCH PAPER

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Design of Controlled Release Non-erodible Polymeric Matrix Tablets of Theophylline Using Sintering Technique

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The objective of the present study is to formulate and evaluate theophylline polymeric matrix tablets for controlled release using sintering technique. The powder of ethylene vinyl acetate copolymer 1802 was prepared by a novel spray technique. The micromeritics of the powdered vinyl acetate copolymer were studied. Matrix tablets of theophylline in vinyl acetate copolymer were prepared in different drug and polymer ratios using direct compression and subsequent sintering technique at various temperatures. The sintered tablets were evaluated for various tablet characteristics including dissolution rate. A comparative dissolution rate study was conducted with the optimized formula against three commercial theophylline sustained release products. A simple process for powdering of vinyl acetate copolymer was developed. The sintering technique produced nonerodible matrix tablets. The *in vitro* dissolution studies have shown a considerable sustained release of theophylline from the matrix tablets of different drug polymer ratios. The control of release of theophylline from the sintered tablets depended on the polymer-drug ratio, temperature of sintering and time of sintering. Tablet formulation with a drug-polymer ratio of 75:25 sintered at 60° for a period of 1.5 h gave maximum percent of drug release in 12 h. The cumulative percent of drug released from this tablet formulation is better than two commercial products and comparable to the other one.

The objective in dosage form design is to optimize the delivery of medication so as to achieve a measure of control of therapeutic effect in the face of uncertain fluctuations *in vivo* environment in which drug release takes place[1]. There are several physical approaches by which the drug release from a dosage form can be retarded. One such method to retard drug release is a heterogeneous dispersion of drug particles in a solid matrix which can be either biodegradable or non-biodegradable and which controls drug release by diffusion through the matrix, by erosion of the matrix, or by a combination of both diffusion and erosion.

Controlled release systems for macromolecules can be formulated by dissolution of ethylene vinyl acetate copolymer in an organic solvent (dichloromethane), adding powdered macromolecules, casting the mixture in a mold at low temperature and vacuum[2]. Cohen *et al.*[3] developed a method for making polymeric systems for the controlled release of macromolecular drugs, which involved mixing drug and vinyl acetate copolymer (EVA) powders below the glass transition temperature of the polymer and sintering the compressed mixture at a temperature above the glass transition point. The kinetic studies indicated that there was sustained release, and the bioactivity of macromolecules tested was unchanged throughout the sintering and release processes. Verhoeven *et al.*[4] studied the effect of hydrophilic excipients on drug release from the matrix tablets. In that they reported that adding more drug creates more pores between the polypropylene particles thereby greater release of drug.

The investigations of Jambhekar and Breen[5] about the factors that control drug release from non-disintegrating cylindrical slow release tablets using sodium salicylate as model drug showed that the drug release was controlled by

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PROCESS VALIDATION OF ORAL SOLID DOSAGE FORM: TABLET – AN OVERVIEW

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ABSTRACT

Establishing documented evidence which provides a high degree of assurance that a specific process for manufacturing of tablets will consistently produce a product meeting its pre-determined specifications and quality attributes. It mainly involves the steps to be followed to evaluate and qualify the acceptability of the manufacturing process of Tablets. The process is limited to the three batches manufactured of specific batch size with specified equipments and control parameters for Tablets. The results suggest providing documentary evidence that all the manufactured Tablets were evaluated as per specifications. The steps involved such as Blend uniformity results between 90% - 110%, compression assay results between 95%-105% were found within acceptable limits. Other tests related to compression such as hardness, thickness, disintegration, dissolution and for coatings such as weight gain, dissolution were found within acceptable limit.

KEYWORDS: Solid dosage form; Validation; Process validation; Tablet.

INTRODUCTION[1]

"Quality assurance" is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development. The objective of the design and manufacture of the compressed tablet is to deliver orally the correct amount of drug in the proper form, over a period of time and in the desired location and at the desired rate.

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PROCESS VALIDATION OF ORAL SOLID DOSAGE FORM: TABLET – AN OVERVIEW

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RESEARCH ARTICLE

FORMULATION AND EVALUATION OF GASTRORETENTIVE DRUG DELIVERY SYSTEM OF ALFUZOSIN HYDROCHLORIDE

Kadam.V.S[1], Hambarde.S.K.[1]*, Jadhav S.B.[1], Bharkad.V.B[1], Zammrudin M.[1], Lone.V.R[1], Darshanwar Varun S.[1], Shendarkar.G.R.[2]

1. Department of Pharmaceutics, Indira College of Pharmacy, Vishnupuri, Nanded, Maharashtra, India-431606.
2. Nanded college of Pharmacy, Nanded.

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Abstract

Gastro-retentive drug delivery systems are an approach to prolong gastric residence time, there by targeting site-specific drug release in the upper GIT for local or systemic effect. Gastro-retentive drug delivery systems formulations greatly improves the pharmacotherapy of stomach by releasing the drug locally and thus results into high concentration of drug at the gastric mucosa which can be sustained over a longer duration of time Gastro-retentive drug delivery system formulated by direct compression method using (i) Alfuzosin HCL an antihypertensive drug (ii) Polyethylene oxide WSR301 , Hydroxy propyl methyl cellulose K4M and Xanthan gum as polymers (iii) Sodium bicarbonate used as gas generating base . The effect of these polymers concentration was evaluated with respect to Floating Lag Time, Total Floating Time, Matrix integrity, swelling study and In-*vitro* release behaviors and release kinetics with model fitting. Infrared spectroscopic study confirmed the absence of any drug-polymer interaction. Differential scanning colorometry confirmed melting point, purity of drug and polymers. Incorporation of sodium bicarbonate in the Gastro-retentive drug delivery system proved to be an effective method to achieve desired buoyancy. The designed system, combining excellent buoyant ability and suitable drug release pattern, from the study it was concluded that, controlled release Alfuzosin HCL floating tablets can be achieved with success using direct compression technique.

Keywords: Gastroretention , Alfuzosin HCl, Hydroxy Propyl Methyl Cellulose, Polyox WSR301 , Xanthan gum, *In- vitro* floating,

Introduction

Oral route of drug administration is the most convenient and commonly used method of drug delivery. However, this route has several physiological problems. Including an unpredictable gastric emptying rate that varies from person to person, a brief gastrointestinal transit time (80-12h), and the existence of an absorption window in the upper small intestine for several drugs.[1] One novel approach in this area is GRDDSs (gastro retentive drug delivery system). Dosage forms that can be retained in the stomach are called GRDDs. GRDDSs can improve the controlled delivery of drugs that have an absorption window by continuously releasing the drug for a prolonged period of time before it reaches its absorption site[2]. Benign prostatic hyperplasia (BPH) is the most common benign condition affecting men and symptoms can start as early as age 30. Benign prostatic hyperplasia also known as Benign enlargement of the prostate (BPE), Adenofibromyomatous hyperplasia and Benign prostatic hypertrophy. Benign prostatic hyperplasia is a progressive condition characterized by prostate enlargement accompanied by lower urinary tract symptoms. Benign prostatic hyperplasia involves hyperplasia of prostatic stromal and epithelial cells resulting in the formation of large, fairly discrete nodules in the periurethral region of the prostate Benign prostatic hyperplasia can result in the prostatic urethra is compressed which restricts the flow of urine from the bladder, this interference with urine flow may cause uncomfortable symptoms such as frequency, urgency, nocturia, intermittency, decreased stream and hesitancy. Benign prostatic hyperplasia can leads to the risk of urinary tract infection, urinary retention and kidney blockage. Benign prostatic hyperplasia does not lead to the risk of cancer. Initially management for benign prostatic hyperplasia includes lifestyle modification, used alpha blockers and 5-alpha reductase inhibitors. The alpha blockers work to relax the smooth muscle at the prostate and bladder neck by blocking alpha1 receptor. By relaxing the smooth muscle at the prostate neck, the urinary channel is opened which allows a less constricted urinary flow. Alfuzosin HCl is an alpha-1 adrenergic receptor blocker for the treatment of benign prostatic hyperplasia (BPH).Alfuzosin HCl exhibits narrow absorption window in the proximal part of the gastrointestinal tract & jejunum appear to be the main region for absorption. Alfuzosin HCl has a short biological half life (3-5 hours). The dose may range from 2.5 mg thrice a day to a maximum of 10 mg once a day, if it is formulated as conventional tablets it will required multiple daily administration (2-3 times daily) which results into inconveniency to the patients. So Alfuzosin HCl is an ideal candidate for controlled release in the proximal upper parts of the ga-

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Sustained release drug delivery system: review

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ABSTRACT

Sustained release dosage forms are designed to release a drug at a predetermined rate by maintaining a constant drug level for a specific period of time with minimum side effects. The basic rationale of sustained release drug delivery system optimizes the biopharmaceutical, pharmacokinetic and pharmacodynamic properties of a drug in such a way that its utility is maximized, side-effects are reduced and cure of the disease is achieved. There are several advantages of sustained release drug delivery over conventional dosage forms like improved patient compliance due to less frequent drug administration, reduction of fluctuation in steady-state drug levels, maximum utilization of the drug, increased safety margin of potent drug, reduction in healthcare costs through improved therapy and shorter treatment period.

Drug release through matrix system is determined by Water penetration, Polymer swelling, Drug dissolution, Drug diffusion, Matrix erosion have been utilized as formulation approaches. The present article contains brief review on various formulation approaches for Sustained release drug delivery system

Keywords: sustained release system, Matrix tablet, Half-life, Matrix type system, reservoir system.

INTRODUCTION

Oral drug delivery is the most preferred and convenient option as the oral route provides maximum active surface area among all drug delivery system for administration of various drugs because of certain advantages such as unit dosage form, low cost, cheapest for packaging. Tablets are one of the most stable and commonly administered oral dosage forms. Tablets remain popular as dosage form because of the advantages afforded both to the pharmaceutical manufacturers and patient.

The goal in designing sustained or controlled delivery systems is to reduce frequency of dosing or to increase the effectiveness of the drug by localization at the site of action, reducing the dose required, providing uniform drug delivery. Sustained release system is a type of modified drug delivery system that can be used as an alternative to conventional drug delivery system. These systems sustain the release of drug and maintain the plasma drug concentration in therapeutic window except any fluctuation and increase the therapeutic efficacy of drug. They show their action by avoiding peak and trough in dosing and show constant plasma drug concentration in therapeutic window. Sustained release system have benefits like patient compliance, avoid multiple dosing, increase the plasma drug concentration, avoid side effects and overcome the problems associated with conventional system

Oral ingestion has long been the most convenient and commonly employed route of drug delivery. Indeed, for sustained release systems, oral route of administration has received most of the attention with respect to research on physiological and drug constraints as well as design and testing of products [1, 3].

Terminology: Controlled and Sustained Release, both have been used in inconsistent and confusing manner. Both represent separate delivery process. SR constitutes any dosage form that provides medication over an extended time or denotes that the system is able to provide some actual therapeutic control whether this is of a temporal nature, spatial nature or both. It includes any drug delivery system achieves release of drug over an extended period of time, which not depend on time. Hydrophilic polymer matrix is widely used for formulating a Sustained dosage form. The role of ideal drug delivery system is to provide proper amount of drug at regular time interval & at right site of action to maintain therapeutic range of drug in blood plasma [2, 3].

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FORMULATION AND EVALUATION OF SUSTAINED RELEASE MATRIX TABLET OF METOPROLOL SUCCINATE

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KEYWORD: Sustained Release Metoprolol Succinate, Ethyl Cellulose HPMCK4M, Direct Compression and Mathematical model.

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DEVELOPMENT AND EVALUATION OF PULSATILE DRUG DELIVERY SYSTEM OF DILTIAZEM HYDROCHLORIDE

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Abstract:

The main aim of the present work was to develop and evaluate Diltiazem hydrochloride press coated pulsatile tablets which releases the total amount of drug at early morning to tackle the difficulties that occur at cardiac diseases in morning such as angina attack in morning, hypertension, heart attacks etc. prevent hypertension in patients. These systems are designed according to the circadian rhythm of the body, and the drug formulation release drug rapidly and completely as a pulse after a lag time. PDDS (Pulsatile drug delivery system) system employed for treating diseases which show their intense influence at early morning, This press-coated Pulsatile tablets containing Diltiazem hydrochloride in the inner core was formulated with different superdisintegrants fan outer barrier layer by HPMC K4M / HPMC K15M / HPMC K100 / Sodium alginate. The inner core tablet was prepared by the direct compression method and outer barrier layer was applied by press coating technique. The effect of polymer on the lag time of drug release was investigated. Prepared Press Coated Tablets was evaluated for all physical tests. Among all the polymers HPMC K100 showed best lag time for a period of 6 hours and the drug release was prolonged for a period of 8 hours. Compatibility studies carried out by FTIR and DSC studies revealed that all the excipients and polymers were compatible with drug.

Keywords: Chronotherapeutics, Time controlled, lag time, press coated tablets, Diltiazem hydrochloride.

Introduction

Oral controlled release drug delivery system offer anumber of advantages over the conventional immediate release delivery preparations. These systems aredesigned to deliver the drugs at a controlled and predetermined rate thus maintaining their therapeutically effective concentration in systemic circulation fo rprolonged periods. On the other hands, for certain therapies a pulsatile drug release pattern, where the drug is released after well defined lag time, exhibits significant advantages. It is well documented that most of the body functions display circardian rhythms, e.g.heart rate, stroke volume, blood pressure, gastric pH.[1] Time controlled drug delivery system are dosage forms that are designed to mimic the circadian rhythm of the disease by releasing the drug at the appropriate time, by means of an internal pre-programmed clock that is initiated when the dosage forms come in contact with gastrointestinal fluids. Time controlled drug delivery system have been formulated as pellets [2], capsules [3-4] and tablets[5-9]designed to release the drug only after defined lag time. Particularly in the case of cardiovascular disease, bronchial asthma and rheumatoid arthritis, which mostly exhibit circadian manifestations in the early morning, the efficacy and tolerability of a therapy could notably be improved by delivery systems intended to timely release the drug few hours after bedtime administration, thus providing pharmacological protection when it is especially required without involving an unnecessarily

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Design and evaluation of fast dissolving core tablets for press coating

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ABSTRACT

The demand for Fast dissolving tablets has been growing during the last decade especially for elderly and children who have swallowing difficulties. Model drug is commonly used as non steroidal anti-inflammatory. Aceclofenac is used for the treatment of various types of Diseases Related to Arthritis. Formulation and evaluation of mouth dissolving tablet of Aceclofenac by using direct compression method. Formulation was carried out using different three types of super disintegrants (sodium starch glycolate, Crospovidone, Croscarmellose sodium) separately and in combination. The use of combination of superdisintergrants shows better result than the use of single superdisintergrants. In all formulations use of superdisintergrants was in same concentration i.e. (8mg) but the batch A1 was without superdisintergrants. The compatibility of the drug with the excipients was confirmed through FTIR studies. The effects of same concentrations of superdisintergrants on FDT of Aceclofenac were studies. It was found that Aceclofenac tablet passes not only preformulation parameter but also Weight variation, hardness, friability, wetting time, water absorption ratio, disintegration time as well as in vitro dissolution. Among all of the batches the batch A6 shows better results than other batches.

Keywords: Fast dissolving tablet, Aceclofenac, Crospovidone, Core Tablets, Press Coating

INTRODUCTION

The most popular solid dosage forms are being tablets and capsules. However one important drawback of these dosage forms for some patients is the difficulty to swallow. This difficulty in swallowing or dysphasia is currently affecting 35% of general population. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience in convenience in swallowing conventional dosage forms such as when water is not available. For these reasons tablets that can easily dissolve or disintegrate in the oral cavity have attracted a great deal of attention.

Fast dissolving tablet are the fast growing and highly accepted drug delivery system in now a day mainly to improve patient compliance. Fast dissolving tablet have number of advantages over conventional dosage forms, because of that Fast dissolving tablet have emerged as an alternative to conventional dosage forms. Oral route of drug administration have wide acceptance of up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. **[1]**

The concept of fast dissolving Drug Delivery System emerged from the desire to provide patient with more conventional means of taking their medication. It is difficult for many patients to swallow tablets and hard gelatin capsules. Hence they do not comply with prescription, which results in high incidence of non-compliance and ineffective therapy. **[2]**

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REVIEW ON GASTRORETENTIVE DRUG DELIVERY SYSTEM

Ramdas D Shirgire*, Jadhav Suryakant B, Kadam V.S., Bharkad V.B

INDIRA COLLEGE OF PHARMACY,VISHNUPURI, NANDED

ABSTRACT

Controlled release (CR) dosage forms have been extensively used to improve therapy with several important drugs. However, the development processes are faced with several physiological difficulties such as the inability to restrain and localize the system within the desired region of the gastrointestinal tract and the highly variable nature of the gastric emptying process. This variability may lead to unpredictable bioavailability and times to achieve peak plasma levels. The purpose of writing this review on gastroretentive drug delivery systems was to compile the recent literature with special focus on various gastroretentive approaches that have recently become leading methodologies in the field of site-specific orally administered controlled release drug delivery. In order to understand various physiological difficulties to achieve gastric retention, we have summarized important factors controlling gastric retention. Afterwards, we have reviewed various gastroretentive approaches designed and developed until now, i.e. high density (sinking), floating, bio- or mucoadhesive, expandable, unfoldable, super porous hydrogel and magnetic systems. Finally, advantages of gastroretentive drug delivery systems were covered in detail.

KEYWORDS: Gastroretentive, Drug, Oral route.

INTRODUCTION

Oral controlled release (CR) dosage forms (DFs) becoming an interesting topic of research for the past 3 decades due to their considerable therapeutic advantages (Hoffman 1998). However, this approach has not been suitable for a variety of important drugs, characterized by a narrow absorption window in the upper part of the gastrointestinal tract i.e. stomach and small intestine. This is due to the relatively short transit time of the DF in these anatomical segments. Thus, after only a short period of less than 6 h, the CR-DF has already left the upper gastrointestinal tract and the drug is released in non-absorbing distal segments of the gastrointestinal tract. These results in a short absorption phase that is often accompanied by lesser bioavailability. The drugs categorised with narrow absorption window are mostly associated with improved absorption at the jejunum and ileum due to their enhanced absorption properties e.g. large surface area, in comparison to the colon; or because of the enhanced solubility of the drug in the stomach as opposed to more distal parts of the gastrointestinal tract. It was suggested that compounding

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STUDY OF SOLUBILITY AND DISSOLUTION ENHANCEMENT OF ATORVASTATIN CALCIUM BY SOLVENT EVAPORATION METHOD USING NATURAL AND SYNTHETIC POLYMER

Kishor R. Rajmalle*, Mohammad Zameeruddin, Jadhav S.B., Bharkad V.B., Kadam V.S.

Indira College of Pharmacy, SRTM University, Nanded-MH, India (431606).

ABSTRACT

Atorvastatin calcium is a poorly water soluble oral Cardivascular agent. The Atorastatin belongs to BCS class II drug having low solubility and high permeability. In the present study attempt was made to improve solubility and dissolution rate of poorly soluble drug by solid dispersion technique using hydrophilic carriers such as Soluplus and Ghatti gum. according to carrier in which one of the synthetic/artificial polymer (soluplus) and other is natural polymer (Ghatti gum). The FTIR study indicates that there is no interaction between drug and polymers. The solid dispersions were prepared by solvent Eaporation method in three different ratios viz.1:1, 1:2, and 1:4. The prepared solid dispersions were evaluated for physical appearance, solubility study, drug content, and *in-vitro* dissolution study. The optimized batch is AS2 which shows 98.64% drug release within 60 min and solubility is 23.09µg/ml. hence observed that synthetic polymer shows higher solubility and dissolution rate than natural polymer.

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1. High lipophillicity.

2. Strong intermolecular interactions which make the solubilisation of solid energetically costly[1]. Solubility of active pharmaceutical ingredients has always been a concern for formulators, since inadequate aqueous solubility may hamper development of product and limit bioavailability of oral products. Solubility plays an essential role in drug disposition, since the maximum rate of passive drug transport across the biological membrane; the main pathway for drug absorption is a

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FORMULATION OF FLOATING MICROSPHERES OF ZIPRASIDONE HCL MONOHYDRATE BY CROSS LINKING-TECHNIQUE: EFFECT OF $NAHCO_3$ AS GAS FORMING AGENT

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ABSTRACT

Floating microspheres of Ziprasidone HCl Monohydrate was prepared by simple dripping method with an aim of increasing the gastric residence time and for controlled release. A polymeric mixture of Sodium alginate and Eudragit S-100 was used. Sodium bicarbonate was used as the gas-forming gent. The solution was dropped to 1% calcium chloride solution containing 10 % acetic acid for carbon dioxide release and gel formation. The prepared floating microspheres were evaluated with respect to particle size distribution, floating behavior, entrapped, morphology and in vitro release study. Effect of sodium bicarbonate on the above mentioned parameters were evaluated and it was found that the sodium bicarbonate had a pronounced effect on various parameters. The enhanced buoyancy and controlled release properties of sodium bicarbonate containing microspheres made them an excellent candidate for floating dosage form.

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FORMULATION AND EVALUATION OF IMMEDIATE RELEASE TABLET CONTAINING ATORVASTATIN SOLID DISPERSION

Mohammad Zameeruddin, Kishor R. Rajmalle*, Jadhav S.B., Bharkad V.B., Kadam V.S.

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Tinidazole is used in the treatment of protozoal infections. Two simple, sensitive, accurate and economical spectrophotometric methods have been developed for the estimation of Tinidazole in bulk drug and pharmaceutical formulation. Methods are based on measurements of first order and second order derivative spectroscopy adopted to eliminate spectral interference, in which derivative amplitude was measured at 295nm and 213nm respectively. The drug obeys Beer's law in the concentrations range of 4 - 40µg/ml. The results of analysis were validated for accuracy, precision, and ruggedness, limit of detection (LOD) and limit of quantification (LOQ). These results were found to be satisfactory. The proposed methods are simple, sensitive, rapid, economical and suitable for routine quality control applications in pharmaceutical formulation. This method is found to be useful in the method development of tinidazole.

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DEVELOPMENT AND VALIDATION OF UV-SPECTROSCOPIC METHOD FOR THE ESTIMATION OF DIDANOSINE IN TABLET

Mohammad Zameeruddin, Kalyankar Swapnil S*., Solanke S. B., Jadhav S. B., Kadam V.S. and Bharkad V. B.

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ABSTRACT

A simple, sensitive, rapid and accurate UV-Spectroscopic method has been developed for the estimation of Didanosine in bulk drug and tablet dosage form. In order to increase value of absorbtivity and subsequently LOD the drug was dissolved in water and acetonitrile (90:10) and absorbance was measured at 249.60 nm. The linearity of method was found to be between 1-14 µg/ml. The method was validated based on ICH guidelines. Hence useful for the routine analysis of Didanosine.

KEY WORDS: Didanosine, Acetonitrile, UV-Spectrophotometric Method, ICH Guidelines.

INTRODUCTION

Antiretroviral (ARV) therapy is potent, convenient and usually well tolerated, capable of reducing HIV blood concentration to undectable values within a few weeks from treatment initiation and of inducing a robust and sustained cluster of differentiation antigen (CD4 T-cell) gain. [1] Didanosine is chemically, 9-[(2R, 5S)-5-(hydroxymethyl) oxolan-2-yl]-6.9-dihydro-3H-purin-6-one. It is white, not hygroscopic crystalline powder having melting point 160–163 °C, water soluble i.e., (27.3 mg/ml at 25 °C and pH 6.2); soluble in dimethylsulfoxide; slightly soluble in ethanol and methanol; insoluble in chloroform. It is sensitive to acidic pH, but stable at neutral or slightly alkaline pH. At pH less than 3, complete hydrolysis to hypoxanthine and 2′, 3′-dideoxyribose occurs in less than 2 min at 27°C. [2]Mechanism of Action: Didanosine is a synthetic nucleoside analogue of the naturally occurring nucleoside deoxyadenosine in which the 3'-hydroxyl group is replaced by

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IMMEDIATE RELEASE DRUG DELIVERY SYSTEM: A REVIEW

***Vishal G. Rathod[1], Vaishali Kadam[1], S. B. Jadhav[1], Md. Zamiruddin[1], V. B. Bharkad[2], Suprabha P. Biradar[2]**

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ABSTRACT

The drugs administered by oral route are versatile, flexible in dosage strength, relatively stable, present lesser problem in formulation and packaging and are convenient to manufacturer, store, handle and use. Solid dosage forms provide best protection to drugs against temperature, light, oxygen and stress during transportation. As a drug entity nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form. Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. Oral administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly, patient compliance. Tablet is the most popular among all dosage forms existing today because of its convenience of self-administration, compactness and easy manufacturing, however in many cases immediate onset of action is required than conventional therapy. To overcome these drawbacks, immediate release pharmaceutical dosage form has emerged as alternative oral dosage forms. Immediate release solid oral dosage forms are classified as either having rapid or slow dissolution rates. Immediate release dosage forms are those for which ≥85% of labelled amount dissolves within 30 min. For immediate release tablets, the only barrier to drug release is simple disintegration or erosion stage, which is generally accomplished in less than one hour.Disintegrating agents are substances routinely included in tablet formulations and in some hard shell capsule formulations to promote moisture penetration and dispersion of the matrix of the dosage form in dissolution fluids.

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RECENT APPROCHES SOLUBILITY AND DISSOLUTION ENHANCEMENT OF ATORVASTATIN: A REVIEW

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ABSTRACT

A drug should be present a soluble state before produce its therapeutics effects however in now a day in market 40% drug are poorly soluble in water. such a drugs poorly dissolution and absorption rate in gastrointestinal tract which majorly irregular bioavailability .a various solubilization techniques are used. solubility is most important role in targeting a desired plasma concentration of drugs. Hence we are study in this review a different techniques used for solubility enhancement like solid dispersion, smedds, inclusion complexes, hydrotrpy, liqusolid compact etc. we are discuss about BCS II class hypolipidemic drug atorvastatin. ATC are low aqueous solubility resulting in low oral bioavailability (12%) and thus presents a challenge in formulating a suitable dosage form. now a researcher developed the various methods. we discuss a different technique used for solubility enhancement of atorvastatin. mostly solid dispersion was found to be most used technique by researcher as it provide ease in preparation and efficiency in terms of resolving the solubility and dissolution problems associated with atorvastatin.

Keywords: Solubility, Solid Dispersion, Dissolution, Atorvastatin, Bioavailability.

INTRODUCTION

About 90% of chemical compound todays are pharmaceutical drug delivery to be reported that poorly soluble in water. Due to this problems active pharmaceutical ingredients molecular target in to the body system in GIT i.e poor solubility is critical parameter to survive the pharmaceutical development process. it revealed that more than 40% of the drug substances have aqueous solubility below 1mg/ml and the 32% have an aqueous solubility below 0.1mg/ml, Various method have been reported for solubility and dissolution rate

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RECENT ADVANCES OF SUSTAINED RELEASE ORAL DRUG DELIVERY SYSTEM: A REVIEW

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ABSTRACT

The term "sustained release" is known to have existed in the medical and pharmaceutical literature for many decades. Oral drug delivery is the most preferred route for the various drug molecules among all other routes of drug delivery, because ease of administration which lead to better patient compliance. The attractiveness of these dosage forms is due to awareness to toxicity and ineffectiveness of drugs when administered by oral conventional method in the form of tablets & capsules. The basic rationale of sustained release drug delivery system optimizes the biopharmaceutical, pharmacokinetic and pharmacodynamics properties of a drug in such a way that its utility is maximized, side-effects are reduced and cure of the disease is achieved. There are various physiochemical and biological properties which affect the extended release drug delivery system. Extended release drug formulations have been used since 1960's. Sustained Release is also providing promising way to decrease the side effect of drug by preventing the fluctuation of the therapeutic concentration of the drug in the body. This article provides information about the Sustain release formulation, Design and Fabrication of oral controlled release systems. The basic goal of sustained release is provide promising way to decrease the side effect of drug by preventing the fluctuation of the therapeutic concentration of the drug in the body and increase patient compliance by reducing frequency of dose.

KEYWORDS:-Sustained Release, Oral controlled release, Matrix tablet, Patient compliance, Extend release.

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AN OVERVIEW ON FAST DISINTEGRATING TABLETS

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ABSTRACT

Fast dissolving drug delivery systems (FDDS) were first developed in the late 1970s as an alternative to tablets, capsules, and syrups for pediatric and geriatric patients who experience difficulties in swallowing traditional oral solid dosage forms. Over the past three decades, fast disintegrating tablets (FDTs) have gained considerable attention as a preferred alternative to conventional tablets and capsules due to better patient compliance. FDTs are solid dosage forms containing medicinal substances which disintegrate rapidly, usually in a matter of seconds, when placed on the tongue. The convenience of administration and improved patient compliance are important in the design of oral drug delivery system which remains the preferred route of drug delivery inspite of various disadvantages. Such problem can be solved in the novel drug delivery system by formulating "Fast disintegrating tablets" (FDTs) which disintegrates or dissolves rapidly without water within few seconds in the mouth due to the action of superdisintegrant or maximizing pore structure in the formulation. The review describes the various formulation aspects, superdisintegrants employed and technologies developed for FDTs, along with various excipients, evaluation tests, taste masking methods, marketed formulation and drugs used in this research area.

KEYWORDS: Dysphagia, Fast Disintegrating, Disintegration Time, Lyophilization, Direct Compression, Superdisintegrant.

INTRODUCTION

The FDTs emerged with an objective to improve patient compliance. These dosage forms rapidly disintegrate and/or dissolve to release the drug as soon as they come in contact with saliva, thus obviating the need for water during administration, an attribute that makes them highly attractive for pediatric and geriatric patients. Difficulty in swallowing conventional tablets and capsules is common among all age groups, especially in elderly and dysphagic patients. This disorder of dysphagia is associated with many medical conditions including stroke, parkinson's disease, AIDS, thyroidectomy, head and neck radiation therapy and other neurological disorders including cerebral palsy. One study showed that 26% out of 1576 patients experienced difficulty in swallowing tablets due to their large size, followed by their surface, shape and taste. Rapid

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Fast dissolving drug delivery systems (FDDS) were first developed in the late 1970s as an alternative to tablets, capsules, and syrups for pediatric and geriatric patients who experience difficulties in swallowing traditional oral solid dosage forms. Over the past three decades, fast disintegrating tablets (FDTs) have gained considerable attention as a preferred alternative to conventional tablets and capsules due to better patient compliance. FDTs are solid dosage forms containing medicinal substances which disintegrate rapidly, usually in a matter of seconds, when placed on the tongue. The convenience of administration and improved patient compliance are important in the design of oral drug delivery system which remains the preferred route of drug delivery inspite of various disadvantages. Such problem can be solved in the novel drug delivery system by formulating "Fast disintegrating tablets" (FDTs) which disintegrates or dissolves rapidly without water within few seconds in the mouth due to the action of superdisintegrant or maximizing pore structure in the formulation. The review describes the various formulation aspects, superdisintegrants employed and technologies developed for FDTs, along with various excipients, evaluation tests, taste masking methods, marketed formulation and drugs used in this research area.

KEYWORDS: Dysphagia, Fast Disintegrating, Disintegration Time, Lyophilization, Direct Compression, Superdisintegrant.

INTRODUCTION

The FDTs emerged with an objective to improve patient compliance. These dosage forms rapidly disintegrate and/or dissolve to release the drug as soon as they come in contact with saliva, thus obviating the need for water during administration, an attribute that makes them highly attractive for pediatric and geriatric patients. Difficulty in swallowing conventional tablets and capsules is common among all age groups, especially in elderly and dysphagic patients. This disorder of dysphagia is associated with many medical conditions including stroke, parkinson's disease, AIDS, thyroidectomy, head and neck radiation therapy and other neurological disorders including cerebral palsy. One study showed that 26% out of 1576 patients experienced difficulty in swallowing tablets due to their large size, followed by their surface, shape and taste. Rapid

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AN OVERVIEW ON FAST DISINTEGRATING TABLETS

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A REVIEW ON PARENTERAL DRUG DELIVERY SYSTEM

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ABSTRACT

Parenteral formulations, particularly intravascular ones, offer a unique opportunity for direct access to the bloodstream and rapid onset of drug action as well as targeting to specific organ and tissue sites. Parenteral preparation have been traditionally used to accomplish these tasks and there are several products on the market using these injectable & control release novel drug & implant formulations. The broader application of these novel control drug delivary systems in parenteral drug delivery, however, particularly with new chemical entities, has been limited due primarily to the following reasons: a) only a small number of parenteral drug excipients are approved, b) there is increasing number of drugs that are partially or not soluble in conventional oils and other lipid solvents, and c) the ongoing requirement for site-specific targeting and controlled drug release. Thus, there is growing need to expand the array of targetable control drug delivery & drug implant systems to deliver a wide variety of drugs and produce stable formulations which can be easily manufactured in a sterile form, are cost effective and at least as safe and efficacious as the earlier developed systems. These advanced parenteral implant-based systems are at various stages of preclinical and clinical development which include nanoemulsions, nanosuspensions, liposomes, niosomes, nano partical, micro partical,pro- drug and needal free injection. This review article will showcase these injectable controlled release systems, advanced parenteral drug delivary system,implant&novel technologies in implant, recent innovations in sterile drug delivery devices and discuss advances in relation to formulation development, processing and manufacturing, and stability assessment.

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INDO AMERICAN JOURNAL OF PHARMACEUTICAL RESEARCH

POLYELECTROLYTE MULTILAYER CAPSULE: A REVIEW

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ABSTRACT

A few years ago a novel techniques for vesicle called as polyelectrolyte multilayer (PEM) capsule was introduced in the field of drug delivery. Multifunctional polyelectrolyte capsules fabricated by the layer-by-layer (LBL) assembly technique possess remarkable properties, even though they are held together by electrostatic attraction. From the beginning of the nineties controlled radical polymerization techniques such as Atom Transfer Radical Polymerization and Nitroxide mediated Polymerization have used as new tool in polymer chemistry field of drug delivery. Electrostatic interaction between polyelectrolyte and charged surfaces are basis for the formation of multilayer of polyelectrolyte by using alternate charge. The colloidal core can be varied in diameter from 0.1 to 10μm. The thickness of the shell can be in nanometer range by varying the adsorption condition and number of layer. The unique colloidal structure of LBL assembled capsules offers a very versatile platform for encapsulation, storage and delivery of diverse substances. Mobile pH-sensors are developed for monitoring the local pH inside living cells. Ion sensors are obtained by encapsulation of ion-sensitive fluorophores-conjugated dextran into the multilayer microcapsules. The LBL multilayer capsules are coated with kinesin, which can drive cargos such as vesicles, proteins, and organelles along microtubules. The use of polyelectrolyte capsules as carrier in pharmaceutical products, capsules stable for extended periods of time (years) should be developed.

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A REVIEW ON BIOAVAILABILITY ENHANCERS OF HERBAL ORIGIN

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ABSTRACT

Bioenhancers are such agents, which by themselves are not therapeutic entities but when combined with an active drug lead to the potentiation of the pharmacologic effect of the drug. Such formulations have been found to increase the bioavailability / bioefficacy of a number of drugs even when reduced doses of drugs are present in such formulations. Evidence have been obtained for such classes of drugs which are (a) poorly bioavailable and/or efficacious, (b) require prolonged therapy, and (c) are highly toxic and expensive. These are phytomolecules development of which is based on ancient knowledge of Ayurveda. They augment the bioavailability or biological activity of drugs when administered at low doses. They reduce the dose; shorten the treatment period thus reducing drug-resistance problems. The treatment is made cost effective, minimizing drug toxicity and adverse reactions. When used in combination with number of drug classes such as antibiotics, antituberculosis, antiviral, antifungal and anticancerous drugs they are quite effective. Oral absorption of vitamins, minerals, herbal extracts, amino acids and other nutrients are improved by them. They act through several mechanisms which may affect mainly absorption process, drug metabolism or action on drug-target.

Key words: Bioenhancers, Bioavailability, Ayurveda, Herbal plants.

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ANALYTICAL METHODS FOR ESTIMATION OF DIDANOSINE: A REVIEW

Md. Zameeruddin, Kalyankar Swapnil S*., Jadhav S.B., Kadam V.S., Bharkad V.B. and Solanke S.B.

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ABSTRACT

Antiretroviral (ARV) therapy is potent, convenient and usually well tolerated, capable of reducing HIV blood concentration to undectable values within a few weeks from treatment initiation and of inducing a robust and sustained cluster of differentiation antigen (CD4 T-cell) gain. Didanosine (DDI) metabolized intracellularly by series of cellular enzymes to its active moiety, dideoxyadenosine triphosphate, which inhibits the HIV reverse transcriptase enzymes competitively with natural deoxyadenosine triphosphate (DATP). It is white not hygroscopic crystalline powder having melting point 160-163°C, water soluble i.e., (27.3 mg/mL at 25°C and pH 6.2), soluble in dimethylsulfoxide, slightly soluble in ethanol and methanol, insoluble in chloroform. A simple, specific, accurate, economical and precise reversed phase high performance liquid chromatography (RP-HPLC) and UV spectrophotometric method has been developed for the simultaneous estimation and absorption ration method. The method was validated for Linearity, Specificity, Accuracy, Precision, Ruggedness, Robustness, Limit of Detection (LOD) and Limit of Quantification (LOQ). This review chromatographic separation was performed Chromosil column, Lochrospher 100 RP-8, C18 column, C18 catridges with distilled water, methanol, ethanol, acetonitrile, phosphate buffer etc.

Key words: UV spectrophotometric, RP-HPLC, Didanosine, Validation.

INTRODUCTION

A milestone in the history of human immunodeficiency virus (HIV) disease has been the availability of new classes of drug allowing the introduction of combination Antiretroviral

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REVIEW ON ANALYTICAL METHOD VALIDATION OF NITROIMIDAZOLES

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ABSTRACT

Imidazole is a planner five membered ring system with 3 carbon and 2 nitrogen atom in 1 and 3 position. It is soluble in water and other solvents. It presents in two equivalent tautomeric forms i.e the hydrogen atom is located on one of the two nitrogen atoms. Imidazole is entirely soluble in water and highly polar compound as evidenced by a calculated dipole of 3.61 D. It is colurless liquid having high boiling point of 256^0C than all other 5 membered heterocyclic compound due to intermolecular H bonding where there is linear association of molecule. Imidazole drug have broadened scope in remedying various dispositions in clinical medicines. Medicinal properties of imidazole include anticancer .b-lactamase inhibitors, carboxypeptidase inhibitor, antiaging agent, anticoagulants, anti-inflammatory, antibacterial, antiviral, antifungal antitubercular, antidiabetic and antimalarial. Nitroimidazoles class of drugs are a well-established group of antiprotozoal and antibacterial agents that have ability to inhibit the growth of anaerobic bacteria and certain anaerobic protozoa, for example *Trichomonas vaginalis*, *Entamoeba histolytica* and *Giardia lamblia.* This review article presents determination of Ornidazole and Tinidazole was done by UV spectrophotometer, HPLC, potentiometry, calorimetry, titrimetry and HPTLC.

Keywords: Imidazole, Nitroimidazole, Ornidazole and Tinidazole..

INTRODUCTION

Imidazole (1,3 diazo-2,4 cyclopentadiene) is a planner five membered ring system with 3 carbon and 2 nitrogen atom in 1 and 3 position. The simplest member of the imidazole family is imidazole itself, a compound with molecular formula $C_3H_4N_2$ .The systemic name of

WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES

Volume 3, Issue 3, 557-577. Review Article ISSN 2278 – 4357

REVIEW ON ANALYTICAL METHOD VALIDATION OF NITROIMIDAZOLES

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ABSTRACT

Imidazole is a planner five membered ring system with 3 carbon and 2 nitrogen atom in 1 and 3 position. It is soluble in water and other solvents. It presents in two equivalent tautomeric forms i.e the hydrogen atom is located on one of the two nitrogen atoms. Imidazole is entirely soluble in water and highly polar compound as evidenced by a calculated dipole of 3.61 D. It is colurless liquid having high boiling point of 256^0C than all other 5 membered heterocyclic compound due to intermolecular H bonding where there is linear association of molecule. Imidazole drug have broadened scope in remedying various dispositions in clinical medicines. Medicinal properties of imidazole include anticancer .b-lactamase inhibitors, carboxypeptidase inhibitor, antiaging agent, anticoagulants, anti-inflammatory, antibacterial, antiviral, antifungal antitubercular, antidiabetic and antimalarial. Nitroimidazoles class of drugs are a well-established group of antiprotozoal and antibacterial agents that have ability to inhibit the growth of anaerobic bacteria and certain anaerobic protozoa, for example *Trichomonas vaginalis*, *Entamoeba histolytica* and *Giardia lamblia.* This review article presents determination of Ornidazole and Tinidazole was done by UV spectrophotometer, HPLC, potentiometry, calorimetry, titrimetry and HPTLC.

Keywords: Imidazole, Nitroimidazole, Ornidazole and Tinidazole..

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A SHORT REVIEW ON FAST DISSOLVING ORAL FILM

***Mundhe Bhagyashri, Kadam Vaishali, Jadhav Suryakant, Md. Zamiruddin, Bharkad Vishvanath**

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ABSTRACT

In the late 1970's fast-dissolving oral film's are came in existence and is an alternative to tablet, capsules and syrup. Fast-dissolving oral films are helpful to paediatric and geriatric patients who experience difficulties in swallowing traditional oral solid-dosage forms. FDOFs are very similar to postage stamp in their shape, size and thickness. Oral films provide better drug utilization in by-passing the first pass metabolism, enhance drug bioavailability, mask the bitter taste of the drug and do not need water to swallow. FDOF formulations are suitable for cough, cold remedies, sore throat, allergenic conditions, nausea, pain and CNS disorders. Multivitamins, caffeine strips, snoring aid and sleeping aids are also applicable for incorporation in the oral films. The present review shows that how the film is convient to the patient and also focuses on the marketed technologies.

Keywords: fast-dissolving oral film, Film forming polymer, Solvent casting technique, Plasticiser.

INTRODUCTION[1,2,3]

The concept of orally disintegrating dosage forms has emerged from the desire to provide patients with more conventional means of taking their medication. Interestingly, the demand for ODT has enormously increased during the last decade, particularly for geriatric and paediatric patients who experience difficulty in swallowing conventional tablets and capsules. Hence, they do not comply with prescription, which results in high incidence of ineffective therapy[1].

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A REVIEW ON GASTRORETENTIVE DRUG DELIVERY SYSTEM

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ABSTRACT

This review explains the recent advances in gastroretentive drug delivery systems with special focus on floating drug delivery systems. Oral route is the most convenient and painless technique of drug delivery. Gastroretentive drug delivery systems have been developed which overcome physiological conditions in gastrointestinal tract such as short gastric resident time (GRT) and unpredictable gastric emptying times (GET). Various approaches used for prolonging GRT are mucoadhesive systems (Bioadhesive Systems), High Density Systems, Expandable Systems (Swelling Systems), Floating Drug Delivery systems (FDDS). formulations of floating tablets were prepared using direct compression technique with low viscosity polymer such as HPMC K100LV, high viscosity polymers such as HPMC K4M, K15M, and carbopol in different ratios. The evaluation results revealed that all formulations comply with the specification of official pharmacopoeias and/or standard reference with respect to general appearance, content uniformity, hardness, friability and buoyancy. Controlled release (CR) dosage forms have been extensively used to improve therapy with several important drugs. Incorporation of the drug in a controlled release gastroretentive dosage forms (CR-GRDF) which can remain in the gastric region for several hours would significantly prolong the gastric residence time of drugs and improve bioavailability, reduce drug waste, and enhance the solubility of drugs that are less soluble in high pH environment. Several approaches are currently utilized in the prolongation of the GRT, including floating drug delivery systems (FDDS), swelling and expanding systems, polymeric bioadhesive systems, high-density systems, modified-shape systems and other delayed gastric emptying devices.

Key words:-Gastric retention time, Gastro retentive systems; floating drug delivery system; Effervescent; non effervescent.

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ROLE OF SOLID DISPERSION IN IMPROVING SOLUBILTY AND DISSOLUTION RATE: A COMPREHENSIVE REVIEW

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ABSTRACT

Poor water solubility is the major drawback for the various types of drugs and many approaches have been introduced for the solubility enhancement of such drugs. Solid dispersions have been known to be one amongst the recent means of improving the dissolution rate by enhancement of solubility, and hence the bioavailability of poorly water soluble drugs. According, to – Chiou and Riegeman Solid dispersions are "The dispersion of one or more active ingredients in an inert carrier or matrix, where the active ingredients could exist in finely crystalline, solubilised or amorphous state." solid dispersion is a very useful method for pharmaceutical point of view because of its capability to solve the solubility problems by using solid dispersion method. The present article reviews the basic concept about solid dispersion, various types of solid dispersion, and criteria of solvent Selection, the methods of preparation, characterization, their advantages, limitations, applications, future prospect and various types of marketed preparations.

Key words: solid dispersion, solubility enhancement, selection of carrier.

INTRODUCTION

Many potential drug candidates are characterized by a low oral bioavailability. Often poor drug dissolution/solubility rather than limited permeation through the epithelia of the gastrointestinal tract are responsible for low oral bioavailability [1]. Thus aqueous solubility of any therapeutically active substance is a key property as it governs dissolution, absorption

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A REVIEW ON LOZENGES

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Lozenges,
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ABSTRACT

Lozenges are tablets that dissolve slowly in the mouth and so release the drug in the saliva. Lozenges are used for the local medication dissolving in the mouth or throat, e.g. it will produce local anaesthesia, antiseptic and antibiotic action of drugs. There are different types of lozenges such as Chewable Lozenges, Hard Lozenges, and Soft Lozenges. Chewable lozenges are popular with the paediatric population. Hard-candy lozenges are mixtures of sucrose and other sugars and/or carbohydrates in an amorphous state. Soft lozenges have become popular because of the ease of extemporaneous preparation and applicability to a wide variety of drugs. The lozenges are prepared by direct compression and Wet granulation method. Ordered mixing, Drug adsorption, Drug excipient hybrid mixing by spray drying these are methods by which compressed tablet lozenges are prepared. There are some evaluation parameters by which lozenges will be evaluated such as diameter, weight variation, friability, hardness, In-vitro drug dissolution studies, Stability studies etc.

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A REVIEW ON NOVEL APPROACHS IN GASTRORETENTIVE MICROSPHERES

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ABSTRACT

Gastroretentive drug delivery system offers several advantages besides providing better bioavailability to poorly absorbed drugs and a required release profile thus attracting interest of pharmaceutical formulation scientists. Different approaches for Gastroretentive dosage form include floating system, Mucoadhesion or bioadhesion, sedimentation or high density, expansion, modified shape systems etc. These systems are useful to overcome the several problems encountered during the development of a pharmaceutical dosage forms. Microsphere should be primarily aimed to achieving more predictable and increased bioavailability of drugs. Prolonged gastric retention improves bioavailability, reduces drug waste, useful for drugs acting locally in the GIT, drugs which are poorly soluble and unstable in intestinal fluids and also microspheric drug delivery system has gained enormous attention due to its wide range of application as it covers targeting the drug to particular site to imaging and helping the diagnostic features. The purpose of this review is to focus on the recent advances in the field of formulation, characterization, evaluation and applications of Gastroretentive dosage forms. The review also highlights briefly about the floating microspheres, polymeric microspheres which provide a variety of application in life sciences, mucoadhesive microspheres which is one of the most useful drug delivery system with its various advantages, magnetic microspheres which provide drug disease site durg release and different types of radioactive microspheres.

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Gastroretentive drug delivery system offers several advantages besides providing better bioavailability to poorly absorbed drugs and a required release profile thus attracting interest of pharmaceutical formulation scientists. Different approaches for Gastroretentive dosage form include floating system, Mucoadhesion or bioadhesion, sedimentation or high density, expansion, modified shape systems etc. These systems are useful to overcome the several problems encountered during the development of a pharmaceutical dosage forms. Microsphere should be primarily aimed to achieving more predictable and increased bioavailability of drugs. Prolonged gastric retention improves bioavailability, reduces drug waste, useful for drugs acting locally in the GIT, drugs which are poorly soluble and unstable in intestinal fluids and also microspheric drug delivery system has gained enormous attention due to its wide range of application as it covers targeting the drug to particular site to imaging and helping the diagnostic features. The purpose of this review is to focus on the recent advances in the field of formulation, characterization, evaluation and applications of Gastroretentive dosage forms. The review also highlights briefly about the floating microspheres, polymeric microspheres which provide a variety of application in life sciences, mucoadhesive microspheres which is one of the most useful drug delivery system with its various advantages, magnetic microspheres which provide drug disease site durg release and different types of radioactive microspheres.

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REVIEW ON - BILAYER TABLET

Motarwar S.S.*, Jadhav S.B. ,Kadam V. S. , Muttepawar S.S, Bharkad V.B., Md. Zamiruddin

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ABSTRACT

Over the past 30 years as the expense and complications involved in marketing new drug entities have increased ,with concomitant recognition of therapeutic advantages of controlled drug delivery, greater attention has been focused on development of sustained or controlled release drug delivery system.In the last decade interest in developing a combination of two or more active pharmaceutical ingredient(API)in a single dosage form(bilayer tablet)has increased in the pharmaceutical industry, promoting patient convenience and compliance. several pharmaceutical companies are currently developing bilayer tablet for a variety of reason: patentextension, therapeutic ,marketing to name a few. To reduce capital investment quite often existing but modified tablet presses are used to develop and such tablets. Bilayer tablet is suitable for sequential release of two drugs in combination, separate two incompatible substances and also for sustained release tablet in which one layer is immediate release as initial dose and second layer is maintenacedose.Bilayer tablet is improved beneficial technology toovercome short coming of single layer tablet.

Keywords: Bilayer tablet, Approaches, Bilayer tablet presses, GMP requirement for Bilayer Tablets.

INTRODUCTION

Now a day's various developed and developingcountries are moving towards combination therapy for treatment of various diseases and disorders requiring long term therapy such as hypertension, Diabetes and Rheumatoid arthritics. The problem of dose dependent side effects is minimized by combinationtherapies and is advantageous over monotherapy.From

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INDO AMERICAN JOURNAL OF PHARMACEUTICAL RESEARCH

FORMULATION AND *IN-VITRO* EVALUATION OF COMPRESSION COATED TABLET

Jadhav S. B.*[1], Kale S. V.[1], Dr. Kawtikwar P.S.[2], Kadam V. S.[1], Nabde M. K.[1], Rai S. D.[1], Dr. Kshirsagar R.V. [3], Bharkad V.B.[1]

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Keywords
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ABSTRACT

In the present work, lag time increased by using the hydrophilic polymer that get swell when it come in contact with biological fluid and show the burst release of drug after lag time. The fast disintegrating core tablets of model drug Diclofenac potassium were prepared and coated with coating material of different grades of Hydroxypropyl methylcellulose (HPMC) 100-cps, 15-cps and 6-cps respectively. Three batches without combination, and four batches in combination having ratio 1:1:1, 1:2:2, 2:1:2, 2:2:1, were prepared which showed lag time of 8, 3, 4, and 6 respectively. Formulation F4 show greater increase in the lag time. The compression coated tablets showed a clear lag time before a burst release of diclofenac potassium. The FTIR study showed that drug and excipient are compatible with each other. No significant changes were found during the Stability study of best batch, indicating its stability aspect. The result showed that the HPMC hydrophilic polymer can be successfully used in different concentrations to achieve desired lag time.

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IMPROVEMENT OF SOLUBILITY AND DISSOLUTION RATE OF POOORLY SOLUBLE DRUG CARVEDILOL BY SOLID DISPERSION TECHNIQUE USING COMBINED CARRIERS

Kadam Vaishali S*.,Chintale Ashwini G., Jadhav suryakant B., Barkhad Vishwanath S., Ingole Bhaskar d., and Birajdar Ganesh O.

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ABSTRACT

In the present study attempt was made to improve solubility and dissolution rate of poorly soluble drug by solid dispersion technique using combined carriers such as poloxamer 188 and PVP K90. Carvedilol is a poorly water soluble oral antihypertensive agent. The Carvedilol belongs to BCS class II drug having low solubility and high permeability. The FTIR study indicates that there is no interaction between drug and polymer. The solid dispersions were prepared by kneading method in three different ratios viz.1:1, 1:2, and 1:4. The prepared solid dispersions were evaluated for solubility study, drug content, and *in-vitro* dissolution study. The prepared dispersion showed marked increase the saturation solubility and dissolution rate of Carvedilol than that of drug alone. The dispersion with poloxamer 188 (1:4) showed High solubility and faster dissolution rate as compared to the other prepared dispersions.

Key words: Carvedilol, solid dispersion, water soluble carrier, Poloxamer 188.

INTRODUCTION

Nearly about 40% of the newly discovered drugs are lipophilic and failed to reach market due to the poor water solubility. [1] Solubility and dissolution rate is the rate determining step for bioavailability of the BCS class II drugs. The bioavailability problem of the BCS class II drugs can be overcome by increasing the solubility and dissolution rate of the drug in the gastrointestinal fluids. [2]

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Two Wavelength Method for Estimation of Drotaverine Hydrochloride and Mefenamic Acid in their Combined Tablet Dosage Form

Sakhare R.S.[1]*, Roge A.B.[2], Jadhav S.B.[1], Ingole P.G.[1], Jameel Ahmed[1], Jadhav A.B.[1],

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Abstract: A new, simple, accurate and sensitive UV-spectrophotometric Two wavelength method has been developed for simultaneous determination of Drotaverine HCL and Mefenamic Acid in combined pharmaceutical dosage form. Two wavelength i.e. 240 nm and 277 nm were selected for estimation of Drotaverine HCL where as wavelength 233 nm and 253 nm was selected for estimation of Mefenamic Acid using Methanol solution as solvent . Drotaverine HCl and Mefenamic Acid shows linearity in the concentration range of 0-30 µg/ml and 0-30 µg/ml respectively. The method was validated statistically.
Keywords: Drotaverine HCl, Mefenamic Acid, Two wavelength method.

INTRODUCTION:

Drotaverine,1-(3,4-diethoxybenzylidene)-6,7-diethoxy-1,2,3,4-tetrahydroisoquinoline, is an antispasmodic drug, structurally related to papaverine. It is a selective inhibitor of phosphodiesterose 4 and has no anticholinergic effect. It is used in treating renal colic and has also been used to accelerate labor[1-4]

Few methods have been reported for the determination of Drotaverine in dosage forms and in biological fluids including, high performance liquid chromatography (HPLC)[5–8] thin layer densitometric[9] spectrophotometric[9–12] differential spectrophotometric[13,14] computer-aided spectro - photometric[15] and potentiometric[16–19] methods. Also Fulop[20] proposed a polarographic method for determination of Drotaverine in 1M H_2SO_4 at −420 mV in the range 4–80 µg and recently Ziyatdinova[21] proposed voltammetric method for determination of the drug by oxidation at a graphite electrode in 0.1 M H_2SO_4 at 1.05 and 1.28 V, but up to now nothing has been published concerning the adsorptive cathodic stripping voltammetric determination of this drug using HMDE.

Mefenamic acid (MF), *N*-(2,3-Xylyl) anthranilic acid, is a non-steroidal drug. It has analgesic and antipyretic properties. Mefenamic acid is used in musculoskeletal and joint disorders such as osteoarthritis and rheumatoid arthritis[22] the compound is almost insoluble in water but is readily soluble in organic solvents such as dioxane, alcohols and dimethyl formamide.[23]

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Formulation and Evaluation of Dispersible Tablets of Diltiazem Hydrochloride

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Abstract

The objective of this study was to formulate and evaluate dispersible tablets of Diltiazem HCL using wet granulation method for enhanced patient compliance. Dispersible Tablets prepared using Superdisintegrants such as Croscarmellose Sodium (Ac-Di-Sol) and Sodium Starch Glycolate. Formulations were evaluated for the standard of Dispersible Tablets. It was observed that all the formulations were acceptable with reasonable limits of standard required for Dispersible Tablets. The study reveals that Superdisintegrants used were effective in low concentration. It was concluded that Dispersible Tablets of Dispersible Tablets with enhanced dissolution rate can be made using selected Superdisintegrants.

Keywords: Dispersible tablets; Diltiazem; Croscarmellose Sodium (Ac-Di-Sol) and Sodium Starch Glycolate.

INTRODUCTION

The tablet is the most widely used dosage form because of its convenience in terms of self-administration, compactness, and ease in manufacturing. However, geriatric and pediatric patients experience difficulty in swallowing conventional tablets, which leads to poor patient compliance. To overcome this weakness, scientists have developed innovative drug delivery systems known as "Dispersible Tablets". Dispersible Tablets are also known as quick dissolves, fast melts, fast dissolving, fast disintegrating, rapid-dissolve, or orally dissolving tablets. Their characteristic advantages such as administration, anywhere, anytime lead to their suitability to geriatric and pediatric patients. They are also suitable for the mentally ill, the bedridden, and patients who do not have easy access to water. The benefits, in terms of patient compliance, rapid onset of action, increased bioavailability, and good stability make these tablets popular as a dosage form of choice in the current market.[1]

Despite increasing interest in controlled-release drug delivery systems, the most common tablets are those intended to be swallowed whole and to disintegrate and release their medicaments rapidly in the gastrointestinal tract (GIT). The proper choice of

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Formulation and Evaluation of Mouth Dissolving Tablets of Diltiazem Hydrochloride

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ABSTRACT

In this investigation mouth dissolving tablets of Diltiazem hydrochloride were prepared using different superdisintegrants by wet granulation method. MDTs were evaluated for physicochemical properties and in vitro dissolution. Effect of disintegrant on disintegration behavior of tablet in pH 6.8 was evaluated. Wetting time of formulations containing higher concentration of Crospovidone was least and tablets showed fastest disintegration. The drug release from MDTs increased with increasing concentration of superdisintegrants and was found to be highest with formulations containing Crospovidone.

Keywords: Diltiazem hydrochloride, Mouth dissolving tablet, Superdisintegrating agents.

INTRODUCTION

This tablet disintegrates instantaneously when placed on tongue, releasing the drug that dissolves or disperses in the saliva. On placing mouth-dissolving tablet in the mouth, saliva serves to rapidly dissolve the dosage form. The saliva containing the dissolved or dispersed medicament is then swallowed and the drug is absorbed in the normal way. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach & it may produce rapid onset of action. In such a cases Bioavailability of drug is significantly greater than those observed from conventional tablet dosage form. The dispersible tablets allows dissolution or dispersion in water prior to administration but the Mouth Dissolving Tablet instead of dissolving or disintegrating in water is expected to dissolve or disintegrate in oral cavity without drinking water. ODTs are solid unit dosage form, which disintegrate or dissolve rapidly in mouth without chewing and water [1].

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Research article *Open Access*

Simultaneous spectrophotometric determination of methyldopa and hydrochlorothiazide in pharmaceutical dosage form by AUC and first order derivative method

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ABSTRACT

A New, Simple, Accurate And Sensitive UV-Spectrophotometric Method has been developed for simultaneous determination of Methyldopa And Hydrochlorothiazide(HCTZ) in bulk And combined dosage form .Method A is AUC method, which involved measurement of area between 276-286nm and 266-276nm for the estimation of MD and HCTZ respectively. Method B Applied first order derivative Spectrophotometry, which involved measuring the absorbance values at 271.40nm and 251.20nm of first derivative spectrum. Beer's law obeyed in concentration range of 10-60µg/ml and 2-14µg/ml for MD & HCTZ respectively by both Methods. Results of analysis were statistically reported & were found to be satisfactory.

Keywords: Methyldopa, Hydrochlorothiazide, Spectroscopy, AUC Method, First order derivative method.

INTRODUCTION

Methyldopa [3, 4] (MD) (Fig 1)is 3-(3, 4dihydrophenyl)-2-Methyl-L-alanine sequihydrate is Chemical name of methyldopa. It isWhite to yellowish white, Fine powder which may contain friable lumps it is slightly soluble in water, very slightly soluble in Ethanol (95%), practically insoluble in chloroform and in ether. It is freely soluble in dilute hydrochloric acid.

Hydrochlorothiazide [5, 6] (HCTZ)(Fig2) is 6-chloro-3, 4dihydro-2H-1, 2, 4, benzathiadiazine-7-suiphonamide It is White or almost white, crystalline powder, odorless. Soluble in acetone, sparingly soluble in ethanol (95%).Very slightly soluble in water, it dissolves in dilute solution of alkali hydroxides Literature survey revealed UV-Visible spectrophotometric methods such as simultaneous equation method [7], Dual Wavelength method [8] and RP-HPLC [9, 10] for

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STABITY INDICATING DISSOLUTION METHOD DEVELOPMENT FOR ESTIMATION OF METHYLDOPA AND HYDROCHLOROTHIAZIDE IN COMBINE DOSAGE FORM

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Abstract:

The aim of this work was to develop validate a dissolution test for Methyldopa and Hydrochlorothiazide in combination tablets using spectrophotometric method. The dissolution established conditions were 900 ml. of 0.1M HCl pH 1.0 as dissolution medium, using a paddle apparatus at a stirring rate of 50 rpm. The drug release was evaluated by UV spectrophotometric method the areas of solution were recorded at 274-284 nm and266-276 nm for Methyldopa *and Hydrochlorothiazide respectively. It can be concluded that the method developed consists in an efficient alternative for assay of dissolution for tablets. The method was validated to meet requirements for a global regulatory filing which includes linearity, precision, accuracy robustness and ruggedness. In addition, filter suitability and drug stability in medium were demonstrated*

Keywords: *In vitro release, Stability, Dissolution study of methyldopa and Hydrochlorothiazide, Spectrophotometry, Area under curve method, Validation.*

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SYNTHESIS OF SPIRO COMPOUNDS AS MEDICINAL AGENTS; NEW OPPORTUNITIES FOR DRUG DESIGN AND DISCOVERY. PART I: A REVIEW

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ABSTRACT

Spirocyclic compounds isolated from plant and animal origin has important applications in medicinal chemistry. The tetrahedral nature of the spirolinked carbon rendered it important conformational features and structural implications for biological systems. Spiro heterocycles have been found to play fundamental roles in biological processes and have exhibited diversified biological activity and pharmacological and therapeutical properties. Spirocyclic compounds have fascinated chemists for more than a century. Many methods have been reported for the synthesis of spirocyclic compounds, however we decided to present a representative synthetic scheme of various classes belongs to heterocyclic ring systems in a conventional arrangement. The creation of stereogenic quaternary C centers is a challenging task in organic chemistry, because of their ability to generate a surrounding asymmetrical space in spirans-centres; the syntheses of these spirans-centres have been exploited for asymmetric synthesis, molecular recognition and catalysis in recent years.

KEYWORDS: Azaspirocycles, spiro-β-lactams, spirocyclic compounds, spirocyclic oxetanes, spiroindoles, synthesis.

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DEVELOPMENT AND VALIDATION OF UV-SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF NIZATIDINE IN PLASMA.

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ABSTRACT

Simple, precise and cost effective UV spectrophotometric method has been developed for the estimation of nizatidine in plasma. Nizatidine shows λ_{max} at 314.0 nm in plasma. The drug follows Beer-Lambert law in the concentration range of 2.0-20.0 µg/ml with correlation coefficient of 0.998. The method was validated by analytical performance parameters suggested by the international conference on harmonization. All validation parameters were found to be within the acceptable range. The developed method was successfully applied to estimate the amount of nizatidine in plasma.

KEYWORDS: Analytical Method, Nizatidine, Plasma, UV-Spectrophotometric Method

INTRODUCTION

Nizatidine is chemically, N-[2-[[[2-(Dimethylamino)methyl]-4thiazoyl]methyl]-thio]ethyl]-N'- methyl-2-nitro1,1 ethandiamin.[1] Nizatidine are specific H_2-receptor antagonists. It is more potent than cimetidine in inhibition of gastric acid secretion induced by various stimuli and they lack cimetidine's anti-androgenic and hepatic microsomal inhibiting effects.[2] Nizatidine also found to enhance gastrointestinal motor activity in experimental animals and in humans by facilitating the cholinergic system due to the antiacetylcholinesterase (AChE) activity. Because inhibition of AChE activity increases the availability of endogenous ACh, it is possible that nizatidine might increase duodenal HCO_3^- secretion through inhibition of

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Simultaneous spectrophotometric estimation of Aceclofenac and Diacerhein in Tablet dosage form

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ABSTRACT:

A simple, accurate, cost effective and reproducible spectrophotometric method; Q Analysis(Absorbance ratio), has been developed for the simultaneous estimation of Diacerhein and Aceclofenac in tablet dosage form. Method involves formation of 'Q-absorbance Equation' at 257.0 nm (λmax of Diacerhein) and 278.0 nm (isoabsorptive point) in distilled water. Beer's law were obeyed (at isoabsorptive point) in the concentration range of 2-20 µg/ml for Diacerhein having line equation y = 0.04950x + 0.03520 with correlation coefficient of 0.99987 and 4-40µg/ml for Aceclofenac having line equation y = 0.10246x + 0.03990 with correlation coefficient of 0.99925. The developed method was validated as per ICH guidelines with respect to linearity, accuracy (recovery), precision and specificity. The percentage recovery of Diacerhein ranged from (98.67 ± 0.2421) and Aceclofenac ranged from (98.54 ± 0.3330) in tablet dosage form. By treating the data statistically and by recovery study, results of study were validated.

Keywords: Aceclofenac, Diacerhein, Q Analysis, Absorbance ratio, Ultravoilet spectrophotometry, validation.

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A Novel RP-HPLC method for simultaneous estimation of diacerhein and aceclofenac in oral pharmaceutical formulation.

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ABSTRACT

A selective and accurate high performance liquid chromatographic method has been developed and validated for simultaneous estimation of diacerhein (DIC) and aceclofenac (ACF) in oral pharmaceutical formulation. The chromatographic separation was achieved by RP- HPLC using mixture of methanol, water and acetic acid as mobile phase using HiQ Sil C18 column and UV detection at 275.0 nm. The method was validated for linearity, precision, accuracy, selectivity and robustness. All the parameters examined met the current recommendation of bioanalyical validation development. The proposed method can be successfully used for routine analysis, quality control and stability studies of marketed for oral pharmaceutical formulation.

Keywords: Aceclofenac, Diacerhein, RP-HPLC, Validation, Simultaneous estimation.

1.INTRODUCTION

Aceclofenac is a (2-[2-[2-(2, 6-dichlorophenyl) aminophenyl] acetyl] oxyacetic acid)[1] which is structurally related to diclofenac is used in various painful indications[2] and proved as effective as other NSAIDs with lower indications of gastro-intestinal adverse effects and thus, resulted in a greater compliance with treatment.[3] It is a new analgesic and anti-inflammatory drug used in the management of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis [4] scapulohumeral periarthritis.[5, 10]Diacerhein[6] is a 4, 5-Bis (acetyloxy)-9, 10-dioxo-2-anthracenecarboxylic acid, is a low molecular weight heterocyclic compound, also known as Diacetylrhein (DIC, Figure 2).

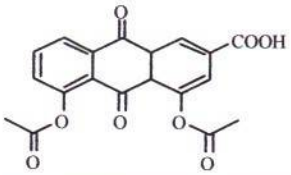

Figure 1: Chemical structure of Aceclofenac

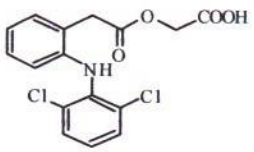

Figure 2: Chemical Structure of Diacerhein

Literature survey reveals spectrophotometric[7] HPLC,[8] Spectrofluorometric,[9] Reverse phase HPLC,[10] LC,[7] High performance liquid Chromatography and Pharmacokinetic,[11] Densitometric,[12] stripping Voltammetry,[13] and spectrophotometric,[14] HPLC,[15] method for estimation of aceclofenac and diacerhien in bulk drug substance. There are no HPLC methods for simultaneous estimation of both drugs in combined dosage form. Hence an attempt has been made to develop simple, sensitive, rapid, accurate, precise and economical HPLC method for simultaneous estimation of ACF and DIC in tablet dosage form. Aceclofenac (ACF) and Diacerhein (DIC) are available in tablet dosage form in the ratio of 2:1.

MATERIALS AND METHODS

Materials:

A standard gift sample of Aceclofenac and Diacerhein were procured from Wockhardt pharmaceutical Ltd with 99.99% w/w assay value and was used without further purification. All chemicals and reagents used were of HPLC grade. Double distilled water of HPLC grade was prepared in the laboratory in all glass two stage distillation assembly. Commercial formulations Dycerin® (Glenmark Pharmaceutical, Mumbai) containing 50mg of DIC and 100mg of ACF were purchased from the local market.

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Figure 3: Chromatogram obtain by using Mobile Phase Methanol: Water: Acetic acid (80:20:1) flow rate- 1.5 ml/min

Instrument and Cchromatographic Conditions:

Quantitative HPLC was performed on JASCO HPLC PU-2080 PLUS with L-7100 double reciprocating pump (Maximum discharge pressure 39.2 MPa) with JASCO – UV 2075 PLUS detector. The chromatographic mode selected was Isocratic. The chromatographic separations were performed using HiQ Sil C-18W 4.5mm X 250mm column maintained at ambient temperature, eluted with mobile phase at a flow rate of 1.5 ml/min for 5 min. The mobile phase consisted of methanol, water, and acetic acid in ratio 80:20:1 v/v/v. Measurements were made with injection volume 20µl and ultraviolet (UV) detection at275 nm.

Standard preparation:

Stock solutions (1 mg/ml) of DIC and ACF were prepared separately by dissolving accurately about 100 mg of each drug in 100 ml N, N- Dimethylacetamide (AR grade) in 100 ml volumetric flask to obtain standard stock solutions of each drug of concentration 1000 µg/ml. The stock solutions were filtered through a 0.2 µ membrane filter paper.

Sample preparation:

For analysis of dosage form, twenty tablets were accurately weighed and powdered. The powder equivalent to 100 mg of Aceclofenac and 50 mg of Diacerhein was weighed accurately and mixed with 70 ml N, N- Dimethylacetamide (AR grade) in 100 ml volumetric flask. The mixture was allowed to stand for 15 min with intermittent shaking. The mixture was then filtered through a Whatman filter paper no.44 and the residue was washed thoroughly with N, N- Dimethylacetamide. The filtrate and washings were combined in 100 ml volumetric flask and volume was made up to the mark with N, N- Dimethylacetamide. The sample solution was filtered through a 0.2 µ membrane filter paper and the amount of Aceclofenac and Diacerhein present in the solution was computed from calibration curve.

RESULT AND DISCUSSION

Method development:

Standard solution of Diacerhein and Aceclofenec were injected into the HPLC system and run in different mobile phase systems such as A) methanol (100%),

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Research Article

FORMULATION AND EVALUATION OF SUSTAINED RELEASE TABLETS OF ACECLOFENAC USING HYDROPHILIC MATRIX SYSTEM

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ABSTRACT

The objective of the present study was to develop "once daily" sustained release tablets of Aceclofenac (200mg) by wet granulation using hydrophilic polymer like Hydroxy propyl methyl cellulose K -100. The drug excipient mixtures were subjected to preformulation studies. The tablets were subjected to physicochemical studies, *in- vitro* drug release, kinetic studies and stability studies. FTIR studies shown there was no interaction between drug and polymer. The physicochemical properties of tablets were found within the limits. Aceclofenac is a non steroidal anti-inflammatory agent used in symptomatic treatment of rheumatoid arthritis, osteoarthritis and spondylitis. The drug release from optimized formulations was extended for a period of 24 hrs. The kinetic treatment of selected formulation (F8) showed that the release of drug follows zero order models. The optimized formulations were subjected to stability studies for one month at 45° temperature with RH 75±5% and showed there were no significant changes in drug content, physicochemical parameters and release pattern. Results of the present study indicated the suitability of hydrophilic polymers in the preparation of matrix based sustained release formulation of Aceclofenac.

Keywords: Aceclofenac, Matrix tablets, Sustained release, Wet granulation, Hydroxy Propyl Methyl Cellulose K -100

INTRODUCTION

Non-steroidal anti-inflammatory drugs (NSAIDs) are considered to be the first-line drugs in the symptomatic treatment of rheumatoid arthritis, osteoarthritis and spondylitis, Aceclofenac is one of them[1]. It is a newer derivative of Diclofenac with low gastrointestinal complications. The short biological half-life (3- 4h) and dosing frequency more than one per day make Aceclofenac an ideal candidate for sustained release. To reduce the frequency of administration and to improve patient compliance, a once-daily sustained release formulation of Aceclofenac is desirable.

Matrix tablets composed of drug and polymer as release retarding material offer the simplest approach in designing a sustained release system. The present study aims to develop sustained release matrix tablets using hydrophilic matrix materials[2], such as HPMC- K 15 and HPMC- K 100 along with drug in varying proportions by wet granulation method. For sustained release systems, the oral route of drug administration has received the most attention as it is natural, uncomplicated, convenient and safer route[3]. Matrix tablets were prepared by either wet granulation or direct compression method. Currently available sustained matrix tablets are generally prepared by wet granulation method. The aim of the present work was to prepare sustained release matrix tablets of Aceclofenac and to study the effect of *in-vitro* release characteristics, kinetics of the prepared formulations and stability studies[10].

MATERIALS

Aceclofenac, Hydroxy propyl methyl cellulose K-100 and, Hydroxyl propyl methyl cellulose K-15 were obtained as gift samples from Arvind Remedies Ltd, Tamil nadu, India. Lactose, Mannitol, Povidone (PVP K-30) were purchased from Unify chemicals, Jothi Aromas and DK Enterprises respectively. Magnesium stearate, Talc and Aesrosil were purchased from S.D.Fine-Chem Limited, Mumbai, India. All other chemicals used were of analytical grade.

METHODS

Preformulation studies

Micromeritic properties

The physical mixtures were prepared by triturating drug and excipients in a dried mortar for 5 min. The angle of repose of Aceclofenac and its Physical mixtures with other excipients were determined by fixed funnel method. The angle of repose, Compressibility index (C.I.), Degree of compression (c) and the Hausner's ratio were calculated[4] using following equations. The result was shown in table no: 1

$\theta = \tan^{-1}(h/r)$ ---------- (1)

Where, θ =Angle of repose

h=Height of granule above flat surface

r=Radius of circle formed by the granule pile.

$C.I. = \{(\rho t - \rho 0) / \rho t\} \times 100$ ------- (2)

Where, ρt - tapped density, ρ0 - bulk density.

$C = (Ho-Hp / Ho) \times 100$---------- (3)

Where, C - Degree of compression

Ho - height of granule bed in the die before compression.

Hp - height of granule bed in the die at a pressure p.

Hausner's ratio = TBD / LBD ---------- (4)

Where, TBD - Tapped Bulk Densities

LBD - Loose Bulk Density

Drug-excipient compatibility studies

Infrared (IR) spectroscopy was conducted using a FTIR Spectrophotometer (Jasco FT-IR 410) and the spectrum was recorded in the wavelength region of 4000 to 400 cm−1. The procedure consisted of dispersing a sample (drug alone or mixture of drug and excipients) in KBr and compressed into discs by applying a pressure of 5 tons for 5 min in a hydraulic press. The pellet was placed in the light path and the spectrum was obtained.

Preparation of tablets

Tablets weighing 320mg were prepared containing 200 mg of Aceclofenac and Lactose, Mannitol and HPMC K100. Polyvinyl pyrrolidone (2.8%) was used as binder. Magnesium stearate (2.8%) and Talc (1.8%) was added as lubricant prior to compression. Different tablet formulations were prepared by wet granulation technique. All the powders were passed through 24 mesh. Required quantity of drug, diluents and polymers were mixed thoroughly and a sufficient quantity of binding agent was added slowly. After enough cohesiveness was obtained, the mass was sieved through 16 mesh. The granules were dried at 50ºC for 45minuts and were

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RESEARCH ARTICLE

Phytochemical Analysis of Methanolic Extract of Roots of *Kalanchoe pinnata* by HPLC and GCMS

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1. INTRODUCTION:

Various species of KALANCHOE are used medicinally in Indo-China and Philippines Islands, whereas *Kalanchoe pinnata* Pers. (Family Crassulaceae) is naturalized throughout the hot and moist parts of India. The leaves and bark is bitter tonic, astringent to the bowels, analgesic, carminative, useful in diarrhoea and vomiting [5]. Antiulcer [10], antiinflammatory [9, 11] and antimicrobial activity [1] of leaf extract was reported. Oral treatment with leaf extract significantly delayed onset of disease in BALB/c mice infected with *Leishmania amazonensis* as compared to untreated mice or mice receiving *K. pinnata* by the intravenous or topical routes [2]. Potent cytotoxic compounds bersaldegenin-1,3,5-orthoacetate [16] and bufadienolide-bryophyllin B [15] were isolated. Other chemical constituents from this plant are bryophyllol, bryophollone, bryophollenone, bryophynol and two homologous phenanthrene derivatives 2(9-decenyl)-phenanthrene (I) and 2-(undecenyl)-phenanthrene (II) from leaves [12]. Isolation and structure elucidation of 24-epiclerosterol [24(*R*)-stigmasta-5, 25-dien-3β-ol], 24(*R*)-5α-stigmasta-7, 25-dien-3β-ol, 5α-stigmast-24-en-3β-ol and 25-methyl-5α-ergost-24 (28)-en-3β-ol from aerial parts was done [13]. This species is also included in the plants species, which are used by the tribals of Kerala for treating cancer symptoms [6] Juice of the fresh leaves is used very effectively for the treatment of jaundice in folk medicines of Bundelkhand region of India, but no systemic study to assess this activity has been carried out.

As the aerial parts of plant have many pharmacological activity but roots of this plant was not focused yet hence the present investigations were carried out to evaluate phytoconstituent of roots of plant with the help of HPLC and GC-MS, which will help for further pharmacological evaluation.

2. MATERIALS AND METHODS:

2.1. Collection of plant material:

The roots of *Kalanchoe pinnata* was collected from Satpuda hills near Akkalkuwa, Dist: Nandurbar, Maharashtra, India, in June 2010, cleaned and dried at room temperature in shade and away from direct sunlight. The plant authenticated by T. Chakraborthy, Deputy Director Botanical Survey of India, Koregaon Road Pune, by comparing morphological features and a sample voucher specimen of plant was deposited for future reference (Voucher specimen number QMAKP1).

2.2. Preparation of extract:

The root of *Kalanchoe pinnata* was collected and dried in the shade and then pulverized in a grinder. The powdered drug was utilized for extraction. Material was passed through 120 meshes to remove fine powders and coarse powder was used for extraction. A method described in Mukherjee was used for extraction of powdered plant. Extraction was done by methanol. [7]

2.3. Preliminary phytochemical screening:

The extract was then subjected to preliminary phytochemical screening to detect the presence of various phytoconstituent. The results show presence of Steroids, Saponins, Alkaloids, Glycosides, Flavonoids, Tannins and carbohydrates in the methanolic extract. [4]

2.4. HPLC analysis for flavonoids: [8]

Column: Hypersil- ODS Column (250mm × 4.6mm), 5µm particle size
Mobile phase: Acetonitrile: Phosphate buffer pH 2.4 (25:75)
Flow rate: 1.2 ml/ min
Detection: 266 nm

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Simultaneous Spectrophotometric Determination Of Aceclofenac And Diacerhein in Tablet Dosage Form

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Abstract: A simple, accurate, cost effective and reproducible spectrophotometric method; Simultaneous equation, has been developed for the simultaneous estimation of Aceclofenac and Diacerhein in Tablet dosage form. Absorption maxima of Aceclofenac and Diacerhein in operating solvent were found to be 274 and 257.2 nm respectively. Beer's law was obeyed in concentration range 4-40 µg/ml having line equation y = 0.1203x + 0.002 with correlation coefficient of 0.9999 for Aceclofenac and 2-20 µg/ml having line equation y = 0.2155x + 0.0463 with correlation coefficient of 0.9998 for Diacerhein. The percentage recovery of Aceclofenac ranged from (99.79 ± 0.2738) and Diacerhein ranged from (99.51 ± 0.3089) in tablet dosage form. The developed method was validated as per ICH guidelines with respect to linearity, accuracy (recovery), precision and specificity.

Keywords: Aceclofenac, Diacerhein, Simultaneous equation, Ultravoilet spectrophotometry.

Introduction:

Aceclofenac (ACF) and Diacerhein (DIC) are available in tablet dosage form in the ratio of 2:1. Chemically, Aceclofenac (ACF, Figure 1) (2-[2-[2-(2,6-dichlorophenyl)aminophenyl] acetyl]oxyacetic acid), a nonsteroidal antiinflamatory drug (NSAID) has been indicated for various painful indications[1] and proved as effective as other NSAIDs with lower indications of gastro-intestinal adverse effects and thus, resulted in a greater compliance with treatment[2]. it is a new analgesic and antiinflammatory drug used in the management of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis[3]. It is official in BP[4], which describes a liquid chromatographic method for its quantitation. Literature survey reveals spectrophotometric[5], HPLC[6-7], spectrofluorometric[8] and densitometric[9] stripping voltammetry[10] methods for the estimation of aceclofenac from pharmaceutical formulation. Diacerhein (DIC, Figure 2) an oral agent described as 4, 5-Bis(acetyloxy)-9,10-dioxo-2-anthracenecarboxylic acid, is a low molecular weight heterocyclic compound[11]. Literature survey reveals HPLC[12] method for estimation of drug in bulk drug substance. There are no UV spectrometric methods for simultaneous estimation of both drugs in combined dosage form. Hence an attempt has been made to develop simple, sensitive, rapid, accurate, precise and economical UV spectrophotometric estimation of ACF and DIC in tablet dosage form.

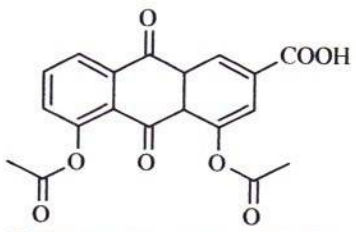

Figure 1: Chemical structure of Aceclofenac

TITLE

Once Daily Gastro Retentive Mucoadhesive Cephalexin Monohydrate Tablet:Formulation and In-Vitro Evaluation

AUTHOR(S) shaikh, Afsar C.; khan, Tarique; Nazim, Sayyed; Siraj, Shaikh; Zameeruddin, Mohammad

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ABSTRACT Oral drug administration has been the predominant route for drug delivery due to the ease of administration, patient convenience and flexibility in formulations. Mucoadhesive tablets of Cephalexin monohydrate were prepared with an objective to increase the bioavailability by minimizing the first pass metabolism and also to reduce the frequency of administration. Carbopol 934p as a primary polymer and HPMC K15M, HPMC K4M, and HPMC K100M as secondary polymers in different

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RECENT TRENDS IN APPLICATIONS OF PULMONARY DRUG DELIVERY: A REVIEW

Siraj Shaikh

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ABSTRACT

Pulmonary drug delivery system is a needle free technique. The origin of inhaled therapies seen in back 4000 years ago to India, where people smoked the leaves of the Atropa belladonna plant to suppress cough. In the 19th and early 20th centuries, asthmatics smoked asthma cigarettes that contained stramonium powder mixed with tobacco to treat the symptoms of their disease. Now a day's pulmonary drug delivery remains the preferred route for administration of various drugs. It is an important research area which impacts the treatment of illnesses including asthma, chronic obstructive pulmonary disease and various diseases. Drug is delivered directly to the conducting zone of the lungs. In this article, we summarize recent advances in applications of pulmonary drug delivery system. previously pulmonary drug delivery is used for management of Asthma and COPD only but due advancement in application nowadays Pulmonary drug delivery is useful to treat Diabetes, angina pectoris, cancer , bone disorders ,migraine,tuberculosis,acute lung injury and others. .

Key Words: Asthma, pulmonary route, application, bone disorders, inhalation therapy.

INTRODUCTION

The development of an inhalation therapy that is effective and safe depends not only on a pharmacologically active molecule, but also on a delivery system and its applications. The respiratory tract is exposed to a relatively large number of biological and non biological particulates. These are contained in the 20,000 L of air that must be inhaled daily to accomplish gas exchange. It is a characteristic of the effectiveness of lung defense mechanisms that in healthy people's lungs are sterile below the larynx. [1]

By pulmonary route drug goes gives direct to a target organ. In the treatment of obstructive respiratory diseases, pulmonary delivery can

Mohamed Hassan Dehghan
Bio

Article

A study on Hydrotrope corn starch gelled as a carrier for topical drug delivery

Sayyed Nazim · M H G Dehghan · Siraj Shaikh · Pravin Gomase · Mohammed Zameeruddin · Majaz Quazi

Der Pharmacia Lettre 01/2011; 3:110-119

ABSTRACT Starches form an important class of gel forming material of natural origin, hydrotropic salts not only induce swelling and gelatinisation of starch at reduced temperatures but at fairly high concentrations increase the solubility of poorly soluble drugs in water. The present research work mainly concern with to evaluate the potential of hydrotropic gelled corn starch as a suitable vehicle for topical drug delivery and to determine the effect of change in starch/ hydrotropic salt concentration on Rheology of the gel with Rofecoxibs invitro drug release study from the formulated gel. In this study the potential of hydrotrope-gelled starch as a carrier for topical

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REVIEW ARTICLE

Herb's Used in Psychological Disorders

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Abstracts: An Herb is a plant or plant extract, including leaves, bark, berries, roots, gums, seeds, stems and flowers which are bestowed with nourishing and healing. An herb is a plant or plant extract, including leaves, bark, berries, roots, gums, seeds, stems and flowers which are bestowed with nourishing and healing elements. Herbs are the endowment of Mother Nature which has been used for healthcare through out different ages and cultures of human history. Herb's have various useful chemical constituents which is useful for treatment of various Psychological disorder like Schizophrenia. Depression, Anxiety & Panic Disorders, Hallucination, Illusion, Insomnia, Body Dysmorphic Disorder, Signs of Mental illness, Suicide, False Memory. So we require Pharmacognostic, Pharmacological, Ethano-pharmacological parameters of the Herbs for studying the activities useful in the treatment of Psychological disorders. So our study aim's at screening the all parameters related to Herbs which is for Researchers and the students whose work on those topics. The present study elicits on all the aspects of the herbs and throws attention to set the mind of research scientist to carry out the work for developing its various formulations used in Psychological disorders which can ultimately beneficial for humans beings.

Key Words: Psychological disorders, Anti-psychotic drugs, herbal treatment

INTRODUCTION

In the twentieth century in the United States, a mental hygiene movement developed, aiming to prevent mental disorders. Clinical psychology and social work developed as professions. World War I saw a massive increase of conditions that came to be termed "shell shock." The term stress, having emerged out of endocrinology work in the 1930s, was increasingly applied to mental disorders. Electroconvulsive therapy, insulin shock therapy, lobotomies and the "neuroleptic" chlorpromazine came to be used by mid-century. An antipsychiatry movement came to the fore in the 1960s. Deinstitutionalization gradually occurred in the West, with isolated psychiatric hospitals being closed down in favor of community mental health services. A consumer/survivor movement gained momentum. Other kinds of psychiatric medication gradually came into use, such as "psychic energizers" and lithium. Benzodiazepines gained widespread use in the 1970s for anxiety and depression, until dependency problems curtailed their popularity [1].

The prevalence of mental health problems, particularly depression and anxiety, in the general population is around one in six people, and around 40% of people with mental health problems will have symptoms of both anxiety and depression. Drug acting on the central nervous system (CNS) include the centrally acting (mainly opoid) analgesics, anti-epileptics and anti-parkinsonian agents, as well as those for psychiatric disorders. Increasing number of patients express a preference for the use of remedies they perceive to be natural and Physicians recommend herbal remedies in the selected cases. It is becoming increasingly important for physician to be familiar with the herbal remedies commonly used in the patient problems they serve. Since the mental illness are diverse and individual patients are biochemically unique, a larger number of drugs will increase the likelihood of finding a beneficial medication, Hence in future times psychiatric patients will probably have medications with improved effectiveness and with less side effects.

Herb's have various useful chemical constituents which is useful for treatment of various Psychological disorder like Schizophrenia. Depression, Anxiety & Panic Disorders, Hallucination, Illusion, Insomnia, Body Dysmorphic Disorder, Signs of Mental illness, Suicide, False Memory. So we require Pharmacognostic, Pharmacological, Ethano-pharmacological parameters of the Herbs for studying the activities useful in the treatment of Psychological disorders. So our study aim's at screening the all parameters related to Herbs which is for Researchers and the students whose work on those topics. It is helpful for many mental health professionals, particularly psychiatrists, seek to diagnose individuals by ascertaining their particular mental disorder [2].

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The present study elicits on all the aspects of the herbs and throws attention to set the mind of research scientist to carry out the work for developing its various formulations used in Psychological disorders which can ultimately beneficial for humans beings. Drugs of plant origin are important in all these areas, although not usually for self-medication. They are also of historical interest; for example, the antipsychotic drug reserpine, isolated from *Rauwolfia* species, revolutionized the treatment of schizophrenia and enabled many patients to avoid hospitalization before the introduction. A Psychological disorder or mental illness is a psychological or behavioral pattern that occurs in an individual and is thought to cause distress or disability that is not expected as part of normal development or culture [3].

HERB's

An Herb is a plant or plant extract, including leaves, bark, berries, roots, gums, seeds, stems and flowers which are bestowed with nourishing and healing. An herb is a plant or plant extract, including leaves, bark, berries, roots, gums, seeds, stems and flowers which are bestowed with nourishing and healing elements. Herbs are the endowment of Mother Nature which has been used for healthcare through out different ages and cultures of human history. Being negligent to the value of herbs due to chemical medicines, human lost synchronization to the rhythm of Nature and thus suffered various side effects. Herbs have the elements that help the human body to live in harmony with nature and its laws. According to the most ancient system of natural medication, Ayurveda, herbs work depending on the Self Correcting Mechanism and balance of three elements "Vata", "Pitta" and "Kaplan" in the human body. Herbal treatment not only heals but also looks after the body to live a healthy and fruitful life. Herbs have been used for healthcare through out the human history and are once again being recognized for their true value [4, 5].

What Drugs Treat Anxiety Disorders? [6]

Antidepressants, particularly the SSRIs, may also be effective in treating many types of anxiety disorders. Other anti-anxiety medications include the benzodiazepines, such as Valium, Ativan, and Xanax. These drugs do carry a risk of addiction so they are not as desirable for long term use. Other possible side effects include drowsiness, poor concentration, and irritability.

What Drugs Treat Psychotic Disorders?

Antipsychotics are a class of drugs used commonly to treat psychotic disorders. The antipsychotics vary in their side effects, and some people have more trouble with certain side effects than with others. The doctor can

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Review Article

RECENT ADVANCES IN PULMONARY DRUG DELIVERY SYSTEM: A REVIEW

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ABSTARCT

The lung has served as a route of drug administration for thousands of years. Now a day's pulmonary drug delivery remains the preferred route for administration of various drugs.

In this article, we summarize the rationale behind the advances of pulmonary drug delivery system. Pulmonary drug delivery is an important research area which impacts the treatment of illnesses including asthma, chronic obstructive pulmonary disease and various other diseases. Inhalation gives the most direct access to drug target. In the treatment of obstructive respiratory diseases, pulmonary delivery can minimize systemic side effects, provide rapid response and minimize the required dose since the drug is delivered directly to the conducting zone of the lungs .It is a needle free several techniques have been developed in the recent past, to improve the Quality of pulmonary drug delivery system without affecting their integrity. This article focuses on recent advances in the technologies, devices, formulation and applications of pulmonary drug delivery system.

Key words: Inhaler, Aerosol, Pulmonary drug delivery, Dry powder inhaler, Meter dose inhaler,nebulizer, Fine particle fraction.

INTRODUCTION

Pulmonary route have been used to treat various respiratory diseases for centuries. Ancient inhalation therapies included the use of leaves from plants, vapors from aromatic plants, balsams, and myhrr. However, around the turn of the 19th century, with the invention of liquid nebulizers, these early treatments developed into legitimate pharmaceutical therapies. In the 1920 s adrenaline was introduced as a nebulizer solution, in 1925 nebulizer porcine insulin was used in experimental studies in diabetes, and in 1945 pulmonary delivery of the recently discovered penicillin was investigated, steroids had been introduced in the mid 1950s for the treatment of asthma and nebulizers were enjoying widespread use. In 1956 the pressured metered dose inhaler (pMDI) was introduced, over the past 5 decades, helped by the advances in molecule design and drug discovery the pMDI has risen to become the main stay of asthma treatment .[1]

Over the decade certain drugs have been sold in compositions suitable for forming drug dispersion for pulmonary delivery to treat various conditions in humans. Such pulmonary drug delivery compositions are designed to be delivered by inhalation by the patient of a drug dispersion so that the active drug within the dispersion can reach the lung. It has been found that certain drugs given by pulmonary route are readily absorbed through the alveolar region directly into blood circulation. Pulmonary route possesses many advantages over other routes of administration for the treatment of specific disease states, particularly lung associated large protein molecules which degrade in the gastrointestinal conditions and are eliminated by the first pass metabolism in the liver can be delivered via the pulmonary route if deposited in the respiratory zone of the lungs. Devices used to deliver drug by pulmonary route area based on one of three platforms pressurized metered dose inhaler, nebulizer and dry powder .In the treatment of disease, aerosol administration represents a valuable means by which a therapeutic agent may be delivered.[2]

IDEAL CHARACTERSTICS OF THERAPEUTIC AEROSOL

Contain a safe and efficacious drug.

Contain minimal quantities of inert excipients.

Monodisperse, small particle size

Low velocity after generation

High concentration and rate of generation

Highly reproducible characteristics

Low bioburden (solids) or sterile (liquids)

ADVANTAGES OF PULMONARY DRUG DELIVERY

Inhaled drug delivery puts drug where it is needed.

It requires low and fraction of oral dose i.e. drug content of one 4 mg tablet of salbutamol equals to 40 doses of meter doses.

Pulmonary drug delivery having very negligible side effects since rest of body is not exposed to drug.

Onset of action is very quick with pulmonary drug delivery.

Degradation of drug by liver is avoided in pulmonary drug delivery.

In asthma and diabetes requires long term treatment if it is given by pulmonary drug delivery safety is maximum because rest of body is not exposed to drug.[3]

CHALLENGES IN PULMONARY DRUG DELIVERY

Low Efficiency of inhalation system

Efficiency of presently available inhalation systems has generally too low which is important challenge in pulmonary drug delivery. Optimum aerosol particle size is very important for deep lung delivery. Optimum particle size for deep lung deposition is 1-5 mm. Aerosol system should have to produce optimum size particles because they are too small, they will be exhaled. If the particles are too large, they affects on the oropharynx and larynx.

Less drug mass per puff

To get adequate effect with the pulmonary drug delivery practical delivery of many drug which require milligram doses but With most existing systems, the total amount of drug per puff delivered to the lower respiratory tract is too low less than 1000 mcg.

Poor formulation stability for drug

Most traditional small molecule asthma drugs are crystalline and, in the case of corticosteroids, relatively moisture resistant in the dry