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Research Article

Comparitive In-Vitro Evaluation Of Commercially Available Generic And Branded Propranolol Hydrochloride Immediate Release Tablets

M Gayathri Devi*, M Savithri, P Uma Devi, B Nagamani, PV Madhavi Latha, Y Tarakeswar Rao, V Mounika

Vinayanadha Institute of Pharmaceutical Sciences-Visakhapatnam

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Abstract

The present work describes about the comparative *in-vitro* study of commercially available generic and branded Propranolol Hydrochloride tablets. The generic and branded Propranolol hydrochloride tablets were taken and evaluated for different parameters like weight variation, hardness, friability, disintegration, percentage purity and dissolution studies. According to USFDA, generic drugs are identical and are within the acceptable bioequivalent range to the brand-name counterpart with respect to pharmacokinetic and pharmacodynamic properties. Generics are almost identical to that of branded drugs which are 80% cheaper on average. The generic drugs of various pharmaceutical companies are sold at low cost and are checked for their therapeutic efficacy by comparing with that of branded ones. The *in-vitro* results of both generic and branded were compared and found to be within the limits and claimed that generics are almost equal to branded drugs in all aspects except cost.

Key words: Branded formulations, Generic drugs, Percentage purity, USFDA, Dissolution studies.

INTRODUCTION

In present scenario most of the people are suffering with high blood pressure due to different food habits, stress and lack of exercise, so we focused our work on this aspect and selected Propranolol Hydrochloride as the drug of choice. It is the drug widely used for the treatment of Hypertension. Branded vs Generics: The difference between a brand-name product and a generic one is designed to be transparent. Once the patent life expires on a brand-name drug product, it is eligible to be made into a "generic drug." To do this, the generic drug manufacturer must ensure that the drug they are producing contains the same active ingredient(s) as the brand-name product, in the same dosage form, at the same dose or concentration, and for the same route of administration .The drug may differ in color, shape, taste, inactive ingredients, preservatives and packaging, however. Because of these differences, the generic drug manufacturers are required to submit additional paperwork to the FDA to prove that their product is manufactured in accordance with good manufacturing practices (GMPs), and is as pure and stable as the brand-name product. Additionally, the generic needs to meet pharmacokinetic parameters in the body, which means it must dissolve (in a beaker) at the same rate and to the same extent as the original. This process ensures that the two products are bioequivalent and behave the same inside the body [1-4].

MATERIALS AND METHODS

Propranolol Hydrochloride [5-8]:

Propranolol Hydrochloride is a non-cardio selective sympatholytic beta blocker that crosses the blood brain barrier. It is useful for treating atrial fibrillation and in patients with angina. It is used to decrease the risk of heart death and to manage certain types of tremors.

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PRELIMINARY PHYTOCHEMICAL INVESTIGATION AND BIOLOGICAL EVALUATION OF THE LEAVES OF *NEOLAMARCKIA CADAMBA*

Dr. Venu Sampath Kumar Golla[1], D. Aruna Kumari[2], K. Fathima Nilesh*[2,3] and Ch. S. Phani Kumar[4]

[1]A.U. College of Pharmaceutical Sciences, Andhra University, Visakhapatnam, Andhra Pradesh, India.

[2,3]Viswanadha Institute of Pharmaceutical Sciences, Mindivanipalem, Visakhapatnam, Andhra Pradesh, India

[4]Vikas Institute of Pharmaceutical Sciences, Nidigatla, Rajamahendhravaram, Andhra Pradesh, India.

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***Corresponding Author**
K. Fathima Nilesh
Viswanadha Institute of Pharmaceutical Sciences, Mindivanipalem, Visakhapatnam, Andhra Pradesh, India.

ABSTRACT

Natural compounds can be a lead compounds, allowing the design and rational planning of new drugs, biomimetic synthesis development and the discovery of new therapeutic properties not yet attributed to known compounds (S.M.K. Rates, 2011). The present study has made an attempt to evaluate the microscopic characters of *Neolamarckia cadamba* by determining leaf constants, trichomes and stomata, Phytochemical screening by using Qualitative chemical tests & column chromatography. The study includes biological evaluation of antibacterial and antifungal activity. Phytochemical screening of the crude methanolic extract of the leaves of *Neolamarckia cadamba* showed the presence of Alkaloids, Tannins, Saponins, Steroids and Glycosides. In Biological Evaluation, the antibacterial and antifungal activities of extracts (50, 75, 100 µg/ml) of *Neolamarckia cadamba* were tested against Gram-positive—*Staphylococcus aureus*, Gram-negative—*Escherichia coli*. Zone of inhibition of extracts were compared with that of standards like Amikacin for antibacterial activity and fluconazole for antifungal activity Post hoc analysis showed the remarkable inhibition of the bacterial growth was shown against the anti-bacterial organisms and a minute inhibition for anti-fungal organism.

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF SILDENAFIL IN BULK AND TABLET DOSAGE FORM BY RP-HPLC

M. Gayathri Devi*, R. Parimala, P. V. Madhavi Latha, B. Nagamani, P. Uma Devi

Viswanadha Institute of Pharmaceutical Sciences Visakhapatnam.

*Corresponding Author: M. Gayathri Devi
Viswanadha Institute of Pharmaceutical Sciences Visakhapatnam.

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ABSTRACT

A new RP-HPLC method for the quantitative determination of sildenafil was developed and validated as per ICH guidelines. The drugs were injected into Inertsil C18 column (250×4.6, 5 µm), maintained at ambient temperature and effluent monitored at 224 nm. The mobile phase consisted of Acetonitrile: Water (70:30 V/V). The flow rate was maintained at 1.0 ml/min. The calibration curve for Sildenafil was linear from 5-37.5µg/ml (r^2 for sildenafil = 0.99). The proposed method was adequate, sensitive, reproducible, accurate and precise for the determination of Sildenafil in bulk and pharmaceutical dosage forms.

KEYWORDS: Sildenafil, Linearity, Validation.

INTRODUCTION

Sildenafil is a phosphodiesterase type-5 inhibitor, vasodilator agent and urological agent that is used in the treatment of erectile dysfunction and primary pulmonary hypertension.It functions as a selective and competitive inhibitor of type 5 phosphodiesterases on smooth muscle cells in the penis and pulmonary vasculature, and is used extensively for erectile dysfunction and less commonly for pulmonary hypertension. It has been associated with rare instances of clinically apparent liver injury. It is chemically 5-[2-ethoxy-5-(4-methylpiperazin-1-yl) sulfonylphenyl]-1-methyl-3-propyl-4h-pyrazolo[4,3-d]pyrimidin-7-one.It occurs as solid crystals and is water soluble. It has a chemical formula of $C_{22}H_{30}N_6O_4S$.[1-6] Various analytical methods have been reported for the estimation of Sildenafil, including spectrophotometric methods and HPLC. HPLC is the most widely used technique for the estimation of Sildenafil in human plasma, saliva, cerebrospinal fluid, and human blood cells, as well as for studying the drug metabolites in the urine. The suggested HPTLC and HPLC methods for assay of Sildenafil are quite expensive and need complex and sophisticated instrumentation. The present research work describes a HPLC and UV spectrophotometric method for estimation of Sildenafil in API.[7-13] The present method aims at developing a simple, accurate and precise RP-HPLC method for the estimation of Sildenafil in bulk and Pharmaceutical dosage forms.

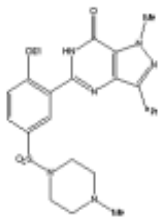

Fig. 1: Chemical structure of Sildenafil.

MATERIALS AND METHODS

Chemicals and solvents

The reference sample of Sildenafil was obtained as a gift sample from Shreeji Pharma International, India. HPLC grade water (prepared by using 0.45 Millipore Milli –Q) was procured from Standard Reagents, Hyderabad. HPLC grade Acetonitrile was bought from Merck, Mumbai.

Instrumentation

A YL- instrument 9300 module equipped with a UV spectrophotometer for finding out the λmax values of the drugs was used throughout this study. An Inertsil ODS C-18(250×4.6, 5 mm) column was employed for the method development. The chromatographic system was monitored by Autochrome software. Analytes were monitored by UV detection at 224 nm using an isocratic

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE ESTIMATION OF DICLOFENAC SODIUM IN BULK AND TABLET DOSAGE FORM BY RP-HPLC

M. Gayathri Devi*, P. V. Madhavi Latha, N. Pravallika Sony, G. Rohini, I. Indu, B. Vamsi Krishna, A. C. S. Rupika and P. Uma Devi

Vinayaadha Institute of Pharmaceutical Sciences Visakhapatnam.

***Corresponding Author: M. Gayathri Devi**
Vinayaadha Institute of Pharmaceutical Sciences Visakhapatnam.

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ABSTRACT
A new RP-HPLC method for the quantitative determination of Diclofenac sodium was developed and validated as per ICH guidelines. The drugs were injected into Inertsil C18 column (250×4.6, 5 µm), maintained at ambient temperature and effluent monitored at 283 nm. The mobile phase consisted of Methanol: Acetonitrile: Water (60:20:20 V/V). The flow rate was maintained at 1.0 ml/min. The calibration curve for Diclofenac sodium was linear from 2-10 µg/ml (r^2 for Diclofenac sodium = 0.99). The proposed method was adequate, sensitive, reproducible, accurate and precise for the determination of Diclofenac sodium in bulk and pharmaceutical dosage forms.

KEYWORDS: Diclofenac sodium, Linearity, Accuracy, Validation.

INTRODUCTION

Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID) taken or applied to reduce inflammation and as an analgesic reducing pain in certain conditions. In the United Kingdom, United States, India, and Brazil diclofenac may be supplied as either the sodium or potassium salt; in China, it is most often supplied as the sodium salt, while in some other countries it is only available as the potassium salt. It has a molecular formula of $C_{14}H_{10}Cl_2NNaO_2$. The IUPAC name is sodium 2-[2-(2,6-dichloroanilino)phenyl]acetate with a molar mass of 318.129 g/mol. The primary mechanism responsible for its anti-inflammatory, antipyretic and analgesic action is thought to be inhibition of prostaglandin synthesis by inhibition of the transiently expressed prostaglandin-endoperoxide synthase-2 (PGES-2) also known as Cyclooxygenase-2 (COX-2). It also appears to exhibit bacteriostatic activity by inhibiting bacterial DNA synthesis. Diclofenac has a low to moderate preference to block the constitutively expressed COX-1 isoenzyme (approximately 10-fold) and is said to have, therefore, a somewhat lower incidence of gastrointestinal complaints than noted with aspirin which irreversibly inhibits COX-1. Besides the COX-inhibition, a number of other molecular targets of diclofenac possibly contributing to its pain-relieving actions like Blockage of voltage-dependent sodium channels, Blockage of acid-sensing ion channels that have recently been identified.[1-4] Various analytical methods have been reported for the estimation of Diclofenac sodium, including spectrophotometric methods and HPLC. The suggested HPTLC and HPLC methods for assay of Diclofenac sodium are quite expensive and need complex and sophisticated instrumentation. HPLC is the most widely used technique for the estimation of Diclofenac sodium in human plasma, saliva, cerebrospinal fluid, and human blood cells, as well as for studying the drug metabolites in the urine. The present research work describes a HPLC and UV spectrophotometric method for estimation of Diclofenac sodium, in API.[5-10] The present method aims at developing a simple, accurate and precise RP-HPLC method for its estimation in bulk and Pharmaceutical dosage forms.

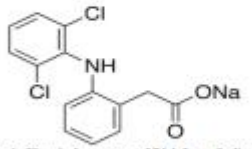

Fig. 1: Chemical structure of Diclofenac Sodium.

Evaluation of anti-inflammatory activity of Hydroalcoholic extract of *Ananas cosmosus* fruit peel by HRBC membrane stabilisation.

Mr. Uma Sankar Gorla*, Dr. M. Savithri, Dr. G.S.N. Koteswara Rao, Ms. Y. Niharika, Ms. P. Devi Sree Sathya, Ms. V. Harika

Viswanadha Institute of Pharmaceutical Sciences, Visakhapatnam, Andhra Pradesh, India.

*Corresponding Author E-mail: **umasankargorla@gmail.com**

ABSTRACT:

Objectives: To evaluate invitro anti-inflammatory activity of hydroalcoholic extract of *Ananas cosmosus* fruit peel by HRBC membrane stabilisation.

Methods: Hydroalcoholic extract was prepared by soxhlet extraction and thereafter subjected for membrane stabilisation assay to evaluate anti-inflammatory property. 10% human red blood cell suspension was subjected to hyptonicity induced hemolysis and inhibition of membrane damage by the extract was compared to the standard drug diclofenac sodium.

Results: Hypotonicity induced HRBC membrane lysis was inhibited by hydroalcoholic extract of *Ananas cosmosus* fruit peel in a concentration dependent manner. Hydroalcoholic extract showed 72.86% protection of HRBC membrane at 250µg/ml and showed significant membrane stabilisation compared with standard drug diclofenac sodium at the same concentrations.

Conclusion: *Ananas cosmosus* fruit peel extract showed appreciable HRBC membrane stabilisation and may have potential anti-inflammatory property. Further analysis is to be carried out to isolate active chemical constituent responsible for anti-inflammatory activity and its mechanism involved.

KEYWORDS: *Ananas cosmosus*, HRBC membrane, anti-inflammatory, hemolysis, soxhlet.

INTRODUCTION:

Inflammation is a pervasive form of body's defense,[1] a complex physiological response of vascular tissues to harmful stimuli or injury associated with pain and increases vascular permeability, protein denaturation, and membrane alteration[2] and initiates the healing process.[3, 4]

Inflammatory mediators such as histamine, serotonin, slow reacting substances of anaphylaxis (SRS-A), prostaglandins etc[5] induces characteristic inflammatory changes including vasodilatation, increases capillary permeability, destruction and healing of tissues.[6, 7]

Anti-inflammatory drugs stabilize lysosomal membrane[8] and inhibit the release of inflammatory mediators and there by inhibits the process of inflammation.[9] Human red blood cell membrane resemblances lysosomal membrane,[10] hence the erythrocyte membrane stabilization may correlate with

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF PARACETAMOL AND ETORICOXIB IN PHARMACEUTICAL DOSAGE FORMS BY RP-HPLC

G. Lakshmi Priyanka*, P.V. Madhavi Latha

Department of Pharmacy, Viswanadha Institute of Pharmaceutical Sciences, JNTUK, Visakhapatnam - 530009, A.P, INDIA

*Corresponding author E-mail:-priyankavarma9697@gmail.com

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Key Words

Etoricoxib, Paracetamol, RP-HPLC

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ABSTRACT

A simple, Accurate, precise technique was developed for the simultaneous estimation of the Paracetamol and Etoricoxib in Tablet dosage form. Chromatogram was run through Inertsil-ODS C_{18} (250 x 4.6mm, 5µ) column. Mobile phase containing Methanol: Acetonitrile: Phosphate Buffer taken in the proportions 40:25:35v/v was pumped through column at flow rate of 1.0ml/min. Temperature was kept ambient. Optimised wavelength selected was 241nm. Retention time of Paracetamol and Etoricoxib were observed to be 2.5min and 4.3min. %RSD of the Paracetamol and Etoricoxib were and observed to be 0.362 and 0.129 respectively. %Recovery was obtained as 100.12% for Paracetamol and 99.73% for Etoricoxib respectively. LOD, LOQ values obtained from regression equations of Paracetamol and Etoricoxib were 0.33, 1.02 and 1.44, 3.27 respectively. Regression equation of Paracetamol is y = 51886x + 1315, and y = 55508x + 940.6 of Etoricoxib . Retention times were decreased and that run time was decreased, so the technique developed was simple and conservative that can be embraced in regular quality control test in industries.

INTRODUCTION

Etoricoxib is a non-steroidal anti-inflammatory drug (NSAID) used to treat Rheumatoid Arthritis , Gout and Osteoarthritis and Paracetamol is also NSAID used to relieve mild to moderate aches and pains associated with headache, migraine, cold n flu as well as anti-pyretic drug (fever reducer). The combination of Etoricoxib and Paracetamol work by blocking the release of certain chemical messengers in the brain that cause pain and fever and also used in the treatment of headaches , arthritis, backache and the symptoms of cold. [1-2]

MATERIALS and METHODS

Preparation of buffer: reparation of phosphate (KH_2PO_4 0.1M) buffer: Approximately weighed 3.8954g of di-sodium hydrogen phosphate and 3.4023g of potassium dihydrogen phosphate in to a beaker containing 1000 mL of distilled water and dissolved completely. Then pH was adjusted to 3.5 using orthophosphoric acid and then filtered through 0.45µm membrane filter.

Preparation of diluents: Depending on the nature of solubility of the selected drugs, Methanol, Acetonitrile and phosphate buffer in the ratio of 40:25:35 V/V was prepared after degassing and filtering the solution using 0.45 µm membrane filter. [3]

Stock solution:

Preparation of standard stock solution: The solution was prepared by dissolving 50mg of accurately weighed Paracetamol and 10mg Etoricoxib in Mobile phase, in two 100.0mL

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FORMULATION AND CHARACTERIZATION OF SUSTAINED RELEASE MATRIX TABLETS OF AN ANTI DIABETIC DRUG

Medisetty Gayatri Devi[1], Lakshmi Usha Ayalasomayajula[2*], Radha Rani Earle[3] and Dr. P. Uma Devi[4]

[1,4]Department of Pharmaceutics, Viswandha Institute of Pharmaceutical Sciences, Sontyam, Visakhapatnam.
[2,3]Department of Pharmaceutics, Maharajah's College of Pharmacy, Vizianagaram, A.P., India.

***Corresponding Author: Lakshmi Usha Ayalasomayajula**
Department of Pharmaceutics, Maharajah's College of Pharmacy, Vizianagaram, A.P., India.

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ABSTRACT

Diabetes Mellitus is a result of reduced insulin secretion from pancreas, and insulin action in the body or both. They are several natural as well as synthetic drugs like insulin, biguanides, sulphonylureas, thiazolidinediones, meglitinides etc. for the treatment of diabetes. Vildagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor that enhances incretin hormone activity, sustains insulin levels, and reduces glycemia in Type II diabetes mellitus. Therefore it is an anti-diadetic drug used in the treatment of Type II diabetes mellitus and has been selected to prepare sustained release dosage forms. In present investigation an attempt has been made to design and develop Vildagliptin sustained release matrix tablets using Xanthan gum, Guar gum and their combination as release retarding polymers by direct compression method. Xanthan gum, Guar gum and their combination are used in various concentrations in the preparation of tablets. Hence sustained-release tablets were evaluated for various physical parameters namely– Hardness, Weight variation, Friability, Drug Content uniformity test etc. Drug release studies were also carried out in pH 6.8 phosphate buffer. By evaluating all the physical parameters and drug release studies F11 containing a mixture of Xanthan gum and Guar gum as release retarding polymer was optimized as the best formulation.

KEYWORDS: Diabetes Mellitus, Sustained release matrix tablets, Direct compression method, Xanthan gum, Guar gum.

INTRODUCTION

Drug delivery is the method or process of administering a pharmaceutical compound to achieve a therapeutic effect in humans or animals. Among the various drug delivery routes, the oral drug delivery has gained more attention due to its unique advantages like ease of administration, feasibility for solid formulations, patient compliance and an intensified immune response as in the case of vaccines. In addition, to these a large surface area of GIT (>300 m^2) lined with a viscous mucosal layer paves the way for drug attachment and subsequent absorption. Moreover in the GIT, drug molecules trapped within mucus are protected against the shear stresses caused by flowing gastric juices.[1]

A number of terms have been used to describe the oral dosage forms that represent modified release properties; which include delayed release, repeated action, prolonged release, sustained release, extended release and controlled release. Each drug delivery system is focused at eliminating the cyclical changes in plasma drug concentration seen after administration of conventional delivery systems. Modified release dosage forms are designed to provide quick achievement of a drug plasma level that remains constant at a value within the therapeutic range of a drug for a significant period of time or achievement of a plasma concentration of a drug that delivers at a slow rate (i.e. sustained release) that stays within the therapeutic range for a longer period of time.[2] Sustained release, sustained action, prolong action, controlled release, extended action, depot are terms used to identify drug delivery systems that are designed to achieve prolong therapeutic effect by continuously releasing medication over an extended period of time after administration of single dose. Most of sustained release dosage form follows the mechanism of diffusion, dissolution or combination of both, to produce slow release of drug at predetermined rate. Hypothetically, a sustained release dosage form should release the drug by a zero-order mechanism which maintains drug plasma level time similar to intravenous infusion.[3]

Diabetes Mellitus is a chronic metabolic disorder due to impaired metabolism of carbohydrates, fats and proteins, characterized by hyperglycemia resulting from decreased utilization of carbohydrates and excessive glycogenolysis and gluconeogenesis from aminoacids and fatty acids. Diabetes may be identified by characteristic symptoms such as thirst, polyurea, blurring of vision and weight

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Research Article

Solubility and dissolution rate enhancement of nevirapine solid dispersions using skimmed milk powder

Medisetty Gayatri Devi[1], Earle Radha Rani[2], A. Lakshmi Usha[2], P. Uma Devi[1]

1. Department of Pharmaceutical Technology, Viswanatha Institute of Pharmaceutical Sciences, Visakhapatnam, AP, India

2. Department of Pharmaceutical Technology, Maharajah's College of Pharmacy, Vizianagaram, A.P., India.

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ABSTRACT

This research was aimed in enhancing solubility and rate of dissolution of nevirapine by employing solid dispersions. Saturation solubility studies and pH solubility profile were determined for nevirapine. Nevirapine solid dispersions with skimmed milk powder were prepared using techniques like solvent evaporation, physical mixing and microwave method. The obtained solid dispersions were tested for *in vitro* dissolution data and were characterized by FTIR analysis. Twelve different formulations of nevirapine with skimmed milk were prepared using solvent evaporation, physical mixing and microwave techniques. FTIR studies indicated absence of interactions between excipients and drug used. Nevirapine exhibited 16.2 % dissolution in 45 minutes, while dissolution rate of solid dispersion of nevirapine: skimmed milk powder (1:7) prepared by solvent evaporation showed 87.66 % drug release. Dissolution rate of nevirapine could be enhanced by preparation of solid dispersions with skimmed milk.

*** Corresponding author:**
M. Gayatri Devi, Assistant Professor, Viswanatha Institute of Pharmaceutical Sciences, Visakhapatnam, AP, India. Email ID: gayatri.minnu@gmail.com

Research Article

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Role of Clinical Pharmacist in the Management of Myocardial Infaraction: A Prospective Observational Study

Behara Prathyusha, Rushi Tarra, Yerni Kumari Tippana.

Department of Pharmacy Practice, Vinivaradha Institute of Pharmaceutical Sciences, Mindhanigalem, Vizakhapatnam, 531173

ABSTRACT

The aim of the present study was to analyse myocardial infarction- Age related risk factors, complications and management Valuation of age related risk factors in MI patients, Identification of frequent type of myocardial infarction, Evaluating the effectiveness of thrombolytic therapy and primary intervention in patients with MI, Assessment of complications of MI and Studying the impact of concomitant diseases on different types of complications. A Prospective observational case series study with 130 cases of patients with myocardial infarction and this study were conducted in department of cardiology in maharaja institute of medical sciences and our work conducted for a period 6 months and we have strictly adhere the inclusion and exclution criteria. We concluded that males were more prone to develop MI than females. Incidence of MI was high in age group 51-60 yrs. Cigarette smoking was identified as a major risk factor indicating that life style plays a dominant role than concomitant disorders for early incidence of MI in present generations. Younger population were predisposed to unhealthy life style like smoking, alcohol, fatty diet and we also find out that TLT was effective in treatment of MI. Also, TLT reduced the need for PTCA, and the reason behind subjects required PTCA even after receiving TLT was advanced age. Older subjects were primarily treated with PTCA.

Key words:
Myocardial Infarction,
130 Cases, Concomitant Diseases,
Life Style Management, Six Months.

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*Corresponding Author
Name: Behara Prathyusha
Email: : prathyushavy4126@gmail.com

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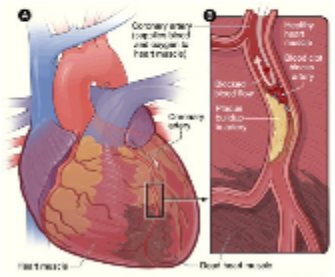
INTRODUCTION

Acute myocardial infarction with or without ST-segment elevation (STEMI or non-STEMI) is a common cardiac emergency, with the potential for substantial morbidity and mortality. The third universal definition of myocardial infarction, Myocardial infarction (MI), commonly known as a heart attack, is defined pathologically as the irreversible death of myocardial cells caused by ischemia. Clinically, MI is a syndrome that can be recognized by a set of symptoms, chest pain being the hallmark of these symptoms in most cases, supported by biochemical laboratory changes, electrocardiographic (ECG) changes, or findings on imaging modalities able to detect myocardial injury and necrosis[1].



The myocardium receives its blood supply from the two large c oronary arteries and their branches. Occlusion of one or more of these blood vessels (CORONARY OCCLUSION) is one of the major causes of myocardial infarction. The occlusion may result from formation of a clot that develops suddenly when an atheromatous plaque ruptures through the sub layers of a blood vessel, or when the narrow roughened inner lining of a sclerosed artery leads to complete thrombosis.Coronary artery disease is the most common type o f heart disease in the United States and many other countries. The risk rises rapidly with age, women tending to develop the disease 15 to 20 years later than men[2].

Incidence of myocardial infarction

Worldwide, about 15.9 million myocardial infarctions occurred in 2015[3]. The incidence of MI in India is 64.37/1000 people these results call for several comments[4]. In the ARIC study, no overall change was detected in the incidence of hospitalized myocardial infarction between 1987 and 1994[5].There were divergences in the trends by race and sex with an alarming increase in myocardial infarction among black women. In the Minnesota Heart Survey, between 1985 and 1995, the rates of hospitalization for acute myocardial infarction declined[6,7]. In both NHS and ARIC, published data do not include persons older than age 74 and is thus not accounting for a growing segment of the population. In the Worcester Heart Attack Study, analyses spanning a 20-year period until 1995 indicated qualitatively flat trends in incidence from the mid 1980s to the mid 1990s[8]. The trends between 1975-99 underscored the importance of examining age and sex-specific patterns in addition to overall rates. Indeed, larger declines in myocardial

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF RILPIVIRINE AND DOLUTEGRAVIR IN BULK AND PHARMACEUTICAL DOSAGE FORMS BY RP-HPLC

T. Sekhar Naidu*, P.V. Madhavi Latha

Department of Pharmacy, Viswanadha Institute of Pharmaceutical Sciences, (Affiliated to JNTUK), Visakhapatnam- 530009, Andhra Pradesh, INDIA

*Corresponding Author E-mail: sekhar.naidu96@gmail.com

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ABSTRACT

For the simultaneous evaluation of Dolutegravir and Rilpivirine in dosage form, a simple, precise, detailed technique has been optimized. The mobile phase comprising of water and methanol (60:40 v / v) ratio was injected into a column at a flow rate of 0.8 ml/min. Chromatogram was run through Discovery-C_{18} (4.6 x 150 mm, 5µm). Optimised wavelength selected at 260nm. Retention time of Dolutegravir and Rilpivirine were found to be 3.013 min and 2.241 min. %Recovery was obtained as 99.66% and 99.57% in that order. LOD, LOQ values obtained from regression equations of Dolutegravir and Rilpivirine were 0.48, 1.44 and 0.17, 0.52 correspondingly. Regression equation of Dolutegravir is y = 50100x + 15520, and y= 34251x + 3054 of Rilpivirine. The approach was simple and cost-effective and can be used in industry with the standard consistency check.

INTRODUCTION

Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) with high potency used in the treatment of HIV infection in adults and children. Rilpivirine blocks the virus from growing and infecting more cells. Dolutegravir is an Anti-Retroviral medication used, together with other HIV medications to treat HIV/AIDS. Rilpivirine and Dolutegravir are likely to be as a nucleoside-reverse transcriptase inhibitor (NRTI)-sparing regimen primarily used for maintenance therapy in persons with stable suppressed HIV. [1-2]

Fig- 1: Structure of Rilpivirine

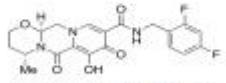

Fig-2: Structure of Dolutegravir

MATERIALS AND METHODS

Methods:

Diluent: In the ratio of 50:50v/v, diluent was selected. Methanol and Water are selected depending on the solubility of the drugs.

Stock Solution:

Preparation of Standard stock solutions: Accurately weighed 12.5mg of Dolutegravir, 6.25mg of Rilpivirine and transferred to 25ml

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF TELMISARTAN AND CHLORTHALIDONE IN BULK AND PHARMACEUTICAL DOSAGE FORMS BY RP-HPLC METHOD

S. Ashitha*, M. Ankitha, P.V. Madhavi Latha, A. Ragasudha Sri, P. Uma Devi

Department of Pharmacy, Viswanadha Institute of Pharmaceutical Sciences,

Affiliated to JNTUK, Visakhapatnam - 531173, A.P, INDIA

***Corresponding author:** ashithasundarapu@gmail.com

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Key Words

Telmisartan, Chlorthalidone, RP-HPLC, ICH.

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ABSTRACT

A simple, accurate, precise technique was developed for the simultaneous estimation of Telmisartan and Chlorthalidone in Bulk and pharmaceutical dosage form. Chromatogram was run through Phenomenex LunaC18 (150 × 4.6mm, 5µl) column. Mobile phase containing Methanol: water pH3.5 adjusted with ortho phosphoric acid taken in the proportions 80:20%v/v was pumped through column at flow rate of 1ml/min. Temperature was kept ambient. Optimized wavelength selected was 225nm. Retention time of Telmisartan and Chlorthalidone was observed to be 2.9min and 4.6min. %RSD of the Telmisartan and Chlorthalidone were observed to be 0.58 and 0.79 respectively. %Recovery was calculated for Telmisartan at 50%, 100% and 150% were 100.27%, 100.14%, 100.03%respectively and for Chlorthalidone at 50%, 100% and 150% were 101.78%, 100.43% and 100.48% respectively. LOD, LOQ values obtained from regression equation of Telmisartan and were 0.17, 0.19 and 0.48, 1.18 respectively. Regression equation of Telmisartan is y = 11487x -47198, and y = 11237x + 2102 of Chlorthalidone. Retention time were decreased and the run time decreased, so the technique developed was simple conservative that can be embraced in regular quality control test in industries.

INTRODUCTION

Telmisartan and Chlorthalidone is a combination medicine used to treat hyper tension. Telmisartan is an angiotensin ii receptor antagonist (ARB) used in the management of hypertension. Generally, antagonist ii receptors blockers (ARBs) such as telmisartan binds to angiotensin ii (AT 1) receptors with high affinity, causing inhibition of action of angiotensiniion vascular smooth muscle, ultimately leading to reduction in arterial blood pressure. Chlorthalidone is diuretic; it is indicated in the management of hypertension by removing excess water and certain electrolytes from the body. Eventually it also relaxes blood vessels and improves blood flow.[1-2]

MATERIALS AND METHODS

Preparation of diluents: Depending on the nature of solubility of the selected drugs, Acetonitrile and water in the ratio of 80: 20 v/v and pH was adjusted to 3.5 using orthophosphoric acid. The solution was prepared after degassing and filtering the solution using 0.45µm membrane filter.

Stock solution:

Preparation of standard stock solution: The solution was prepared by dissolving 45 mg of accurately weighed Telmisartan and 15mg Chlorthalidone in mobile phase, in two 100.0

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METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF SOFOSBUVIR AND VELPATASVIR IN BULK AND TABLET DOSAGE FORMS BY RP-HPLC

M. S. M. Suma*, M. Gowthami, P.V. Madhavi Latha, P. Uma Devi

Department of Pharmacy, Viswanadha Institute of Pharmaceutical Sciences, Affiliated to JNTUK, Vishakhapatnam Andhra Pradesh, INDIA

*Corresponding author E-mail: sumanasv9@gmail.com

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Key words:
RP-HPLC, Sofosbuvir, Velpatasvir

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ABSTRACT

For the simultaneous evaluation of Sofosbuvir and Velpatasvir in tablet dosage form, a simple, precise, detailed technique has been optimized. The mobile phase comprising of methanol and phosphate buffer (60:40 v / v) ratio was injected into a column at a flow rate of 1.0 ml/min. Chromatogram was run through Inertsil-C_{18}.BDS column(4.6 x 150 mm, 5µm). Temperature was maintained at 25°C.Optimised wavelength selected at 254nm. Retention time of Sofosbuvir and Velpatasvirwere found to be 3.049 min and 4.317 min. %Recovery was obtained as 99.99% and 99.76% in that order. LOD, LOQ values obtained from regression equations of Sofosbuvir and Velpatasvir were 0.03, 0.09 and 0.15, 0.47 correspondingly. Regression equation of Sofosbuvir is y = 234504x + 9799.3, and y= 31994x + 2049.3 of Velpatasvir. The approach was simple and cost-effective and can be used in industry with the standard consistency check

INTRODUCTION:

Sofosbuvir is a direct acting anti-viral medication used as a part of combination therapy to treat chronic Hepatitis-C, an infectious liver disease caused by infection with Hepatitis-C virus (HCV). Velpatasvir is also direct acting anti-viral medication used as combination therapy to treat chronic hepatitis-C. Sofosbuvir-velpatasvir is a pangenotypic NS5A-NS5B inhibitor single-pill combination regimen that has potent activity against chronic (long-lasting) hepatitis C virus (HCV).[1-2]

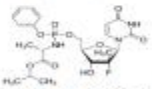

Fig- 1:Structure of Sofosbuvir

Fig-2: Structure of Velpatasvir

MATERIALS AND METHODS

Preparation of phosphate buffer: Phosphate buffer solution of 0.05M was prepared by combining 6.67 gm of potassium di-hydrogen phosphate and 8.55 gm of di potassium hydrogen phosphate in 1 L flask. To this 800ml HPLC grade water was added, sonicated thoroughly, adjusted final volume to 1 L and then filtered through 0.45 microns filter under vacuum filtration.

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METHOD DEVELOPMENT AND VALIDATION FORTHE SIMULTANEOUS ESTIMATION OF OLMESARTAN MEDOXOMIL AND METOPROLOL TARTRATEIN BULK AND SOLID DOSAGE FORM BY RP-HPLC.

Malla. Gowthami*, M. S. M. Suma, P.V. Madhavi Latha, A. Ragasudha Sri, P. Uma Devi

Department of Pharmacy, Viswanadha Institute of Pharmaceutical Sciences, Affiliated to JNTUK, Vizag- 530009, Andhra Pradesh, INDIA

***Corresponding Author E-mail:** visit2gowthu@gmail.com

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Key Words

RP-HPLC, Olmesartan Medoxomil, Metoprolol Tartrate

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ABSTRACT

A simple, Accurate, precise technique was developed for the simultaneous estimation of Olmesartam Medoxomil and Metoprolol Tartrate in bulk and solid dosage form. Chromatogram was run through Symmetry Xterra- C_{18}, BDS column (150 x 4.6mm, 5µ) column. Mobile phase containing Phosphate Buffer (pH-2.8)and Acetonitrile taken in the proportions 35:65 v/v was pumped through column at flow rate of 0.5 ml/min. Temperature was maintained Ambient. Optimised wavelength selected was 284nm. Retention time of Olmesartam Medoxomil and Metoprolol Tartratewere observed to be 3.624min and 5.178min. %RSD of the Olmesartam Medoxomil and Metoprolol Tartratewere and observed to be 0.39 and 0.86 respectively. %Recovery was obtained as99.69% for Olmesartam Medoxomil and99.45% for Metoprolol Tartrate respectively. LOD, LOQ values obtained from regression equations of Olmesartam Medoxomil and Metoprolol Tartrate were 0.015, 0.13 and 0.046, 0.40 respectively. Regression equation of Olmesartam Medoxomilis y = 251942x + 110535, and y = 9709x + 11274 of Metoprolol Tartrate. Retention times were decreased and that run time was decreased, so the technique developed was simple and conservative that can be embraced in regular quality control test in industries.

INTRODUCTION

Olmesartan medoxomil is a potent, orally active, selective angiotensin II receptor (type AT_1) antagonist. Used to treat high blood pressure (hypertension). It is used in lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems. *Metoprololtartrate* is a cardio-selective beta-adrenergic blocking agent. It is used to treat and prevent heart attacks, lower high blood pressure and reduce chest pain (angina). Olmesartan Medoxomil + Metoprolol Succinate is used in the treatment of Hypertension (high blood pressure). [1-2]

MATERIALS and METHODS:

Preparation of phosphate buffer: Accurately weighed 1.36 gm of potassium dihydrogen ortho phosphate was taken into a 1000ml of volumetric flask, add about 900ml of distilled water. The flask was shaken until the particles get dissolved, made up to the mark with water and then ad 1ml of triethylamine. The pH was

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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF DIACEREIN AND GLUCOSAMINE IN BULK AND TABLET DOSAGE FORMS BY RP-HPLC

Karri Sravya *, P.V. Madhavi Latha

Department of Pharmacy, Viswanadha Institute of Pharmaceutical Sciences, Affiliated to JNTUK, Visakhapatnam - 530009, A.P, INDIA

*Corresponding author E-mail: sravyakish@gmail.com

ARTICLE INFO

Key Words

Diacerein , Glucosamine , RP-HPLC

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ABSTRACT

A simple, Accurate, precise technique was developed for the simultaneous estimation of Diacerein and Glucosamine in Tablet dosage form. Chromatogram was run through Ascentis Express- C_{18}, BDS column (150 x 4.6mm, 5µ) column. Mobile phase containing Acetonitrile: Potassium Di-hydrogen phosphate Buffer taken in the proportions 50:50v/v was pumped through column at flow rate of 1.0ml/min. Temperature was kept ambient. Optimised wavelength selected was 210nm. Retention time of Diacerein and Glucosamine were observed to be 2.586min and 3.182min. %RSD of the Diacerein and Glucosamine were and observed to be 0.90 and 0.90 respectively. %Recovery was obtained as 99.89% for Diacerein and 100.35% for Glucosamine respectively. LOD, LOQ values obtained from regression equations of Diacerein and Glucosamine were 0.01, 0.06 and 0.04, 0.19 respectively. Regression equation of Diacerein is y = 28958x + 476.75, and y = 21702x + 1528 of Glucosamine . Retention times were decreased and that run time was decreased, so the technique developed was simple and conservative that can be embraced in regular quality control test in industries.

INTRODUCTION

Diacerein is a symptomatic slow acting drug in Osteoarthritis (SYSADOA) with anti-inflammatory, anti-catabolic and peo-anabolic properties on cartilage and synovial membrane. Glucosamine plays a vital role in building cartilage and also used as a supplement to treat arthritis and osteoarthritis. The combination of Diacerein and Glucosamine are commonly used in the treatment of Symptomatic mild to moderate knee Osteoarthritis to relieve joint pain and delay joint destruction and cartilage loss. [1-3]

Fig-1: structure of Diacerein

Fig-2: structure of Glucosamine

MATERIALS and METHODS

Preparation of buffer:

Preparation of phosphate buffer: Accurately weighed 1.36g of potassium di-hydrogen ortho phosphate was taken into a 1000 mL of volumetric flask, and add about 900ml of distilled water. The flask was shaken until the particles get dissolved, made up to the mark with water and then add 1ml of triethylamine.

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

Archana Barla*, Poluri Venkata Madhavi Latha and Kiran Kumar Buralla

Department of Pharmacy, Viswanadha Institute of Pharmaceutical Sciences, Affiliated to JNTUK, Visakhapatnam, A.P, India

*Corresponding author E-mail: archana2721995@gmail.com

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Key Words

Nilotinib, Tyrosine kinase inhibitor, PDA, Validation, RP-HPLC

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ABSTRACT

This paper describes the development of a simple, accurate, sensitive, precise and rapid method for analysis and quantification of Nilotinib by reverse phase high performance liquid chromatography (RP-HPLC) was developed and validated. The main objective was to identify the robust chromatographic conditions where an adequate separation of the components with quality peaks, within acceptable run time can be achieved. Nilotinib in bulk and formulations were analyzed and quantification. Nilotinib in bulk and Pharmaceutical dosage form were analyzed on Phenomenex enable C_{18} column (15x4.6mm, 5µm particle size) as stationary phase. Mobile phase was composed of acetonitrile and phosphate buffer (pH 5) in the ratio of 60:40 %v/v at a flow rate of 1ml/min. The elution was analyzed using PDA detector at a detection wavelength of 260nm. The proposed method was validated by International Council for Harmonisation (ICH) guidelines. In this study, the chromatographic peaks of Nilotinib showed good resolution with retention time of 3.257min. Nilotinib showed an excellent linearity with 0.998 of correlation coefficient. The LOD was about 10.43 ng/ml and LOQ were about 31.63 ng/ml. Other validation parameters including precision, specificity, accuracy and robustness demonstrated good reliability in the quantification of Nilotinib. Thus the newly developed and validated method can be conveniently used for the quantification of Nilotinib in bulk and Pharmaceutical dosage form. Retention times were decreased and that run time was also decreased so the method developed was simple and economical that can be adopted in regular quality control test in industries.

INTRODUCTION

Nilotinib is a second generation tyrosine kinase inhibitor (TKI) and the chemical name is 4-methyl-N-[3-(4-methyl-1H-imidazol-1-yl)-5-(trifluoromethyl)phenyl]-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino] benzamide, mono hydro chloride (Fig. 1), monohydrate is a white to slightly yellowish to slightly greenish yellow powder with molecular formula $C_{28}H_{22}F_3N_7O.HCl.H_2O$ and molecular weight 584. [1-12] Rational design of novel inhibitors exhibiting effectiveness against imatinib-resistant mutants of BCR-ABL protein was carried out by researchers based upon the crystal structure of the imatinib-ABL complex and Nilotinib is a novel, selective BCR-ABL inhibitor so designed to fit into the ATP-binding site of the BCR-ABL protein with higher affinity than imatinib. [1] Literature survey revealed that Nilotinib was determined in pharmaceutical dosage forms by

ORIGINAL RESEARCH PAPER

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METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF GRAZOPREVIR AND ELBASVIR IN BULK AND PHARMACEUTICAL DOSAGE FORM BY RP-HPLC

Pharmaceutical Science

Kudithi Gayathri* *Corresponding Author

Gowthami Varri

Dr. P.V. Madhavi Latha

Dr. P. Uma Devi

ABSTRACT

A simple, Accurate and precise method was developed for the simultaneous estimation of Grazoprevir and Elbasvir Tablets. Chromatogram was run through Std Discovery C8 250 x 4.6 mm, 5m. Mobile phase containing Buffer 0.1% OPA: Acetonitrile taken in the ratio 45:55 was pumped through column at a flow rate of 1 ml/min. Buffer used in this method was 0.1% OPA buffer. Temperature was maintained at 30°C. Optimized wavelength selected was 260 nm. Retention time of Elbasvir and Grazoprevir and were found to be 2.503 min and 3.004. %RSD of the Elbasvir and Grazoprevir were and found to be 0.3 and 0.4 respectively. %Recovery was obtained as 98.17% and 99.83% for Grazoprevir and Elbasvir respectively. Obtained LOD, LOQ values from regression equations of Grazoprevir and Elbasvir were 0.24, 0.73 and 0.06, 0.19 respectively. Regression equation of Grazoprevir is y = 24933 x + 37206 and that of Elbasvir is y = 21941x +756.6. Results show that the retention and run time were decreased, so its evident that the method developed was simple and economical that can be adopted in regular Quality control test in Industries.

KEYWORDS

AIM

The main aim of the present study is to develop an accurate, precise, sensitive, selective, reproducible and rapid analytical technique for simultaneous estimation of Grazoprevir, Elbasvir tablets in bulk.

Objective and Plan:

objectives of the present work includes

- To develop a new stability indicating HPLC method for simultaneous estimation of Grazoprevir and Elbasvir and to develop the validated method according to ICH guidelines.
- To apply the validated method for the simultaneous estimation of Grazoprevir and Elbasvir in pharmaceutical formulation

3. MATERIALS AND METHODS

Materials:

Grazoprevir and Elbasvir, Combination of Grazoprevir and Elbasvir tablet dosage forms, distilled water, Acetonitrile, phosphate buffer, ammonium acetate buffer, glacial acitic acid, methanol, potassium dihydrogen phosphate buffer, tetra hydrofuran, tri ethyl amine, ortho-phosphoric acid etc.

Instrument:

HPLC instrument used was of WATERS HPLC 2965 SYSTEM with Auto Injector and PDA Detector. Software used is Empower 2. UV-VIS spectrophotometer PG Instruments T60 with special bandwidth of 2nm and 10mm and matched quartz was be used for measuring absorbance for Grazoprevir and Elbasvir solutions.

METHODS:

Preparation of buffer:

Buffer: (0.1% OPA)

Accurately 1ml of OPA in a 1000ml of Volumetric flask add about 900ml of milli-Q water added and degas to sonicate and finally make up the volume with water.

Standard Preparation:

Accurately Weighed and transferred 10mg of Grazoprevir and 5mg of Elbasvir working Standards into a 10ml clean dry volumetric flask, add 3/4th volume of diluent, sonicated for 5 minutes and make up to the final volume with diluents. 1ml from the above stock solution was taken into a 10ml volumetric flask and made up to 10ml.

Sample Preparation:

1 tablet was weighed, powdered and then was transferred into a 100ml. volumetric flask, 50ml. of diluent added and sonicated for 25 min, further the volume made up with diluent and filtered. From the filtered solution 1 ml was pipetted out into a 10 ml volumetric flask and made upto 10ml with diluent.

Linearity:

Linearity solutions are prepared such that 0.25, 0.5, 0.75, 1, 1.25, 1.5ml from the Stock solutions of Grazoprevir and Elbasvir are taken in to 6 different volumetric flasks and diluted to 10ml with diluents to get 25ppm, 50ppm, 75ppm, 100ppm, 125ppm, 150ppm of Grazoprevir, and 12.5ppm, 25ppm, 37.5ppm, 50ppm, 62.5ppm, 75ppm of Elbasvir.

Preparation of buffer:

%OPA Buffer:

1ml of ortho phosphoric acid was diluted to 1000ml with HPLC grade water.

Validation:

System suitability parameters:

The system suitability parameters were determined by preparing standard solutions of Grazoprevir (100ppm) and Elbasvir (50ppm) and the solutions were injected six times and the parameters like peak tailing, resolution and USP plate count were determined. The % RSD for the area of six standard injections results should not be more than 2%.

Specificity:

Checking of the interference in the optimized method. We should not find interfering peaks in blank and placebo at retention times of these drugs in this method. So this method was said to be specific.

Precision:

Preparation of Standard stock solutions:

Accurately weighed 10mg of Grazoprevir, 5mg of Elbasvir and transferred to 10ml volumetric flasks and 3/4 th of diluents was added to these flask and sonicated for 10 minutes. Flask were made up with diluents and labeled as Standard stock solution. (1000µg/ml of Grazoprevir and 500µg/ml Elbasvir)

Preparation of Standard working solutions (100% solution):

1ml from each stock solution was pipetted out and taken into a 10ml volumetric flask and made up with diluent. (100µg/ml of Grazoprevir and 50µg/ml of Elbasvir)

Linearity:

25% Standard solution:

0.25ml each from two standard stock solutions was pipetted out and made up to 10ml. (25µg/ml of Grazoprevir and 12.5µg/ml of Elbasvir)

50% Standard solution:

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A review article on fast dissolving tablets

Dr. R. Santosh Kumar
GITAM Institute of Pharmacy, GITAM University, Rushikonda, Visakhapatnam, Andhra Pradesh, India

M. Gayatri Devi
Viswanatha institute of pharmaceutical sciences, Anandapuram, Visakhapatnam, Andhra Pradesh, India

***Abstract*---For the majority of patients, oral administration is the preferred method of drug delivery. Tablets and capsules are the most often used oral solid dose forms all over the world. Around 80% of patients have had trouble swallowing tablets and capsules, according to reports. When spit comes into contact with the dose frames, they swiftly degrade, releasing the medication, reducing the amount of water required throughout the organization. These distinguishing characteristics appeal to both paediatric and geriatric patients. Gulping difficulties with standard pills and containers are frequent in people of all ages, but especially in the elderly and dysphagia patients. [1] Furthermore, robust oral conveyance frameworks do not necessitate sterilization. The rapid dissolving drug delivery system has played an important role in adapting and meeting the needs of patients. The oral course organization is the most important method that has been credited with having a fundamental impact. The conventional tablet is widely recognised as the most popular pharmaceutical measurement shape because of its ease of transportation and low assembly cost. These structures break down fast in the mouth, increasing bioavailability. Mouth dissolving doses are a type of quick-dissolving measuring construction.**

***Keywords*---oral delivery, bio availability, excipients, dissolution test.**

Introduction

Drug distribution by oral route is chosen by the vast majority of patients. Oral solid dosage forms such as tablets and capsules are widely utilized around the world. According to statistics, almost 80% of patients have difficulty swallowing tablets and capsules. As soon as the dosing frames come into touch with spit, they begin to disintegrate, releasing the medication and lowering the overall water consumption. These unique features appeal to a wide range of patients, including

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I -V Simulation of Amperometric Biosensor in Detection of Cancer through Cyclic Voltammetry Technique

Publisher: IEEE Cite This PDF

Kalyan Babu Killana ; Rama Devi Killana All Authors

Abstract:

This electronic A biosensor, which is electro chemical in nature comprises amperometric, potentiometric and conductometric types, and is very versatile in detection of different pathogens. They are also highly useful in detection of different cancers at a early stage. A biosensor is one which has a ligand and a transducer. Ligand refers to a biological element and transducer is th one which converts one form of energy to another. Amperometric biosensors yield current in micro amperes as output. Basing upon the range of current, the state of art can be defined. In this paper the cancer is detected at an early stage using an amperometric biosensor. Cancer is not a pathogen or a microbial cell, but it is unregulated, uncontrolled growth of living cells due to genetic imbalance. The early detection results in early health recovery. The amperometric biosensor can be fabricated with a composition of ferro ferry and glucose oxidase. Ferro ferry which is a start-up potential for amperometric biosensor for detection of pathogens. Electro chemical polymerization of aniline (PANI) test yields amine (NH2) and amene (NH) helps in detection of cancer with high sensitivity, limit of quantification and detection of oxygen content in the blood analyte of interest. The detecting element is glucose oxidase (GOx) which acts as a catalyst and is a ligand in detection of cancer at early and later stage. The detection is based on Michaelis and Menton equation yielding gluconic lactone and oxygen at anode and cathode respectively. The Oxygen content decides the cancer cell activity by measuring its sensitivity to redox potentials. The redox potentials are carried out by an electro chemical method called direct current cyclic voltammetry (DCCV) technique. In this research article, the electrochemical model in MATLAB Simulink was developed and simulated for current versus time and potential versus time. It was found that the current and potential were decreased drastically with respect to