V. V. INSTITUTE OF PHARMACEUTICAL SCIENCES

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

CALENDER YEAR 2019

S.No.	Title of paper	Name of the author/s	Department	Name of journal	ISSN number
1	Analytical Method Development and Validation for the Estimation of Cinnarizine by RP-HPLC in Bulk and Pharmaceutical Dosage Forms	A Lakshmana Rao	Pharmaceutical chemistry	Asian Journal of Pharmaceutical and Health Sciences	2231- 2331
2	Analytical Method Development and Validation for the Estimation of Cinnarizine by RP-HPLC in Bulk and Pharmaceutical Dosage Forms	T Prasanthi	Pharmaceutical analysis	Asian Journal of Pharmaceutical and Health Sciences	2231- 2331
3	Development and Validation of a Stability Indicating RP-HPLC-UV Method for the Simultaneous Determination of Epalrestat and Pregabalin in Combined Pharmaceutical Formulation	A.Lakshmana Rao	Pharmaceutical chemistry	Chromatography and Separation Techniques Journal	2231-2781
4	Development and Validation of Stability Indicating RP-HPLC Method for Simultaneous Estimation of Ibuprofen and Carisoprodol in Pharmaceutical Formulation	A.Lakshmana Rao	Pharmaceutical chemistry	Open Journal of Analytical and Bioanalytical Chemistry	2689-7628

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5	A Novel Stability Indicating Rp-Hplc Method For Simultaneous Estimation Of Anti-Viral Class Of Elbasvir And Grazoprevir In Bulk And Pharmaceutical Dosage Form	A Lakshmana Rao	Pharmaceutical chemistry	International Journal of Pharmaceutical Sciences And Research	0975-8232
6	Method Development and Validation for the Estimation of Dothiepin Hydrochloride by Using RP-HPLC in PURE and Tablet Dosage Form	T Prasanthi	Pharmaceutical Analysis	Indian Journal of Pharmaceutical Education and Research	0019-5464
7	Method Development and Validation for the Estimation of Dothiepin Hydrochloride by Using RP-HPLC in PURE and Tablet Dosage Form	A Lakshmana Rao	Pharmaceutical chemistry	Indian Journal of Pharmaceutical Education and Research I	0019-5464
8	Development And Validation Of Stability Indicating Hplc Method For The Determination Of Ulipristal Acetate In Pharmaceutical Dosage Form	A Lakshmana Rao	Pharmaceutical chemistry	International Journal of Research in AYUSH and Pharmaceutical Sciences	2456-9909
9	Stability Indicating RP-HPLC Method for Simultaneous Estimation of Metformin and Ertugliflozin	A Lakshmana Rao	Pharmaceutical chemistry	Journal of Pharmaceutical and Medicinal Chemistry	2455-8346
10	Evaluation of Analgesic Activity of Ficus palmata	Sk.Aminabee	Pharmacology	Iranian Journal of Pharmaceutical Sciences	1735-2444
11	Evaluation of Analgesic Activity of Ficus palmata	A Lakshmana Rao	Pharmaceutical chemistry	Iranian Journal of Pharmaceutical Sciences	1735-2444

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12	Stability-indicating high performance liquid chromatographic method for simultaneous assay of pibrentasvir and glecaprevir: Method development, validation and application to tablet dosage forms	A Lakshmana Rao	Pharmaceutical chemistry	Journal of Research in Pharmacy	2630-6344
13	Preparation And Evaluation Of Lamivudine Nanoparticles	A Lakshmana Rao	Pharmaceutical chemistry	International Journal Of Research In Pharmacy And Chemistry	2231-2781
14	Simultaneous Determination of Canagliflozin and Metformin in Human Plasma by LC–MS/MS Assay and its Application to a Human Pharmacokinetic Study	A Lakshmana Rao	Pharmaceutical chemistry	Indian Journal of Pharmaceutical Education and Research	0019-5464
15	Evaluation of Anthelmintic Activity of Delonix Regia.	Sk.Aminabee	Pharmacology	The Pharma Review	0973-399X
16	Evaluation of Anthelmintic Activity of Delonix Regia.	A Lakshmana Rao	Pharmaceutical chemistry	The Pharma Review	0973-399X
17	Synthesis and Hypoglycemic and Anti-inflammatory Activity Screening of Novel Substituted 5-[Morpholino(Phenyl)Methyl]-Thiazolidine-2,4-Diones and Their Molecular Docking Studies	.Srikanth Kumanchi	Pharmaceutical chemistry	Turkish Journal of Pharmaceutical Sciences	2148-6247
18	Synthesis and Hypoglycemic and Anti-inflammatory Activity Screening of Novel Substituted 5-[Morpholino(Phenyl	A Lakshmana Rao	Pharmaceutical chemistry	Turkish Journal of Pharmaceutical Sciences	2148-6247

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	)Methyl]-Thiazolidine-2,4-Diones and Their Molecular Docking Studies				
19	Formulation And Invitro Evaluation Of Lamivudine Niosomes	T. Sravani	Pharma cuetics	Indo American Journal Of Pharmaceutical Sciences	2349-7750
20	Formulation And Invitro Evaluation Of Lamivudine Niosomes	T. Balakrishna	Pharma cuetics	Indo American Journal Of Pharmaceutical Sciences	2349-7750
21	Formulation And Invitro Evaluation Of Lamivudine Niosomes	A Lakshmana Rao	Pharmaceutical chemistry	Indo American Journal Of Pharmaceutical Sciences	2349-7750
22	Laboratory Models for Cardiotonic Drugs Screening	A. Sai Datri	Pharmaceutical analysis	Scholars Academic Journal of Pharmacy	2347-9531
23	Laboratory Models for Cardiotonic Drugs Screening	A Lakshmana Rao	Pharmaceutical chemistry	Scholars Academic Journal of Pharmacy	2347-9531
24	Formulation & Evaluation of Simvastatin Sustained Release Tablets by Using Different Polymers	V.L.Vinod Kumar	Pharmaceutics	Scholars Academic Journal of Pharmacy	2347-9531
25	Formulation & Evaluation of Simvastatin Sustained Release Tablets by Using Different Polymers	A Lakshmana Rao	Pharmaceutical chemistry	Scholars Academic Journal of Pharmacy	2347-9531
26	Formulation & Evaluation of Simvastatin Sustained Release Tablets by Using Different Polymers	A. Sai Datri	Pharmaceutical analysis	Scholars Academic Journal of Pharmacy	2347-9531
27	Review On Transdermal Drug Delivery System	A. Sai Datri	Pharmaceutical analysis	World Journal Of Pharmacy And Pharmaceutical Sciences	2278 – 4357

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28	Review On Transdermal Drug Delivery System	A Lakshmana Rao	Pharmaceutical chemistry	World Journal Of Pharmacy And Pharmaceutical Sciences	2278 – 4357
29	Review On Transdermal Drug Delivery System	V.L.Vinod Kumar	Pharmaceutics	World Journal Of Pharmacy And Pharmaceutical Sciences	2278 – 4357
30	Rp-Hplc Method Development And Validation For Simultaneous Estimation Of Linagliptin And Empagliflozin	A Lakshmana Rao	Pharmaceutical chemistry	Indian Drugs	0019-462X
31	Rp-Hplc Method Development And Validation For Simultaneous Estimation Of Linagliptin And Empagliflozin	T Prasanthi	Pharmaceutical Analysis	Indian Drugs	0019-462X
32	Stability Indicating RP-HPLC Method for Estimationof Pantoprazole and Ondansetron in Pharmaceutical Dosage Form	A Lakshmana Rao	Pharmaceutical chemistry	International Journal of Pharma Research and Health Sciences	2348-6465
33	Stability Indicating Rp-Hplc Method Development And Validation For Simultaneous Estimation Of Metformin And Glipizide	A Lakshmana Rao	Pharmaceutical chemistry	International Journal of Research in AYUSH and Pharmaceutical Sciences	2456-9909
34	Estimation Of Paroxetine Hydrochloride From Its Tablet Formulation By UV Spectrophotometry	A Lakshmana Rao	Pharmaceutical chemistry	International Journal of Research in AYUSH and Pharmaceutical Sciences	2456-9909
35	Morpho-Anatomical Features on Blumea Mollis (D. Don) Merr. (Asteraceae) Leaves	A Lakshmana Rao	Pharmaceutical chemistry	Acta Scientific Medical Sciences	2582-0931

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36	Pharmacognostic Study Of Mansoa Alliacea Leaf.	A Lakshmana Rao	Pharmaceutical chemistry	International Journal of Research in AYUSH and Pharmaceutical Sciences	2456-9909
37	Design, Synthesis And Molecular Docking Studies Of Novel N[1]Substituted-2-(Furan-3-Yl)-1h-Benzimidazole Derivatives	K. Srikanth Kumar	Pharmaceutical chemistry	International Journal of Research in AYUSH and Pharmaceutical Sciences	2456-9909
38	Design, Synthesis And Molecular Docking Studies Of Novel N[1]Substituted-2-(Furan-3-Yl)-1h-Benzimidazole Derivatives	A Lakshmana Rao	Pharmaceutical chemistry	International Journal of Research in AYUSH and Pharmaceutical Sciences	2456-9909
39	Bioanalytical Method Development and Validation for Simultaneous Determination of Chlorthalidone and Cilnidipine Drugs in Human Plasma by RP-HPLC	A.Lakshmana Rao	Pharmaceutical chemistry	International Journal of Research in Pharmacy and Chemistry	2231-2781
40	Development and Validation of Stability Indicating RP-HPLC Method for Simultaneous Estimation of Dapagliflozin and Saxagliptin in Pure and Pharmaceutical Dosage Form	A.Lakshmana Rao	Pharmaceutical chemistry	The Pharma Review	2231-2782

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41	Bioanalytical Method Development and Validation for Simultaneous Determination of Prazosin and Polythiazide Drugs in Spiked Human Plasma by RP-HPLC	A.Lakshmana Rao	Pharmaceutical chemistry	International Journal of Pharmaceutical, Chemical and Biological Sciences	0974-360X
42	Analytical Method for the Simultaneous Estimation of Sitagliptin and Simvastatin using RP-HPLC	A.Lakshmana Rao	Pharmaceutical chemistry	Journal of Pharmaceutical & Medicinal Chemistry	2455-8346
43	Method Development and Validation for Estimation of Dalfampirridine in Pure and Tablet Dosage Form	T.Prasanthi	Pharmaceutical Analysis	Journal of Pharmaceutical & Medicinal Chemistry	2455-8346
44	Method Development and Validation for Estimation of Dalfampirridine in Pure and Tablet Dosage Form	A.Lakshmana Rao	Pharmaceutical chemistry	Journal of Pharmaceutical & Medicinal Chemistry	2455-8346
45	Development and Validation of HPTLC Method for the Analysis of Tolperisone hydrochloride in Pharmaceutical Dosage Form	A.Lakshmana Rao	Pharmaceutical chemistry	International Journal of Research in Ayush and Pharmaceutical Sciences	2456-9909

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Analytical method development and validation for the estimation of Cinnarizine by RP-HPLC in bulk and pharmaceutical dosage forms

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ABSTRACT

A simple, sensitive, accurate and precise RP-HPLC method was developed for the determination of Cinnarizine in bulk and pharmaceutical dosage forms. The method was developed by using ODS C18 column (250 × 4.6 mm, 5 µ) and the mobile phase composed of acetonitrile: buffer (0.1% *ortho*-phosphoric acid) in the ratio of 80:20v/v. The buffer pH was adjusted to 3. The retention time for Cinnarizine was found to be 4.427 min. Linearity range for Cinnarizine was found to be 10-60 µg/mL and the regression equation was found to be y = 130638x + 2529.6. % RSD for intra- and inter-day precision was found to be 0.52% and 0.29%. Average mean recovery was found to be 99.06%. LOD and LOQ values obtained for Cinnarizine were found to be 1.27 and 3.25 µg/mL respectively. The results are analyzed statistically and are found to be satisfactory. Hence this method can be successfully employed for analysis of Cinnarizine in tablet dosage form.

INTRODUCTION

Cinnarizine (Fig. 1) is a specific competitive H_1 receptor antagonist [1]. It inhibits contractions of vascular smooth muscles by blocking L-type and T-type voltage gated calcium channels preferably in the arterial smooth muscle. It is chemically 1-(diphenylmethyl)-4-(3-phenylprop-2-en-1-yl) piparazene [2,3]. Cinnarizine has also been implicated in binding to dopamine D_2 receptors, histamine H_1 receptors, and muscarinic acetylcholine receptors. Cinnarizine is used to control the vestibular symptoms of both peripheral and central origin and of labyrinth disorders including vertigo, dizziness, nystagmus, tinnitus, nausea and vomiting and prophylaxis of motion sickness. Cinnarizine also used for adjunct therapy for symptoms of peripheral arterial disease, prevention and treatment of kinesis.

A survey of literature found that several HPLC methods [4-12] were reported for estimation of Cinnarizine in combined dosage forms but limited methods were reported for individual estimation of Cinnarizine [13] by HPLC. However the reported methods required long run time, hence there is an attempt has been made to develop a simple, rapid and accurate RP-HPLC method for estimation of Cinnarizine in tablet dosage forms.

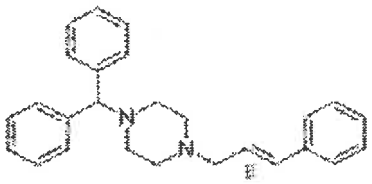

Fig. 1: Structure of Cinnarizine

MATERIALS AND METHODS

Instrument

Agilent 1260 infinity binary pump HPLC with open lab software was used for chromatographic studies.

Chemicals

Cinnarizine was purchased from Yarrow Chemicals, Mumbai, India. HPLC grade acetonitrile, ortho phosphoric acid, triethylamine were purchased from E. Merck (India) Ltd. Cinnarizine tablets were purchased from local market. Triple distilled water was used throughout experiment.

Preparation of Mobile phase

Buffer preparation

1 mL of *ortho*-phosphoric acid was transferred to 1000 mL volumetric flask and made upto volume with water. Adjusted the pH to 3.0 using triethylamine and the solution was filtered and sonicated for 5 min.

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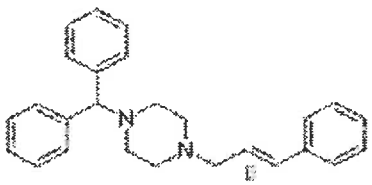

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Preparation of Mobile phase

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1 mL of *ortho*-phosphoric acid was transferred to 1000 mL volumetric flask and made upto volume with water. Adjusted the pH to 3.0 using triethylamine and the solution was filtered and sonicated for 5 min.

Research Article

Development and Validation of a Stability Indicating RP-HPLC-UV Method for the Simultaneous Determination of Epalrestat and Pregabalin in Combined Pharmaceutical Formulation

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ABSTRACT

An accurate, rapid, selective and specific stability indicating RP-HPLC-UV method was developed for the simultaneous determination of Epalrestat and Pregabalin in combined pharmaceutical formulation. Chromatographic separation was achieved on Discovery ODS C18 column (250 × 4.6 mm, 5 µm) with UV detection at 241 nm. The mobile phase consisting of 0.1% Ortho Phosphoric Acid (OPA) and acetonitrile in a ratio of 50:50, v/v and at a flow rate of 1.0 mL/min. The method was linear over the concentration range for Epalrestat 37.5-225 µg/mL and for Pregabalin 18.75-112.5 µg/mL. The retention times for Epalrestat and Pregabalin were found to be 2.166 min and 3.020 min respectively. The mean percentage recoveries of Epalrestat and Pregabalin were found to be 100.32% and 100.29% respectively. The method was validated and was successfully employed for the routine quantitative analysis of pharmaceutical formulations containing Epalrestat and Pregabalin in combined tablet dosage form.

INTRODUCTION

Epalrestat (Figure 1), chemically 2-[(5Z)-5-[(E)-2-methyl-3-phenylprop-2-enylidene]-4-oxo-2-sulfanylidene-1,3-thiazolidin-3-yl]acetic acid is an aldose reductase inhibitor used for the treatment of diabetic neuropathy [1,2]. It reduces the accumulation of intracellular sorbitol which is believed to be the cause of diabetic neuropathy [3].

Pregabalin (Figure 2), chemically (3S)-3-(aminomethyl)-5-methylhexanoic acid is an anticonvulsant drug used for neuropathic pain, as an adjunct therapy for partial seizures and in generalized anxiety disorder [4,5]. It binds to the alpha2-delta subunit of the voltage-gated calcium channel in the central nervous system [6].

In literature review there are a few analytical methods were reported for estimation of Epalrestat and Pregabalin alone or in combination with other drugs in pharmaceutical dosage forms. But only few methods are available for the simultaneous estimation of Eparlestat and Pregabalin by using RP-HPLC [7-12]. The main objective of the present work describes a simple, rapid, precise and accurate reversed phase stability indicating HPLC method for the simultaneous determination of Epalrestat and Pregabalin in combined pharmaceutical dosage forms as per ICH guidelines [13,14].

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Keywords: Ibuprofen; Carisoprodol; HPLC; Validation

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Research Article

Development and Validation of Stability Indicating RP-HPLC Method for Simultaneous Estimation of Ibuprofen and Carisoprodol in Pharmaceutical Formulation

Abstract

A novel, rapid, precise and accurate stability indicating RP-HPLC method was developed and validated for the simultaneous estimation of Ibuprofen and Carisoprodol in combined pharmaceutical formulation. Chromatographic separation was achieved on Kromasil C18 column (250×4.6mm, 5µm) with UV detection at 260nm. The mobile phase consisting of 0.1% Ortho Phosphoric Acid (OPA) and acetonitrile in a ratio of 40:60v/v and adjusted the flow of mobile phase to 1.0mL/min. The method was showing linear response in the concentration range over 100-600µg/mL for Ibuprofen and 43.75-262.5µg/mL for Carisoprodol. The peaks for Ibuprofen and Carisoprodol were detected 2.256 min and 3.141 min respectively. The mean percentage recoveries of Ibuprofen and Carisoprodol were found to be 99% and 99.18% respectively. The method was validated and was successfully employed for the routine quantitative analysis of pharmaceutical formulations containing Ibuprofen and Carisoprodol in combined tablet dosage form.

Introduction

Ibuprofen (Figure 1) is a nonsteroidal anti-inflammatory agent with analgesic and antipyretic properties [1]. Chemically it is 2-[4-(2-methylpropyl)phenyl]propanoic acid [2]. Ibuprofen is a non-selective inhibitor of cyclooxygenase, an enzyme invovled in prostaglandin synthesis via the arachidonic acid pathway [3].

Carisoprodol (Figure 2) is a centrally acting skeletal muscle relaxant [4]. Chemically it is 2-[(carbamoyloxy)methyl]-2-methylpentyl N-(propan-2-yl)carbamate [5]. It is used as an adjunct in the symptomatic treatment of musculoskeletal conditions associated with painful muscle spasm [6].

In literature review no analytical HPLC methods were reported for simultaneous estimation of Ibuprofen and Carisoprodol in combined pharmaceutical dosage form. Hence, the main objective of the present work describes a simple, rapid, precise and accurate stability indicating RP-HPLC method for the simultaneous estimation of Ibuprofen and Carisoprodol in combined pharmaceutical dosage form as per ICH guidelines [7,8].

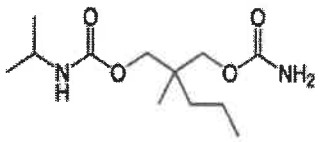

Figure 2: Structure of Carisoprodol

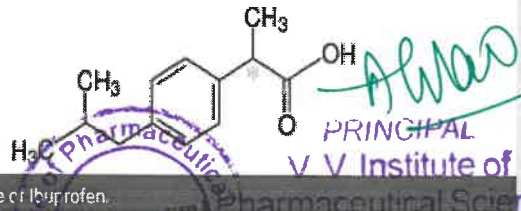

Figure 1: Structure of Ibuprofen

Materials and Methods

Materials

Pure samples (API) of Ibuprofen and Carisoprodol were procured from Spectrum Pharma Research Solutions, Hyderabad, India. Combination of Ibuprofen and Carisoprodol tablets were obtained from local pharmacy store. Acetonitrile,

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A NOVEL STABILITY INDICATING RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ANTI-VIRAL CLASS OF ELBASVIR AND GRAZOPREVIR IN BULK AND PHARMACEUTICAL DOSAGE FORM

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Keywords:

Elbasvir, Grazoprevir, Method development, RP-HPLC, Validation, Degradation

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ABSTRACT: Objective: To develop accurate, precise stability indicating a method for simultaneous estimation of Elbasvir and Grazoprevir in bulk and pharmaceutical dosage form. **Materials and Methods:** Simple, rapid, precise, sensitive and reproducible validated stability-indicating Reverse-Phase High-Performance Liquid Chromatography (RP-HPLC) method for the quantitative analysis of Elbasvir and Grazoprevir in the pharmaceutical dosage form. Chromatographic separation was carried out on waters Alliance-2695, by using Luna C18 (150 mm × 4.6 mm, 5 µm) column and the mobile phase containing OPA buffer (0.1%) and acetonitrile in the ratio of 50:50 v/v. The flow rate was 1.0 ml/min; detection was carried out at 258 nm using a photodiode array detector at ambient temperature. **Results:** The number of theoretical plates and tailing factor for Elbasvir and Grazoprevir were obtained to be NLT 2000 and should not more than 2 respectively. The linearity of the method was excellent over the concentration range 1.53-22.95 µg/ml and 3.05-45.75 µg/ml for Elbasvir and Grazoprevir respectively. The correlation coefficient was 0.999%. The relative standard deviation of peak areas of all measurements was less than 2.0. The proposed method was validated according to ICH guidelines. **Conclusion:** The method was found to be a simple, economical, suitable, precise, accurate and robust method for quantitative analysis of Elbasvir and Grazoprevir in combination and its stability.

INTRODUCTION: Major issue concerned to global health found worldwide nowadays is hepatitis C. More than 150 million people worldwide are infected with the hepatitis C virus (HCV), the leading cause of liver disease and liver transplantations [1], about 3 million deaths occur worldwide each year due to hepatitis C virus (HCV) related cases.

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According to the centers for disease control and prevention estimates of the people infected, Grazoprevir (an NS3/4 protease inhibitor) and Elbasvir (an NS5A inhibitor) are being developed by Merck [2]. The combination is being studied as a once-daily, single-tablet regimen, with or without ribavirin. The two drugs are active against multiple genotypes of hepatitis C [3, 4].

Elbasvir is a drug approved by the FDA for the treatment of hepatitis C. It was developed by Merck and completed phase III trials, used in combination with the NS3/4A protease inhibitor Grazoprevir [5, 6]. The IUPAC name for Elbasvir is Dimethyl N, N'- ([(6S) -6H -indolo [1, 2-c] [1, 3]

Original Article

Method Development and Validation for the Estimation of Dothiepin Hydrochloride by using RP-HPLC in PURE and Tablet Dosage Form

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ABSTRACT

Aim: A simple, sensitive, accurate and precise RP-HPLC method was developed for the determination of Dothiepin HCl (DTH) in pure and tablet dosage form. **Methods:** The method was developed by using Phenomenex C_{18} (250 X 4.6 mm, 5 µm) and the mobile phase composed of buffer (0.1M sodium acetate): acetonitrile in the ratio of 50:50 v/v. The buffer pH was adjusted to 2.8. The retention time for Dothiepin HCl was found to be 3.44 min. Linearity range for Dothiepin HCl was found to be 10-60 µg/mL and the regression equation was found to be y = 14691x-12844. % RSD for intra- and inter-day precision was found to be 0.27% and 0.84%. Average mean recovery was found to be 99.94%. LOD and LOQ values obtained for Dothiepin HCl were found to be 0.825 µg/mL and 2.498 µg/mL respectively. **Conclusion:** The results are analysed statistically and are found to be satisfactory. Hence this method can be successfully employed for analysis of Dothiepin HCl in tablet dosage form.

Key words: Dothiepin HCl, RP-HPLC, Linearity, Dosage form, Precision.

INTRODUCTION

Dothiepin HCl (Figure 1) formerly known as Dosulepin, is a tricyclic antidepressant drug prescribed for the treatment of depression of and associated anxiety/panic disorders. It is chemically (3E)-3-(6*H*-benzo[c] [1] benzothiepin-11-ylidene)-N, N-dimethylpropan-1-amine; hydrochloride.[1-2] It is also useful in chronic pain disorders and insomnia. It acts as a Serotonin–Norepinephrine Reuptake Inhibitor (SNRI) and also has other activities including antihistamine, antiadrenergic, antiserotonergic, anticholinergic and sodium channel -blocking effects. Dothiepin HCl inhibits the reuptake of biogenic amines, increasing available neurotransmitter levels at the synaptic cleft. The use of Dothiepin is only recommended in patients who are intolerant or unresponsive to alternative antidepressant therapies.[3-4]

A survey of literature[5-15] found that few HPLC methods were reported for estimation of Dothiepin HCl in pharmaceutical dosage forms. However the reported methods required long run time, hence there is an attempt has been made to develop a simple, rapid and accurate RP-HPLC method for estimation of Dothiepin HCl in tablet dosage form.

MATERIALS AND METHODS

Instrument

Agilent 1260 infinity binary pump HPLC with open lab software was used for chromatographic studies.

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Original Article

Method Development and Validation for the Estimation of Dothiepin Hydrochloride by using RP-HPLC in PURE and Tablet Dosage Form

Prasanthi Thayi[1*], Lakshman Rao Atmakuri[2], Nandini Mandada[3], Hemanth Mandava[3], Bhuvaneswari Mandru[3], Chaitanya Manne[3]

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Key words: Dothiepin HCl, RP-HPLC, Linearity, Dosage form, Precision.

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Research Article

DEVELOPMENT AND VALIDATION OF STABILITY INDICATING HPLC METHOD FOR THE DETERMINATION OF ULIPRISTAL ACETATE IN PHARMACEUTICAL DOSAGE FORM

A. Lakshmana Rao*, Alimunnisa, D. Sai Tejaswini, G. L. Vagdevi Jaya Lakshmi, V. Bhavya Naga Vani

Department of Pharmaceutical Analysis, V. V. Institute of Pharmaceutical Sciences, Gudlavalleru, Andhra Pradesh, India.

Keywords: Ulipristal Acetate, HPLC, Validation, Dosage Form.

ABSTRACT

A simple, novel, precise and accurate stability indicating RP-HPLC method was developed and validated for the estimation of Ulipristal Acetate in pharmaceutical dosage form. A Phenoxneome C18 (150 mm x 4.6 mm, 5 µm) column was used as stationary phase with mobile phase consisting of 0.1% ortho phosphoric acid and acetonitrile in the ratio of 50:50 v/v (pH was adjusted to 4.0 with triethyl amine). The flow rate was maintained at 1.0 mL/min and effluents were monitored at 223 nm. The retention time was 1.895 min. The linearity of the method was observed in the concentration range of 20-100 µg/mL with correlation coefficient of 0.999. The method developed was validated for linearity, precision, accuracy, system suitability and forced degradation studies like acidic, alkaline, oxidative and neutral stress conditions were performed as per ICH guidelines. The results obtained in the study were within the acceptable limits and hence this method can be used for the estimation of Ulipristal Acetate in pharmaceutical dosage form.

INTRODUCTION

Ulipristal Acetate (Figure 1) is the selective progesterone receptor modulator (SPRM) for the treatment of uterine fibroids and also used as medication for emergency birth control [1]. Chemically it is [(8S,11R,13S,14S,17R)-17-acetyl-11-[4-(dimethylamino)phenyl]-13-methyl-3-oxo-1,2,6,7,8,11,12,14,15,16-decahydrocyclopenta [a]phenanthren-17-yl] acetate. Ulipristal Acetate prevents progesterone from binding to the receptor, leading to blockage of gene transcription inhibiting synthesis of proteins necessary to begin and maintain pregnancy and also acts by inhibiting the ovulation. [2-4]

Literature survey revealed that few HPLC methods [5-6] were reported for the estimation of Ulipristal Acetate in pharmaceutical formulations. Hence a new, sensitive and efficient HPLC method was developed and validated as per ICH guidelines [7-8] for the estimation of Ulipristal Acetate in bulk and pharmaceutical dosage form.

MATERIALS AND METHODS

Instrumentation

To develop a high pressure liquid chromatographic method for quantitative estimation of Ulipristal Acetate using Agilent Technologies 1260 infinity binary HPLC instrument on a Phenoxneome C18 (150 mm x 4.6 mm, 5 µm) analytical column was used. The instrument is equipped with a pump, sampler and PDA detector. A 20 µL rheodyne injector port was used for injecting the samples. Data was analyzed by using EZ Chrome Open Lab software.

Chemicals and solvents

The reference sample of Ulipristal Acetate was obtained from Shree Icon Pharmaceutical Laboratories, Vijayawada, India. Commercially available Ulipristal Acetate tablets claimed to contain 5 mg of Ulipristal Acetate was purchased from local market. Methanol (HPLC grade), acetonitrile (HPLC grade), ortho phosphoric acid (AR grade) and triethyl amine (AR grade) were purchased from Merck (India) Ltd, Mumbai, India.

Original Article

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Stability Indicating RP-HPLC Method for Simultaneous Estimation of Metformin and Ertugliflozin

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A Lakshmana Rao, U Krishnaveni. Stability Indicating RP-HPLC Method for Simultaneous Estimation of Metformin and Ertugliflozin. J Pharmaceut Med Chem. 2019;5(2):65-73.

Abstract

A simple, rapid, precise and accurate stability indicating reverse phase high performance liquid chromatography (HPLC) method was developed for the simultaneous estimation of Metformin and Ertugliflozin. Isocratic separation was achieved on Denali C18 (150 x 4.6 mm, 5 µm) column with mobile phase comprising of 0.01 N KH_2PO_4: acetonitrile (60:40 V/V), pH adjusted 5.4 with 0.01% ortho phosphoric acid. The flow rate was maintained at 1 mL/min and analytes were screened with UV detector at 224 nm. The method was validated according to ICH guidelines with respect to linearity, accuracy, precision and specificity. The drugs were exposed to various stress conditions like, acid, alkali, oxidation, thermal, UV and neutral and the stressed samples were analysed by the proposed method. No co-eluting, interfering peaks from excipients, impurities were observed during stress conditions and all the degraded peaks are well resolved from parent peaks.

Keywords: Metformin; Ertugliflozin; Validation; HPLC.

Introduction

Metformin is an oral antidiabetic drug in the biguanide class. It is the first-line drug of choice for the treatment of type 2 diabetes mellitus[1]. Chemically it is 1,1-dimethylbiguanide (Fig. 1).[2] Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.[3]

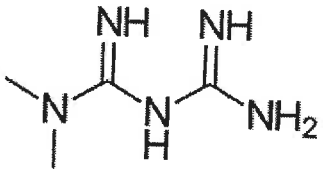

Fig. 1: Chemical structure of Metformin

Ertugliflozin is potent and selective inhibitors of the sodium-dependent glucose co transporters (SGLT).[4] Chemically it is (1S, 2S, 3S, 4R, 5S)-5-{4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl}-1-(hydroxymethyl)-6,8-dioxabicyclo [3.2.1] octane-2,3,4-triol (Fig. 2).[5] SGLT2 is the predominant transporter responsible for the resorption of glucose back into circulation from glomerular filtrate. Ertugliflozin inhibits the reabsorption of glucose mediated by this specific transporter, which increases the renal excretion of glucose and helps decrease glucose levels in circulation.[6] Ertugliflozin, in combination with Metformin hydrochloride, is indicated to improve glycemic control in patients with diabetes type 2 diabetes mellitus.[7]

Literature survey revealed that few HPLC methods were reported for simultaneous estimation of Metformin and Ertugliflozin in combined pharmaceutical dosage form.[8] The

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Original Article

Evaluation of Analgesic Activity of Ficus Palmata

Skaik Aminabee*, A. Lakshmana Rao, K. Sowmya, D. Nymisha, K. Kusuma Naga Lakshmi, K.V.N.S. Manikanta, P. Praveen Kumar

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Abstract

Ficus palmata (FI) is an important and widely used medicinal plant. It is principally used as an item of diet in the treatment of constipation and diseases of the lungs and bladder. The sap is used in the treatment of warts. Ficus palmata plant is used in various disease e.g. gastrointestinal, hypoglycemic, antitumor, anti-ulcer, anti-diabetic, lipid lowering and antifungal activities. This study evaluates both the central and peripheral analgesic effect of the different extracts of Ficus palmata in the experimental animals. Methods: Acute toxicity test was done following the Organization of Economic Co-operation and Development guidelines. Ficus palmata extracts (250 mg/kg, 500 mg/kg) body weight was evaluated for central analgesic activity by the hot plate method, tail immersion method and formalin test models using tramodol (20 mg/kg b.w.) as the standard drug. Results: In all the models, chloroform extract showed significant inhibition as well as the elongation of time at a dose of 500 mg/kg body weight. A linear dose response relationship was also observed which was comparable with that of the standard drug tramodol ($p<0.01$, $p<0.05$). Conclusion: The study showed significant central and peripheral analgesic activity of Ficus palmata which may be attributed to the inhibition of prostaglandin synthesis, phospholipase A2, and tumor necrosis factor alpha. Ficus plamata as a commercial source of analgesic drug should be subjected to further research.

Keywords: Ficus palmata, Analgesic activity, Hot plate method, Tail immersion method, Formalin test.

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1. Introduction

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Ficus palmata (FI) is an important and widely used medicinal plant. It is principally used as an item of diet in the treatment of constipation and diseases of the lungs and bladder. The sap is used in the treatment of warts. Ficus palmata plant is used in various disease e.g. gastrointestinal, hypoglycemic, antitumor, anti-ulcer, anti-diabetic, lipid lowering and antifungal activities. This study evaluates both the central and peripheral analgesic effect of the different extracts of Ficus palmata in the experimental animals. Methods: Acute toxicity test was done following the Organization of Economic Co-operation and Development guidelines. Ficus palmata extracts (250 mg/kg, 500 mg/kg) body weight was evaluated for central analgesic activity by the hot plate method, tail immersion method and formalin test models using tramodol (20 mg/kg b.w.) as the standard drug. Results: In all the models, chloroform extract showed significant inhibition as well as the elongation of time at a dose of 500 mg/kg body weight. A linear dose response relationship was also observed which was comparable with that of the standard drug tramodol ($p<0.01$, $p<0.05$). Conclusion: The study showed significant central and peripheral analgesic activity of Ficus palmata which may be attributed to the inhibition of prostaglandin synthesis, phospholipase A2, and tumor necrosis factor alpha. Ficus plamata as a commercial source of analgesic drug should be subjected to further research.

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JRP Journal of Research in Pharmacy

Research Article

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Stability-indicating high performance liquid chromatographic method for simultaneous assay of pibrentasvir and glecaprevir: Method development, validation and application to tablet dosage forms

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ABSTRACT: Pibrentasvir and glecaprevir combination therapy acts by inhibiting RNA replication and viron assembly in hepatitis C virus. The aim and objective of the present investigation is to develop and validate a stability indicating RP-HPLC method for simultaneous quantification of pibrentasvir and glecaprevir in bulk and tablets. Pibrentasvir and glecaprevir were separated and analyzed on Agilent Eclipse column (4.6 mm × 150 mm, 5 µm). The mobile phase consisted of 0.1% orthophosphoric acid and methanol (30:70, v/v), that was isocratically delivered at a flow rate of 1.0 mL/min. Retention times were 1.857 min for glecaprevir and 2.681 min for pibrentasvir. Good regression coefficients were obtained in range of 50-250 µg/mL for glecaprevir and 20–100 µg/mL for pibrentasvir. The results of validation parameters like selectivity, precision, accuracy and robustness are satisfactory. Tablet sample containing pibrentasvir and glecaprevir was subjected to degradation with 0.1N HCl, 0.1N NaOH, 30% hydrogen peroxide, thermal and photo conditions. The resulting degradants produced during the applied degradation conditions were well resolved from the peaks of pibrentasvir and glecaprevir. The utility of the proposed method was demonstrated by application to tablets containing pibrentasvir and glecaprevir combination. No interference from additives was observed. Therefore the method can be adapted in routine analysis of pibrentasvir and glecaprevir in quality control laboratories. The method can also be used for purity and degradation assessment of pibrentasvir and glecaprevir in tablets.

KEYWORDS: Antiviral drugs; pibrentasvir; glecaprevir; stability indicating; liquid chromatography.

1. INTRODUCTION

Hepatitis C virus is an RNA virus which causes progressive damage to the liver. As a result, liver cirrhosis and hepatocellular carcinoma might occur. Approximately 64 to 103 million people are infected chronically with hepatitis C virus [1]. As per WHO (World Health Organization), 350000 to 500000 people die each year because of this virus associated liver diseases. Though this virus was found worldwide, majorly affected regions included North Africa, Central Asia and East Asia [2, 3]. After better studying the properties of RNA, proteins and life cycle of hepatitis C virus, effective antiviral treatments were developed. The duration of therapy with antiviral and probability of response to antiviral depends on the number and genotype of RNA in hepatitis C virus [4].

The approval of pibrentasvir and glecaprevir combination was given by Food and Drug Administration in 2017 August [5]. This is used in healing the adult patients with chronic hepatitis C virus genotypes 1 to 6 (with no/mild cirrhosis), with kidney disease, those patients on dialysis, patients infected with hepatitis C virus genotype 1 who were already treated either with an NS5A inhibitor or an NS3/4A protease inhibitor, but not both in the past [6-8]. The enzymes, nonstructural protease 3A (NS3A), 4A (NS4A) and 5A (NS5A) are

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Research Article

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PREPARATION AND EVALUATION OF LAMIVUDINE NANOPARTICLES

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ABSTRACT

Nanoparticles represent a promising drug delivery system of controlled and targeted drug release. They are specially designed to release the drug in the vicinity of targeted tissue. Polymeric nanoparticles have been considered as promising drug delivery systems for variety of drugs like anticancer agents, biological macromolecules and vaccines. Various polymers have been used in the formulation of nanoparticles for drug delivery research to increase therapeutic benefit, while minimizing the side effects. Nanoparticles mediated targeting plays an important role in inhibiting inflammation, angiogenesis and tumor progression. Especially polymeric nanoparticles have greater deal that provides numerous properties such as simple to synthesize, inexpensive, biocompatible, biodegradable, non-toxic, non-immunogenic and water soluble for an effective drug delivery and drug targeting. The main applications of nanotechnology in medicine are materials and devices for diagnosis and for drug delivery. The aim of this study is to formulate the Lamivudine loaded nanoparticles of chitosan, cross linked with Tween 80 for antiretroviral therapy, in order to enhance the bioavailability and to reduce the dose frequency. Formulations of Lamivudine loaded nanoparticle were prepared by double emulsion solvent evaporation and solvent diffusion methods. Fourier transmission infrared spectroscopy studies indicated no chemical interaction between drug and polymer. *In vitro* release studies were performed by the dialysis membrane method. All the drug loaded batches were followed first order and sustained drug release over a period of 20 hrs.

Keywords: Lamivudine, Nanoparticles, Double emulsion solvent evaporation and Solvent diffusion.

INTRODUCTION

Nanoparticles are defined as particulate dispersions or solid particles with size in range of 10-1000 nm in which drug is dissolved, entrapped, encapsulated or attached to a nanoparticle matrix[1]. Polymeric nanoparticles with a size in the nanometer range protect drugs against *in vitro* and *in vivo* degradation. It releases the drug in a controlled manner and also offers the possibility of drug targeting[2-3]. The use of polymeric drug nanoparticles is a universal approach to increase the therapeutic performance of poorly soluble drugs in any route of administration. There are many methods were there to prepare nanoparticles includes emulsification-solvent diffusion, solvent diffusion, emulsion evaporation, nanoprecipitation method, salting out method, polymerization method, emulsion polymerization[4-8]. The major goals in designing nanoparticles as a delivery system are to control particle size, surface properties and release of pharmacologically active agents in order to achieve the site-specific action of drug at therapeutically optimal rate and dose regimen[9-10].

Lamivudine is a synthetic nucleoside analogue which acts as a reverse transcriptase inhibitor. Lamivudine is used for the treatment of Chronic Hepatitis and Human immunodeficiency Virus (HIV) infections with a half-life of nearly 5-7 hours. Conventional

Original Article

Simultaneous Determination of Canagliflozin and Metformin in Human Plasma by LC–MS/MS Assay and its Application to a Human Pharmacokinetic Study

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ABSTRACT

Objective: The main objective of this work was to develop a simple, rapid and sensitive liquid chromatography/tandem mass spectrometry (LC–MS/MS) method for the simultaneous quantification of Canagliflozin and Metformin. **Methods:** Deuterated compounds of respective drugs were used an internal standard. Sample extraction was carried out using a simple Protein Precipitation (PP) technique. A C_{18} column with an isocratic mobile phase composed of 5mM ammonium acetate with 0.01% formic acid and methanol were used for chromatographic separation. **Results:** The method was validated in the linearity range of 10.00–6028.00 ng/mL for Canagliflozin and 10.00–3027.00 ng/mL for Metformin. The precision and accuracy results over five concentration levels in five different batches were well within the acceptance limits. A variety of stability tests were executed in plasma and in neat samples are comply with the FDA guidelines. **Conclusion:** The proposed assay method is simple, rapid and sensitive for the simultaneous determination of Canagliflozin and Metformin in human plasma. This method was successfully used to quantitate the *in vivo* plasma concentrations obtained from a pharmacokinetic study.

Key words: Canagliflozin, Metformin, Human Plasma, LC–MS/MS, Method Validation, Pharmacokinetics.

INTRODUCTION

Type 2 Diabetes (T2DM) is a complex metabolic disorder characterized by impaired insulin secretion and impaired insulin action.[1] Chronic hyperglycaemia and uncontrolled glucose levels results T2DM progression and enhanced risk of complications and mortality. To achieve optimal glucose, control it is often necessary to rely on combination therapy of multiple drugs or insulin.[2]

Canagliflozin, a Sodium–glucose co–transporter 2 (SGLT2) inhibitor used to manage T2DM. By inhibiting SGLT2, Canagliflozin reduces reabsorption of filtered glucose and lowers the renal threshold for glucose (RT_G) and thereby increases urinary glucose excretion.[3] It is used as an adjunct to diet and exercise.[3-5] Metformin is one of the most commonly prescribed drug worldwide for T2DM therapy. Metformin lowers both basal and Postprandial Plasma Glucose (PPG) and improving the glucose uptake and utilization. Metformin has additional benefits like weight reduction, lowering lipid levels and prevention of some vascular complications.[6–8]

Metformin is a first-line therapy for patients with T2DM. Though, many patients do not achieve effective glycemic control with Met-

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Evaluation of Anthelmintic Activity of *Delonix Regia*

Aminabee SK*, Lakshmana Rao A, Sai Sowmya J, Bhavya Naga Vani V, Teja N & Lakshmi Prasanna P

Abstract: *Development of anthelmintic resistance and high cost of conventional anthelmintic drugs lead to evaluation of medicinal plant as an alternative source of anthelminitics. Delonix regia also known as flame of forest, distributed throughout Madagascar,, India, Africa and Australia. The present study was aimed to investigate the anthelmintic activity of crude chloroform extract of the leaves of Delonix regia on Indian earth worm (Pheretima posthuma). Three concentrations (25, 50, 100 mg/ml) of plant extract were studied in anthelmintic activity which involved the estimation of time of paralysis and time of death of the worms. Albendazole in same concentration as that of extract was included as standard reference and normal saline water with 1% CMC as control. The time of paralysis and time of death were studied and activity was compared with the Albendazole suspension as reference standard. The results show that the plant has the potential to be used as anthelmintic.*

Introduction

Helminthes infections are among the most common infections in people, affecting a large proportion of the world population[1]. Different type of helminths infects the human and animals out of which intestinal round worms *(Ascardia sp.)* are most common[2]. Helminthiasis has been found to result in poor birth outcome, poor cognitive development, poor school and work performance. Soil transmitted helminthiasis are responsible for parasitic infections in as much as quarter of the human population worldwide. The gastro intestinal helminthes become resistant to currently available anthelminthic drugs therefore there is a foremost problem in treatment of helminthes diseases. Helminthiasis may cause chronic illness through malnutrition[3] including vitamin deficiencies, stunted growth, anaemia and protein energy malnutrition.

Delonix regia is a flowering plant belongs to the family *Fabaceae*. It also called as Bojer ex Hook, Poinciana regia, Royal Poincaina[4], Gul mohar, Flame tree[5] and it is a large ornamental tree with fern like bipinnately compound leaves and attractive red peacock flower and native to Madagascar. The flowers and leaves contain most of the active constituents. The leaves of *D. regia* have antiinflammatory[6], antimalarial[7], antifungal[8], anticytotoxic activities[9]. Kameferol and saponin contents of the leaves responsible for the anti ulcer and cytotoxic activities[10] while aqueous extracts of flowers has been used as phytotoxicant to control the weeds viz. *Ischne nippponensis* and *Centella asiatica* in Taiwan[11]. Novel Kunitz like alpha amylase inhibitor has been isolated from the seeds, which have potential to control insect pest[12]. So, it is important to look for alternative strategies against parasites which have led to screening of medicinal plants for their anthelmintic activity.

Materials and Methods

Plant Materials

Fresh *Delonix regia* leaves were collected from the surrounding area of Gudlavalleru and Gudivada region. These plants were identified and authenticated by the Department of Botany Hindu College, Machilipatnam, A.P.

Drugs and Chemicals

Albendazole suspension was used as standard anthelmintic during the experimental protocol, chloroform, CMC were also used in experimental protocol. The entire chemicals used are laboratory and analytical grade.

Preparation of Plant Extract

The fresh leaves were sorted, cleaned and air dried at room temperature. The dried leaves were cut into small pieces and powdered. The powder sample was collected and stored in air and water proof container protected from direct sunlight and

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ORIGINAL ARTICLE

Synthesis and Hypoglycemic and Anti-inflammatory Activity Screening of Novel Substituted 5-[Morpholino(Phenyl)Methyl]-Thiazolidine-2,4-Diones and Their Molecular Docking Studies

Yeni Sübstitüe 5-[Morfolino(Fenil)Metil]-Tiazolidin-2,4-Dionların Sentezi ve Hipoglisemik ve Antienflamatuvar Aktivitelerinin Taranması ile Moleküler Doking Çalışmaları

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[3]Sree Vidyanikethan College of Pharmacy, Department of Pharmaceutical Chemistry, Tirupati, Andhra Pradesh, India

ABSTRACT

Objectives: The aim was the synthesis of novel substituted 5-[morpholino(phenyl)methyl]-thiazolidine-2,4-diones and screening for their *in vivo* hypoglycemic activity and *in vitro* anti-inflammatory activity, as well as molecular docking studies to find out active potential lead molecules.

Materials and Methods: Substituted aromatic aldehydes, thiazolidine-2,4-dione, and morpholine on Mannich reaction gave the title compounds. They were characterized by physical and spectral methods. In vivo hypoglycemic activity was examined in alloxan induced Wistar albino rats by tail tipping method. In vitro anti-inflammatory activity was tested by human red blood cell (HRBC) membrane stabilization and protein denaturation. Using AutoDock, molecular docking studies were carried out to find out the best fit ligands.

Results: Series of substituted 5-[morpholino(phenyl)methyl]-thiazolidine-2,4-diones were synthesized and chemically they were confirmed by spectral techniques. Acute toxic studies of *in vivo* hypoglycemic activity results revealed that compounds 4c, 4h, and 4n exhibited good activity at 35 mg/kg body weight. Chronic toxic study results indicated that compounds 4h and 4n exhibited good activity at 70 mg/kg body weight. Anti-inflammatory activity results indicated the highest inhibition was shown by compounds 4k and 4f at 500 µg/mL in HRBC membrane stabilization. In protein denaturation, the highest inhibition was shown by compound 4k at 500 µg/mL. In molecular docking studies, compounds 4h and 4n exhibited higher binding affinity at PPARγ receptor protein and compound 4k exhibited higher binding affinity at COX-1 and COX-2 actives sites.

Conclusion: Microwave irradiation produced high yield in short reaction times. The presence of electron releasing groups at the para position of the phenyl ring may give the ability to produce hypoglycemic activity and the presence of electron withdrawing groups at the para position of the phenyl ring causes anti-inflammatory activity. The results showed that some compounds exhibited good hypoglycemic and anti-inflammatory activities. Compounds 4h and 4n exhibited higher binding affinity at PPARγ receptor protein and compound 4k exhibited higher binding affinity at COX isoenzymes' active sites in molecular docking studies.

Key words: Thiazolidinediones bearing morpholine, Mannich reaction, *in vivo* hypoglycemic activity, *in vitro* anti-inflammatory activity, docking studies

ÖZ

Amaç: Bu çalışmanın amacı, yeni sübstitüe 5-[morfolino(fenil)metil]-tiyazolidin-2,4-dionların sentezi ve *in vivo* hipoglisemik ve *in vitro* anti-enflamatuvar aktivitelerinin taranması ile olası aktif moleküller için moleküler doking çalışmalarının yapılmasıdır.

Gereç ve Yöntemler: Bileşikler; sübstitüe aromatik aldehidler, tiyazolidin-2,4-dion ve morfolinin mannich reaksiyonu sonucu elde edilmiş, elde edilen bileşikler fiziksel ve spektral yöntemlerle karakterize edilmiştir. *İn vivo* hipoglisemik aktivite, alloxan ile indüklenen Wistar albino farelerde "tail

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FORMULATION AND *INVITRO* EVALUATION OF LAMIVUDINE NIOSOMES

T. Sravani[1], T. Balakrishna[2], A. Lakshmana Rao[3], S. Srinivasa Rao[4], M. Mallika[5], T. Navya Sri[6]

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Abstract:

The aim of present study is an attempt to formulate and evaluate controlled release niosomal formulations by using Lamivudine drug for potentially treating HIV and AIDS related condition. Lamivudine is an antiretroviral drug for the treatment of acquired immune deficiency syndrome (AIDS) & Hepatitis. The present study involves the preparation and characterization of Lamivudine entrapped niosomes and finding the drug carrier qualities of the niosomes. The formulation L1-L6 which were prepared by varying the concentration surfactant (Tween 20 & span 20) by ether injection method. The optimized formulation of lamivudine is prepared by ether injection method was subjected to characterization studies for different evaluation parameters such as vesicle size, % entrapment efficiency, drug content, in vitro release and the stability studies was carried out at different temperature. The present study demonstrates the controlled drug release after encapsulation of Lamivudine into niosomal preparation.

Key Words: *Lamivudine, Niosomes, controlled release, anti-retroviral, Immunodeficiency syndrome, Hepatitis, Tween 20, Span 20.*

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Pharmaceutical Analysis

Laboratory Models for Cardiotonic Drugs Screening

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Abstract Review Article

The human heart is an organ that pumps blood throughout the body via the circulatory system, supplying oxygen and nutrients to the tissues and removing carbon dioxide and other wastes. Thus, to maintain a healthy heart is a crucial factor for overall health and well-being. But because of today's food habits and stress conditions can eventually lead to various heart ailments. These conditions can be cured with cardiotonic agents. Before introducing drugs into market, that drug has to check for its safety and efficacy. For studying the drug activity, both in vitro and in vivo screening models have been developed in the past years. These Systems measures the ability of the test drugs to prevent or cure heart problems in laboratory conditions and on experimental animals. This review reveals some of such animal model to check the activity of cardiotonic drugs.

Keywords: Heart, circulatory, ailments, cardiotonic agents.

INTRODUCTION

The heart (Fig. 1) is a muscular organ in humans, which pumps blood through the blood vessels of the circulatory system [1]. Blood provides the body with oxygen and nutrients, as well as assists in the removal of metabolic wastes [2]. In humans, the heart is located between the lungs, in the middle compartment of the chest [2]. The heart pumps blood with a rhythm determined by a group of pacemaking cells in the sinoatrial node. These generate a current that causes contraction of the heart, traveling through the atrioventricular node and along the conduction system of the heart. If any malfunction of this conducting system causes heart diseases.

Heart diseases [4-6] can be primarily grouped into three major disorders: cardiac failure, ischemia and cardiac arrhythmia. Cardiac failure can be described as the inability of the heart to pump blood effectively at a rate that meets the needs of the metabolizing tissues. This occurs when the muscles that perform contraction and force the blood out of heart are performing weakly. Thus cardiac failures primarily arise from the reduced contractility of heart muscles, especially the ventricles. Reduced contraction of heart leads to reduced heart output but new blood keeps coming in resulting in the increase in heart blood volume. The heart feels congested. Hence the term congestive heart failure. Congested heart leads to lowered blood pressure and poor renal blood flow. This results in the development of edema in the lower extremities and the lung (pulmonary edema) as well as renal failure.

For the treatment of these heart problems, cardiotonic drugs[7] are used. They can treat the heart problems by increase the strength of the muscle contractions, which facilitates the pumping of more blood from the heart.

Cardiac action potential – the electrophysiology of heart [2-9]

The cardiac action potential is a brief change in voltage (membrane potential) across the cell membrane of heart cells [1]. This is caused by the movement of charged atoms (called ions) between the inside and outside of the cell, through proteins called ion channels. The cardiac action potential differs from action potentials found in other types of electrically excitable cells, such as nerves. Action potentials also vary within the heart; this is due to the presence of different ion channels in different cells. The action potential (Fig. 2) in typical cardiomyocytes is composed of 5 phases (0-4), beginning and ending with phase 4.

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Laboratory Models for Cardiotonic Drugs Screening

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Abstract — **Review Article**

The human heart is an organ that pumps blood throughout the body via the circulatory system, supplying oxygen and nutrients to the tissues and removing carbon dioxide and other wastes. Thus, to maintain a healthy heart is a crucial factor for overall health and well-being. But because of today's food habits and stress conditions can eventually lead to various heart ailments. These conditions can be cured with cardiotonic agents. Before introducing drugs into market, that drug has to check for its safety and efficacy. For studying the drug activity, both in vitro and in vivo screening models have been developed in the past years. These Systems measures the ability of the test drugs to prevent or cure heart problems in laboratory conditions and on experimental animals. This review reveals some of such animal model to check the activity of cardiotonic drugs.

Keywords: Heart, circulatory, ailments, cardiotonic agents.

INTRODUCTION

The heart (Fig. 1) is a muscular organ in humans, which pumps blood through the blood vessels of the circulatory system [1]. Blood provides the body with oxygen and nutrients, as well as assists in the removal of metabolic wastes [2]. In humans, the heart is located between the lungs, in the middle compartment of the chest [2]. The heart pumps blood with a rhythm determined by a group of pacemaking cells in the sinoatrial node. These generate a current that causes contraction of the heart, traveling through the atrioventricular node and along the conduction system of the heart. If any malfunction of this conducting system causes heart diseases.

Heart diseases [4-6] can be primarily grouped into three major disorders: cardiac failure, ischemia and cardiac arrhythmia. Cardiac failure can be described as the inability of the heart to pump blood effectively at a rate that meets the needs of the metabolizing tissues. This occurs when the muscles that perform contraction and force the blood out of heart are performing weakly. Thus cardiac failures primarily arise from the reduced contractility of heart muscles, especially the ventricles. Reduced contraction of heart leads to reduced heart output but new blood keeps coming in resulting in the increase in heart blood volume. The heart feels congested. Hence the term congestive heart failure. Congested heart leads to lowered blood pressure and poor renal blood flow. This results in the development of edema in the lower extremities and the lung (pulmonary edema) as well as renal failure.

For the treatment of these heart problems, cardiotonic drugs[7] are used. They can treat the heart problems by increase the strength of the muscle contractions, which facilitates the pumping of more blood from the heart.

Cardiac action potential – the electrophysiology of heart [2-9]

The cardiac action potential is a brief change in voltage (membrane potential) across the cell membrane of heart cells [1]. This is caused by the movement of charged atoms (called ions) between the inside and outside of the cell, through proteins called ion channels. The cardiac action potential differs from action potentials found in other types of electrically excitable cells, such as nerves. Action potentials also vary within the heart; this is due to the presence of different ion channels in different cells. The action potential (Fig. 2) in typical cardiomyocytes is composed of 5 phases (0-4), beginning and ending with phase 4.

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Pharmaceutics

Formulation & Evaluation of Simvastatin Sustained Release Tablets by Using Different Polymers

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Abstract Review Article

Purpose: The main objective of present research investigation is to formulate sustained release tablets of Simvastatin using different polymers. Simvastatin, an anti-hyperlipidemic agent belong BCS class-II agent. ***Methods:*** The SR tablets of Simvastatin were prepared employing different concentrations of HPMCK15M, xanthan gum and carbopol and tablets are prepared by using direct compression method. ***Results and discussion:*** Total six formulations are designed and evaluated for hardness, friability, thickness, % drug content and In-vitro drug release. From the results it was concluded that all the formulations are found to be within the pharmacopeia limits and in-vitro dissolution profiles of all formulation are subjected to different kinetic models, the statistical parameters like slope intercept and regression coefficient were calculated. ***Conclusion:*** It was concluded that the polymeric combination of HPMCK15M with xanthan gum in the ratio 1:1 was able to retarded the release of Simvastatin from the tablets to the24th hour and showed an ideal release pattern necessary for sustained release tablet.

Keywords: Simvastatin, Sustained release tablet, HPMCK15M, Xanthan gum and Carbopol.

INTRODUCTION

Traditional drug delivery system[1] has been characterized by immediate release and repeated dosing of the drug which might lead to the risk of dose fluctuation, this arises the need of a formulation with control release that maintain a near-constant or uniform blood level. The desire to maintain a near-constant or uniform blood level of a drug often translates into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use.

Drawbacks of Conventional Dosage Forms

- Poor patient compliance, increased chances of missing the dose of a drug with short half-life for which frequent administration is necessary.
- The unavoidable fluctuations of drug concentration may lead to under medication or over medication.
- A typical peak-valley plasma concentration time profile is obtained which makes attainment of steady-state condition difficult.
- The fluctuations in drug levels may lead to precipitation of adverse effects especially of a drug with small Therapeutic Index (TI) whenever over medication occur.

Sustained release concept

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. In the case of orally administer this period is measured in hours while in the case of injectables this period varies from days to months[2,3].

Advantages of sustained release dosage forms:[4]

- Control of drug therapy is achieved.
- Rate and extent of drug absorption can be is modified
- Frequency of drug administration is reduced.
- Patient compliance can be improved.

Disadvantages of sustained release dosage forms [5,6]

- It not permits prompt termination of therapy.
- Less flexibility in dose adjustment.
- These dosage forms are designed on the basis of average biological half-life.
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REVIEW ON TRANSDERMAL DRUG DELIVERY SYSTEM

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ABSTRACT

Transdermal drug delivery systems are defined as self contained, discrete dosage forms which, when applied to unbroken skin, deliver the drug through the skin, at a controlled rate to systemic circulation. The transdermal route of administration is recognized as one of the potential route for the local and systemic delivery of drugs. Transdermal patches follow diffusion mechanism for delivery of drugs. Through a diffusion process, the drug enters the bloodstream directly though the skin. Since there is high concentration on the patch and low concentration in the blood, the drug will keep diffusing into the blood, the drug will keep diffusing into the blood for a long period of time, maintaining the constant concentration of drug in the blood flow. TDDS offer many advantages, such as elimination of first pass metabolism, sustained drug delivery, reduced frequency of administration, reduced side effects and improved patient compliance. For the adequate delivery of drug through the transdermal patches can be affected by the different factors. Evolution of transdermal patch is use to ensure its quality, size, time of onset & duration, adhesive property, thickness, weight of patch, moisture of content, uniformity, permeation & toxicological studies.

KEYWORDS: Transdermal drug delivery system, Transdermal patches, Diffusion, Evolution, TDDS.

INTRODUCTION

Transdermal[1] therapeutic system provides controlled continuous delivery of drugs through the skin to the systemic circulation. This type of drug delivery offers many advantages

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RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF LINAGLIPTIN AND EMPAGLIFLOZIN

ABSTRACT

A simple, accurate and precise RP-HPLC method was developed for the simultaneous estimation of the linagliptin and empagliflozin in tablet dosage form. Chromatogram was run through Kromasil 250 x 4.6 mM, 5mM column, mobile phase containing 0.1% *o*-phosphoric acid buffer and acetonitrile in the ratio of 60:40%V/V was pumped through column at a flow rate of 1 mL/min. The optimized wavelength was 230 nm. Retention times of linagliptin and empagliflozin were found to be 2.759 min and 2.139 min. %RSD of the Linagliptin and Empagliflozin were found to be 0.5 and 0.6 respectively. Percentage assay was obtained as 99.91% and 100.15% for linagliptin and empagliflozin, respectively. LOD, LOQ values obtained for linagliptin and empagliflozin were 0.23 µg/ml and 0.44 µg/mL and 0.70 µg/mL and 1.34 µg/mL, respectively. Thus, the current study showed that the developed RP-HPLC method is sensitive and selective for the estimation of linagliptin and empagliflozin in combined dosage form.

Key Words: Linagliptin, Empagliflozin, RP-HPLC, Dosage form, LOD, LOQ.

INTRODUCTION

Linagliptin is chemically 8-[(3*R*)-3-aminopiperidin-1-yl]-7-(but-2-yn-1-yl)-3-methyl-1-[(4-methylquinazolin-2-yl) methyl]-2,3,6,7-tetrahydro-1*H*-purine-2,6-dione. It is a competitive and reversible di-peptidyl peptidase (DPP)-4 enzyme inhibitor that slows the breakdown of insulinotropic hormone glucagon-like peptide (GLP)-1 for better glycemic control in diabetic patients[1]. GLP and glucose-dependent insulinotropic polypeptide (GIP) are incretin hormones that increase the production and release of insulin from pancreatic beta cells and decrease the release of glucagon from pancreatic alpha cells. This results in a overall decrease in glucose production in the liver and increase of insulin in a glucose-dependent manner[2].

Empagliflozin is chemically (2*S*,3*R*,4*R*,5*S*,6*R*)-2-[4-chloro-3-({4-[(3*S*)-oxolan-3-yloxy]phenyl}methyl)phenyl]-6-(hydroxymethyl)oxane-3,4,5-triol. It is a sodium glucose co-transporter-2 (SGLT-2) inhibitor, indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type-2 diabetes[3-4]. SGLT-2 co-transporters are responsible for re-absorption of glucose from the glomerular filtrate in the kidney[5]. The glucuretic effect resulting from SGLT-2 inhibition reduces renal absorption and lowers the renal threshold for glucose, therefore resulting in increased glucose excretion. Additionally, it contributes to reduced hyperglycemia and also assists weight loss and blood pressure reduction[6].

The survey of literature reveals that few analytical methods[7-18] have been reported for estimation of linagliptin and empagliflozin individually[7,8] and in combined dosage form[9,10]. The reported methods suffer from drawbacks like long run times and more organic phase. Hence, the main objective of the present work was to develop and validate a specific, sensitive, accurate, rapid and precise RP-HPLC method for quantitative determination of linagliptin and empagliflozin in bulk drug and pharmaceutical dosage forms.

MATERIALS AND METHODS

Instrument

WATERS HPLC 2695 SYSTEM with Auto Injector and PDA Detector

Chemicals and Reagents

Linagliptin and empagliflozin pure drugs (API) are procured from Spectram Labs, Hyderabad, Combination of linagliptin and empagliflozin tablets (Glyxambi) are procured from local market. Distilled water, acetonitrile, methanol, *o*-phosphoric acid were purchased from Rankem Chemicals Ltd., Mumbai, India.

Preparation of solutions

Buffer (0.1 % OPA)

1 mL of concentrated *o*-phosphoric acid was dissolved in 1000 ml volumetric flask diluted with distilled water up to the mark. pH wasadjusted to 2.5 by using triethyl amine.

Standard preparation:

Accurately weighed 12.5 mg and 25 mg of linagliptin and empagliflozin working standards were transferred

specific, reproducible, accurate and robust which can be used for simultaneous estimation of linagliptin and empagliflozin in bulk drug and combined dosage form for routine analysis.

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RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF LINAGLIPTIN AND EMPAGLIFLOZIN

ABSTRACT

A simple, accurate and precise RP-HPLC method was developed for the simultaneous estimation of the linagliptin and empagliflozin in tablet dosage form. Chromatogram was run through Kromasil 250 x 4.6 mM, 5mM column, mobile phase containing 0.1% *o*-phosphoric acid buffer and acetonitrile in the ratio of 60:40%V/V was pumped through column at a flow rate of 1 mL/min. The optimized wavelength was 230 nm. Retention times of linagliptin and empagliflozin were found to be 2.759 min and 2.139 min. %RSD of the Linagliptin and Empagliflozin were found to be 0.5 and 0.6 respectively. Percentage assay was obtained as 99.91% and 100.15% for linagliptin and empagliflozin, respectively. LOD, LOQ values obtained for linagliptin and empagliflozin were 0.23 µg/ml and 0.44 µg/mL and 0.70 µg/mL and 1.34 µg/mL, respectively. Thus, the current study showed that the developed RP-HPLC method is sensitive and selective for the estimation of linagliptin and empagliflozin in combined dosage form.

Key Words: Linagliptin, Empagliflozin, RP-HPLC, Dosage form, LOD, LOQ.

INTRODUCTION

Linagliptin is chemically 8-[(3*R*)-3-aminopiperidin-1-yl]-7-(but-2-yn-1-yl)-3-methyl-1-[(4-methylquinazolin-2-yl) methyl]-2,3,6,7-tetrahydro-1*H*-purine-2,6-dione. It is a competitive and reversible di-peptidyl peptidase (DPP)-4 enzyme inhibitor that slows the breakdown of insulinotropic hormone glucagon-like peptide (GLP)-1 for better glycemic control in diabetic patients[1]. GLP and glucose-dependent insulinotropic polypeptide (GIP) are incretin hormones that increase the production and release of insulin from pancreatic beta cells and decrease the release of glucagon from pancreatic alpha cells. This results in a overall decrease in glucose production in the liver and increase of insulin in a glucose-dependent manner[2].

Empagliflozin is chemically (2*S*,3*R*,4*R*,5*S*,6*R*)-2-[4-chloro-3-({4-[(3*S*)-oxolan-3-yloxy]phenyl}methyl)phenyl]-6-(hydroxymethyl)oxane-3,4,5-triol. It is a sodium glucose co-transporter-2 (SGLT-2) inhibitor, indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type-2 diabetes[3-4]. SGLT-2 co-transporters are responsible for re-absorption of glucose from the glomerular filtrate in the kidney[5]. The glucuretic effect resulting from SGLT-2 inhibition reduces renal absorption and lowers the renal threshold for glucose, therefore resulting in increased glucose excretion. Additionally, it contributes to reduced hyperglycemia and also assists weight loss and blood pressure reduction[6].

The survey of literature reveals that few analytical methods[7-18] have been reported for estimation of linagliptin and empagliflozin individually[7,8] and in combined dosage form[9,10]. The reported methods suffer from drawbacks like long run times and more organic phase. Hence, the main objective of the present work was to develop and validate a specific, sensitive, accurate, rapid and precise RP-HPLC method for quantitative determination of linagliptin and empagliflozin in bulk drug and pharmaceutical dosage forms.

MATERIALS AND METHODS

Instrument

WATERS HPLC 2695 SYSTEM with Auto Injector and PDA Detector

Chemicals and Reagents

Linagliptin and empagliflozin pure drugs (API) are procured from Spectram Labs, Hyderabad, Combination of linagliptin and empagliflozin tablets (Glyxambi) are procured from local market. Distilled water, acetonitrile, methanol, *o*-phosphoric acid were purchased from Rankem Chemicals Ltd., Mumbai, India.

Preparation of solutions

Buffer (0.1 % OPA)

1 mL of concentrated *o*-phosphoric acid was dissolved in 1000 ml volumetric flask diluted with distilled water up to the mark. pH wasadjusted to 2.5 by using triethyl amine.

Standard preparation:

Accurately weighed 12.5 mg and 25 mg of linagliptin and empagliflozin working standards were transferred

specific, reproducible, accurate and robust which can be used for simultaneous estimation of linagliptin and empagliflozin in bulk drug and combined dosage form for routine analysis.

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Original Article

Stability Indicating RP-HPLC Method for Estimation of Pantoprazole and Ondansetron in Pharmaceutical Dosage Form

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ABSTRACT

Introduction: A simple, sensitive, precise, and accurate reverse phase high-performance liquid chromatography (RP-HPLC) method was developed and validated for simultaneous estimation of pantoprazole and ondansetron. The combination of pantoprazole and ondansetron is used for the treatment of nausea and vomiting. **Materials and methods:** The chromatographic separation was achieved isocratically on Discovery (250 x 4.6mm, 5µ) using 0.01% potassium dihydrogen phosphate buffer (pH 5.4): acetonitrile (60:40) as mobile phase, at a flow rate 1.0mL/min. The detection was monitored at 260nm. **Results and Discussion:** The separation was achieved within 6minutes, with retention times 2.281 and 2.840minutes for pantoprazole and ondansetron, respectively. %RSD of the pantoprazole and ondansetron were and found to be 1.0 and 0.8, respectively. %Assay was obtained as 99.26% and 99.09% for pantoprazole and ondansetron, respectively. LOD, LOQ values are obtained from regression equations of pantoprazole and ondansetron were 0.10µg/mL, 0.07µg/mL and 0.32µg/mL, 0.21µg/mL respectively. Regression equation of pantoprazole is y = 6589x + 20552, and y = 16218x + 5357 for ondansetron. The analytes were subjected to degradation studies using acid, alkali, oxidative, thermal, and photodegradation. **Conclusion:** The results obtained prove that the method is reproducible and selective for the determination of pantoprazole and ondansetron. The method was validated as per ICH guidelines in terms of accuracy, precision, linearity,, and specificity.

Keywords: Pantoprazole, Ondansetron, Degradation studies, RP-HPLC, Isocratic.

1. INTRODUCTION

Pantoprazole (figure 1a) is a proton pump inhibitor drug that inhibits gastric acid secretion. It acts by controlling the final step in gastric acid production by forming a covalent bond to two sites of the (H^+, K^+) ATPase enzyme system at the secretary surface of the gastric parietal cell. This action is dose-relatedd and leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus [1, 2]. Chemically Pantoprazole is 6-(Difluromethoxy)-2-[(3,4-dimethoxypyridin-2-yl)Methylsulfinyl]-1H-

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Research Article

STABILITY INDICATING RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS ESTIMATION OF METFORMIN AND GLIPIZIDE

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Keywords: Metformin, Glipizide, HPLC, Validation.

ABSTRACT

A novel, precise and accurate stability indicating RP-HPLC method was developed and validated for the simultaneous estimation of Metformin and Glipizide in combined pharmaceutical dosage form. Chromatographic separation was achieved on Microsorb-MV C18 column (250 × 4.6 mm, 5 µm) with UV detection at 257 nm. The mobile phase consists of acetate buffer (pH 4.0) and acetonitrile in the ratio of 60:40 v/v and at a flow rate of 1.0 mL/min. The method was linear over the concentration range of 60-140 µg/mL for Metformin and 10-50 µg/mL for Glipizide. The retention times for Metformin and Glipizide were found to be 2.434 min and 5.710 min respectively. The mean percentage recoveries of Metformin and Glipizide were found to be 100.42% and 100.39% respectively. The method was validated and was successfully employed for the routine quantitative analysis of pharmaceutical formulations containing Metformin and Glipizide in combined pharmaceutical formulation.

INTRODUCTION

Metformin (Fig. 1) is biguanide anti hyperglycemic agent used for treating non-insulin-dependent diabetes mellitus[1]. Chemically it is 1,1-dimethylbiguanide. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity by increasing peripheral glucose uptake and utilization[2,3].

Glipizide (Fig. 2) is a second-generation sulfonylurea, is used to lower blood glucose in patients with diabetes mellitus type II[4]. Chemically it is N-[2-(4-[(cyclohexylcarbamoyl) amino] sulfonyl) phenyl) ethyl]-5-methylpyrazine-2-carboxamide. Glipizide bind to ATP-sensitive potassium channel receptors on the pancreatic cell surface, reducing potassium conductance and causing depolarization of the membrane. Depolarization stimulates calcium ion influx through voltage-sensitive calcium channels, raising intracellular concentrations of calcium ions, which induces the secretion, or exocytosis, of insulin[5,6].

Literature survey revealed that few HPLC methods[7-11] were reported for simultaneous estimation of Metformin and Glipizide in combined pharmaceutical dosage form. But no stability indicating HPLC method was reported. Hence the objective of this method is to develop and validate a simple, rapid, precise and accurate stability indicating RP-HPLC method in accordance with ICH guidelines[12,13] for the simultaneous estimation of Metformin and Glipizide in combined pharmaceutical dosage form.

MATERIALS AND METHODS

Materials

Metformin and Glipizide pure drugs were obtained from Yarrow Chemicals, Mumbai, India. Combination of Metformin and Glipizide tablets (Glynase-MF Tablets) were obtained from local pharmacy store. Acetonitrile, glacial acetic acid, triethylamine and distilled water were obtained from Rankem Chemicals Ltd., Mumbai, India.

Instrumentation

The analysis of drugs was carried out on Agilent 1260 infinity binary pump HPLC system on Microsorb-MV C18 column (250 × 4.6 mm, 5 µm).

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Research Article

ESTIMATION OF PAROXETINE HYDROCHLORIDE FROM ITS TABLET FORMULATION BY UV SPECTROPHOTOMETRY

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Keywords: Paroxetine, Calibration, Validation, Estimation.

ABSTRACT

A simple, precise and accurate UV Spectrophotometric method was developed for the estimation of Paroxetine hydrochloride. The developed method obeyed Beer-Lambert's law in the concentration range of 5-30 µg/ml with a correlation coefficient of 0.995. The recovery study was carried out at three different levels and was found to be satisfactory. The percent amount of drug estimated by this method is 100%, found to be in good agreement with label claim of marketed tablet formulation. The validation parameters like linearity, precision, accuracy, robustness and ruggedness were studied and were found to be within limits. The proposed method can be adopted for routine quality control analysis of estimation of Paroxetine hydrochloride in pharmaceutical formulation.

INTRODUCTION

Paroxetine hydrochloride is a potent and selective serotonin reuptake inhibitor[1,2]. Chemically Paroxetine hydrochloride is (-)-*trans*-4R-(4'-fluorophenyl)-3*S*-[(3',4'-methylenedioxyphenoxy) methyl] piperidine hydrochloride hemihydrate (Fig. 1)[3]. Paroxetine hydrochloride is indicated for the treatment of depression, obsessive-compulsive disorder, panic disorder and social phobia[4]. Paroxetine acts by potentiation of serotonergic activity in the central nervous system resulting from inhibition of neuronal reuptake of serotonin (5-hydroxy-tryptamine, 5-HT)[5].

Literature survey reveals that very few UV Spectrophotometric methods were reported for the determination of Paroxetine hydrochloride[6]. The present study report a simple, rapid, precise and accurate UV Spectrophotometric method for the estimation of Paroxetine hydrochloride in bulk drug and in tablet dosage form and the developed method was validated as per ICH guidelines[7].

MATERIALS AND METHODS

Chemicals and Reagents

Pharmaceutical grade Paroxetine hydrochloride was obtained as gift sample from Spectrum Pharma Research Solutions, Hyderabad, India. Paroxetine hydrochloride (PARADISE XR 12.5) tablets were purchased from local market. Methanol (AR grade) was purchased from E.Merck (India) Ltd., Mumbai, India and was used as solvent. Fresh purified distilled water was used throughout the experiment.

Instruments

UV Spectrophotometer: Shimadzu-UV1800 Double Beam UV-Visible Spectrophotometer

Weighing balance: Shimadzu-BL220H Digital Weighing Balance

Preparation of standard stock solution

10 mg of Paroxetine hydrochloride was accurately weighed, transferred to 10 ml volumetric flask and dissolved in 7 ml of methanol. Sonicated the solution for few minutes and dissolved the drug completely. Then it was filtered through 0.45 µ filter and the volume was made up to 10 ml with methanol to get a concentration of 1 mg/ml stock solution. Further pipetted 1.0 ml of the above stock solution into a 10 ml volumetric flask and diluted up to the mark with diluent to obtain the concentrations of 100 µg/ml. Different aliquots were taken from standard stock solution and diluted with methanol separately to prepare series of concentrations from 5-30 µg/ml.

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Research Article

Morpho-Anatomical Features on *Blumea Mollis* (D. Don) Merr. (Asteraceae) Leaves

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Abstract

Background: *Blumea mollis* belonging to Asteraceae family is a significant therapeutic herb which has been in therapy utilized to treat several pathological marque since ages. It can be commonly referred as Suvattru mullangi in telugu. Though it is an essential herb, till date, no pharmacognostical information had been available on its leaves. Numerous adulterations are located in the market.

Objective: The current research was carried out to analyze the Pharmacognostic details for the rapid recognition and authentication of the herb. Materials and methods: The macroscopic and microscopic features with i quantitative microscopy of *Blumea mollis* leaves were performed utilising distinctive chemicals and reagents.

Results: The plant leaves show single layered, wavy walled cells in upper epidermis. Powder study of leaves shows epidermal cells, pigment cells, anomocytic stomata, covering trichomes and lignifie xylem vessles.

Conclusion: The macroscopic and microscopic characteristics of *Blumea mollis* leaves serves as a tool for low cost, rapid identification and authentication of this plant.

Keywords: Blumea mollis; anomocytic stomata; phytochemical analysis; physicochemical parameters.

Introduction

The usage of natural products or natural product-based medication is strengthening worldwide, particularly in the expanding parts of the world, despite the fact that synthetic medicines are readily available and reliable in healing several illnesses, there are people that still choose using traditional folk medicines because of the fewer hazardous outcome. Around 25% of the prescribed medicines on the globe will be of basically plant source [1]. In the developing countries like India, around 80% people depend on traditional plant-based medicines for their prime health care desires [2].

Modern prevalent desire for plant-derived medicines demonstrates its acknowledgement of the validity of numerous traditional promises about the values of natural products in healthcare [3]. For quality control of conventional medications, phytochemical inspections are mostly employed. Therefore, it creates an excellent value to look at chemical constituents and examine pharmacological activity about this herb because of its therapeutic applications, which is very helpful in the field of medicine as new emerging drug [4]. According to the WHO, medicinal plants are the best sources to obtain a variety of new herbal drug.

Blumea mollis (Asteraceae) is a genus of flowering plants widely distributed in Western and Southern plains of India ascending to 2000 ft in the Himalayas [5]. *Blumea* mollis is an agreeably fragrant annual herb with 30- to 60-cm height and generally seen in the flatlands of India, outer Himalaya, Ceylon (veraltet) and Myanmar. It is an annual erect herb, up to 60cm tall; brenchlets ribbed, pubescent. Leaves obovate, 3.5-9.5 X 1-3.5cm, base attenuate,

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Research Article

PHARMACOGNOSTIC STUDY OF *MANSOA ALLIACEA* LEAF

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Keywords: *Mansoa alliacea,* Pharmacognostic evaluation, Organoleptic evaluation.

ABSTRACT

Mansoa alliacea Lam. (Family: Bignoniaceae) is a native plant from Amazonian basin in South America. Plant derivatives are used as anti-inflammatory, antioxidant, antiseptic and antibacterial agents. The study was aimed to determine the pharmacognostic and phytochemicals present in *Mansoa alliacea.* Micro and organoleptic characteristics of fresh and dried leaf samples had been examined. Physicochemical variables had been done by using WHO suggested variables; preliminary phytochemical of leaf sample had been performed to identify the presence of alkaloids, flavonoids, tannins and phenols, and quinones using the ethanolic extract of the leaves of *M. alliacea.*

INTRODUCTION

According to the World Health Organization[1], approximately 65-80% of the population living in developing countries reports to the use of medicinal plants to address their health care benefits. *Mansoa alliacea* belongs to the family Bignoniaceae is widely used by many of the indigenous peoples of the Amazon, with almost all parts of the plant being used. It is commonly called as garlic vine and Ajossacha[2]. So far, phytochemical studies have revealed some structurally diverse chemicals from the plant alkaloids, flavonoids, steroids, tannins and phenols. The plant has also become a popular treatment in modern herbal medicine in S. America. It is widely used for treating arthritis, rheumatism, body aches, pain and muscle aches and injuries. The leaves and flowers contain the known anti-inflammatory, antioxidant[3] and antibacterial plant steroids, beta-sitosterol, stigmasterol, daucosterol and fucosterol[4]. The genus Mansoa (Bignoniaceae) a source of organosulfur compounds[5]. *M.Alliacea* used for the treatment of reproductive organ infections, renal ailments, dizziness, epilepsy, sickle cell disease, depression, metabolic disorders, skin grievance, leprosy, impetigo, helminthic infections, athlete's foot, tumours[6]. In this study, we make an effort for standardization of *M. alliacea* leaf to analyze the morphological, anatomical, physicochemical and preliminary analysis of leaf was performed.

MATERIALS AND METHODS

Collection of plant materials

The fresh leaves were collected, authenticated and identified by the Department of Botany, Hindu College, Machilipatnam, Andhra Pradesh.

Pharmacognostic evaluation, organoleptic evaluation

Organoleptic characteristics of *Mansoa alliacea* leaf was evaluated by noticing colour, smell, taste, shape, and size as outlined by WHO quality control techniques for herbal medicine[7].

Microscopic evaluation, preparation of sections

Free handed sections of the leaf were cut into thin sections manually with the sharp cutting edge of the blade. After that it is transferred on the slide, cleared by heating with chloral hydrate, stained by way of phloroglucinol and concentrated HCL and mounted in glycerine. The lignified tissues had been identified by using distinct staining approaches[8].

Physicochemical analysis

Physicochemical parameters had been established based on the methods described in WHO quality control methods for herbal materials.

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International Journal of Research in AYUSH and Pharmaceutical Sciences

Research Article

DESIGN, SYNTHESIS AND MOLECULAR DOCKING STUDIES OF NOVEL N-SUBSTITUTED-2-(FURAN-3-YL)-1*H*-BENZIMIDAZOLE DERIVATIVES

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Keywords:
Benzimidazole derivatives, synthesis, characterization, molecular docking, β-tubulin.

ABSTRACT

Benzimidazole pharmacophore possess broad class of curative properties like anthelmintic, antiulcer, antihypertensive, anticancer, etc. In view of this reason benzimidazole derivatives synthesis gained vital significance in recent years. In this investigation, a series of novel substituted benzimidazole derivatives having furan appendage at 2nd position and alkyl/aryl appendage at 1st position were synthesized by using appropriate procedures. All the compounds synthesized were characterized by physically (R_f values, Melting point, Molecular weight, Molecular formula) and were characterized by spectral data (^{1}H-NMR, ^{13}C-NMR, IR and Mass spectra). All the synthesized compounds were screened for molecular docking studies on human gamma-tubulin protein to find out the binding interaction at the target active site. Molecular docking studies at human gamma-tubulin protein states that the compound 4b showed good binding affinity (-8.98 kcal/mol) in comparison to the reference compound Albendazole (-8.47 kcal/mol).

INTRODUCTION

In the current drug discovery research, heterocyclic ring containing drug molecules gained much more importance. Heterocyclic compounds take over various fields such as organic chemistry, medicinal chemistry, biochemistry, agricultural sciences. Heterocyclic compounds chemistry played a fundamental role in the metabolism of most of all living cells[1]. Among different classes of heterocyclic compounds, benzimidazole is the key scaffold which can be found in many active pharmaceutical ingredients. The benzimidazoles contain a phenyl ring fused to an imidazole ring, as indicated in the structure for benzimidazole. Currently used antiulcer drugs- Omeprazole, Lansoprazole, Pantoprazole, Rabeprazole; anthelmintic drugs- Albendazole, Mebendazole, Thiabendazole possessing benzimidazole moiety were mentioned (Fig. 1).

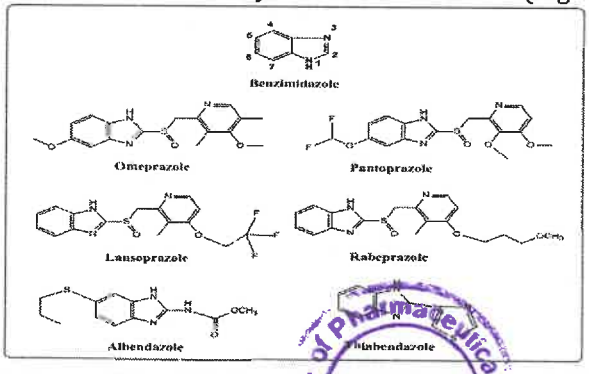

Fig. 1: Commonly used benzimidazole pharmacophore containing drugs

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Research Article

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K. Srikanth Kumar[1]*, A. Lakshmana Rao[1], S. Ravichandra[2], A.N.V.S. Divya[1], Ch. Archana[1], A. Lavanya[1], A.V.D.S. Mani Kumar[1]

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Benzimidazole pharmacophore possess broad class of curative properties like anthelmintic, antiulcer, antihypertensive, anticancer, etc. In view of this reason benzimidazole derivatives synthesis gained vital significance in recent years. In this investigation, a series of novel substituted benzimidazole derivatives having furan appendage at 2nd position and alkyl/aryl appendage at 1st position were synthesized by using appropriate procedures. All the compounds synthesized were characterized by physically (R_f values, Melting point, Molecular weight, Molecular formula) and were characterized by spectral data (^{1}H-NMR, ^{13}C-NMR, IR and Mass spectra). All the synthesized compounds were screened for molecular docking studies on human gamma-tubulin protein to find out the binding interaction at the target active site. Molecular docking studies at human gamma-tubulin protein states that the compound 4b showed good binding affinity (-8.98 kcal/mol) in comparison to the reference compound Albendazole (-8.47 kcal/mol).

INTRODUCTION

In the current drug discovery research, heterocyclic ring containing drug molecules gained much more importance. Heterocyclic compounds take over various fields such as organic chemistry, medicinal chemistry, biochemistry, agricultural sciences. Heterocyclic compounds chemistry played a fundamental role in the metabolism of most of all living cells[1]. Among different classes of heterocyclic compounds, benzimidazole is the key scaffold which can be found in many active pharmaceutical ingredients. The benzimidazoles contain a phenyl ring fused to an imidazole ring, as indicated in the structure for benzimidazole. Currently used antiulcer drugs- Omeprazole, Lansoprazole, Pantoprazole, Rabeprazole; anthelmintic drugs- Albendazole, Mebendazole, Thiabendazole possessing benzimidazole moiety were mentioned (Fig. 1).

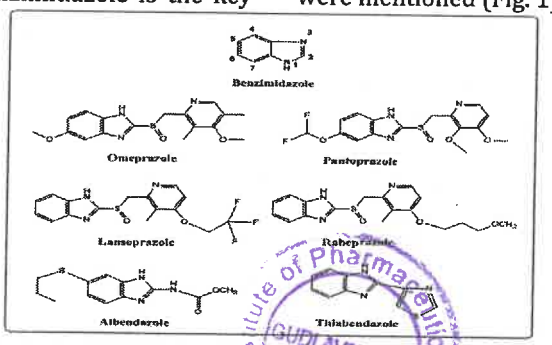

Fig. 1: Commonly used benzimidazole pharmacophore containing drugs

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Research Article

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BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS DETERMINATION OF CHLORTHALIDONE AND CILNIDIPINE DRUGS IN HUMAN PLASMA BY RP-HPLC

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ABSTRACT

A simple, rapid, sensitive, precise and accurate high performance liquid chromatography method was developed for simultaneous determination of Chlorthalidone and Cilnidipine in human plasma using Azilsartan as internal standard (ISTD). The analytes were extracted from 500 µL aliquots of human plasma sample by direct protein precipitation technique using acetonitrile. Evaluation of content of the drugs were done by employing a mixture of acetonitrile and 0.1% orthophosporic acid (OPA) buffer in the ratio of 35:65 v/v as the mobile phase with a flow rate of 1ml/mL and injection volume of 10µL. Chromatographic separation was accomplished using Inertsil C18, (150×4.6 mm; 5µm) analytical column and the effluents were monitored at 248 nm with photo diode array (PDA) detector. The total run time was 8 min with retention time of Chlorthalidone, Cilnidipine and Azilsartan 3.516 min, 3.518 min and 2.308 min respectively. Linearity was established at a concentration range of 0.05-5.00 µg/mL for Chlorthalidone and 0.025-2.5 µg/mL for Cilnidipine. The method was validated as per the US-FDA guidelines and the results were within the acceptance criteria. And proposed method was successfully applied for the simultaneous determination of Chlorthalidone and Cilnidipine in human plasma.

Keywords: Chlorthalidone, Cilnidipine, Protein precipitation, Human plasma and RP-HPLC.

INTRODUCTION

Selective and sensitive analytical methods for the quantitative evaluation of drugs and their metabolites (analytes) are critical for the successful evaluation of preclinical, biopharmaceutical and clinical pharmacological studies. Bioanalytical method validation includes all of the procedures which demonstrate that a particular method used for

dihydro-1*H*-isoindol-1-yl)benzene-1-sulfonamide [Fig. 1]. The molecular formula is $C_{14}H_{11}ClN_2O_4S$ and molecular weight is 338.766 g/mol. It inhibits sodium ion transport across the renal tubular epithelium in the cortical diluting segment of the ascending limb of the loop of henle. By increasing the delivery of sodium to the distal renal tubule, Chlorthalidone indirectly increases potassium

Development and Validation of Stability Indicating RP-HPLC Method for Simultaneous Estimation of Dapagliflozin and Saxagliptin in Pure and Pharmaceutical Dosage Form

V. Rajani[1*], Y. Rajendra Prasad[2] & A. Lakshmana Rao[3]

Abstract: *Combination of Dapagliflozin and Saxagliptin has been successfully used for the treatment of diabetes mellitus. The objective of the present study was to establish a simple, precise, specific and stability indicating RP-HPLC method for the simultaneous estimation of Dapagliflozin and Saxagliptin in bulk and tablet dosage form. The analysis has been performed on Agilent BDS column (250 x 4.6 mm, 5µ) at 30°C using water:acetonitrile (50:50, v/v) as mobile phase. The detection was carried out at 210 nm with a flow rate of 1.0 ml/min. The retention time of Dapagliflozin and Saxagliptin was found to be 3.172 min & 2.583 min respectively. The linearity range was 25-150 µg/ml for Dapagliflozin and 1.25-75 µg/ml for Saxagliptin respectively. The forced degradation studies were performed as per the guidelines of ICH under acidic, alkaline, oxidative, thermal, photo stability & neutral conditions. The developed method was successfully validated for all the parameters and was found to be within the limits. The developed method could be successfully employed for the simultaneous estimation of Dapagliflozin and Saxagliptin in pure and tablet dosage form.*

Introduction

Dapagliflozin (DAP) (Figure 1) is chemically (2S,3R,4R,5S,6R)-2-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-6-(hydroxymethyl) oxane-3,4,5-triol[1]. DAP is indicated for the management of diabetes mellitus type 2, and functions to improve glycemic control in adults when combined with diet and exercise. DAP is a sodium-glucose cotransporter 2 inhibitor, which prevents glucose reabsorption in the kidney[2].

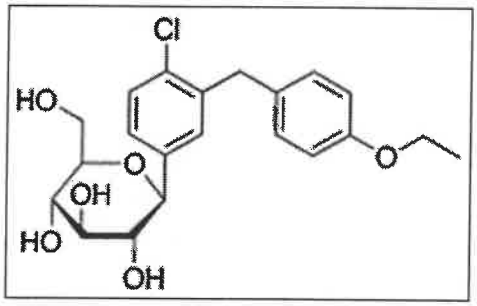

Figure 1: Chemical structure of Dapagliflozin

Saxagliptin (SAX) (Figure 2) is chemically (1S,3S,5S)-2-[(2S)-2-amino-2-(3-hydroxy-1-adamantyl)acetyl]-2-azabicyclo[3.1.0] hexane-3-carbonitrile[3]. SAX is a dipeptidyl peptidase-4 (DPP-4) inhibitor antidiabetic for the treatment of type 2 diabetes. DPP-4 inhibitors are a class of compounds that work by affecting the action of natural hormones in the body called incretins. The new combination of Dapagliflozin and Saxagliptin is indicated as an adjunct to diet and exercise to improve glycaemic (blood sugar level) control in adults with type-2 diabetes[4].

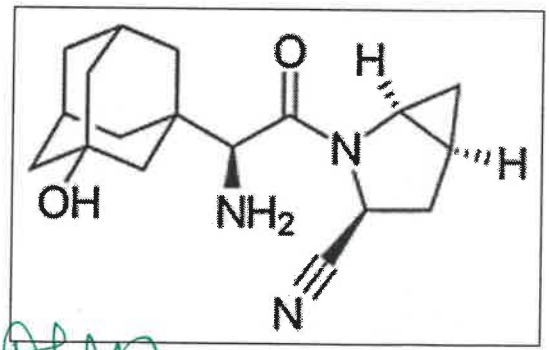

Figure 2: Chemical structure of Saxagliptin

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Research Article

BIOANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS DETERMINATION OF PRAZOSIN AND POLYTHIAZIDE DRUGS IN SPIKED HUMAN PLASMA BY RP-HPLC

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ABSTRACT

A simple, novel, sensitive, rapid, precise and accurate high performance liquid chromatography method has been developed and validated for simultaneous determination of Prazosin and Polythiazide in human plasma using Hydrochlorothiazide as internal standard (ISTD).The analytes were extracted from 500 µl aliquots of human plasma sample by direct protein precipitation technique using acetonitrile. Evaluation of content of the drugs were done by employing a mixture of acetonitrile and potassium dihydrogen orthophosphate buffer in ratio of 35: 65 v/v as the mobile phase with a flow rate of 1 ml/min and injection volume of 10µl. Chromatographic separation was accomplished using Zorbax C18, (150×4.6 mm; 5µm) analytical column and the effluents were monitored at 265 nm with PDA detector. The total run time was 8 min with retention time of Prazosin, Polythiazide and Hydrochlorothiazide was 6.598 min, 5.214 min and 3.579 min respectively. Linearity was established at a concentration range of 5.0-500 ng/ml for Prazosin and 2.5-250 ng/ml for Polythiazide. The method was validated as per the US-FDA guidelines and the results were within the acceptance criteria and proposed method was successfully applied for the simultaneous determination of Prazosin and Polythiazide in human plasma.

Keywords: Prazosin. Polythiazide. Protein precipitation. Human plasma. RP-HPLC.

INTRODUCTION

Selective and sensitive analytical methods for the quantitative evaluation of drugs and their metabolites are critical for the successful evaluation of preclinical, biopharmaceutical and clinical pharmacological studies. Bioanalytical method validation includes all of the procedures which demonstrate that a particular method used for the quantitative measurement of analytes in a given biological matrix, such as blood, plasma, serum, or urine. These methods are reliable and reproducible[1].

Prazosin is a quinazoline derivative, is the first of that chemical class of antihypertensive. Chemically it is designated as 1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-(2-furoyl) piperazine and its structural formula is shown in Fig. 1. Prazosin is a sympatholytic alpha-adrenergic blocker used in the treatment of anxiety, hypertension, refractory pulmonary oedema and panic disorders. It reduces peripheral resistance and blood pressure by vasodilatation of peripheral vessel in arterioles and veins without increasing the heart rate or significantly impairing sympathetic function[2-5]. It is official in Indian pharmacopoeia[6], British pharmacopoeia[7], United States Pharmacopoeia[8].

Polythiazide is an orally effective benzothiadiazine sulfonamide derivative belonging to the class of the thaiazide diuretics. Chemically it is designated as 2*H*-1,2,4-Benzothiadiazine-7-sulfonamide,6-chloro-3,4-dihydro-2-methyl-3-[[(2,2,2-trifluoroethyl) thio]methyl]-1,1dioxide and its structural

Original Article

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Analytical Method for the Simultaneous Estimation of Sitagliptin and Simvastatin using RP-HPLC

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A. Lakshmana Rao, T. Raja. Analytical Method for the Simultaneous Estimation of Sitagliptin and Simvastatin using RP-HPLC. J Pharmaceut Med Chem. 2019;5(1):5-11.

Abstract

A novel, rapid, precise and accurate high performance liquid chromatographic method was developed and validated for the simultaneous determination of Sitagliptin phosphate and Simvastatin in bulk drug and pharmaceutical formulation. The components were separated on Ymc Cyano (150 mm × 4.6 mm I.D., 5 µm particle size) with a mobile phase composed of 20 mM ammonium formate and acetonitrile in the ratio of 50:50 v/v (Adjust the pH to 3.5 with 0.1% formic acid) at a flow rate of 1.2 mL/min. The response was measured at 218 nm. The peaks were detected at 5.33 minutes and 4.19 minutes for Sitagliptin phosphate and Simvastatin respectively. Calibration curves were found to be linear (r^2=0.999 for both Sitagliptin phosphate and Simvastatin respectively) over the concentration range of 2.5-200 µg/mL for Sitagliptin phosphate and 1-80 µg/mL for Simvastatin. The method was validated for linearity, precision, accuracy, ruggedness and robustness. The proposed method can be applicable for simultaneous quantitation of Sitagliptin phosphate and Simvastatin in tablet dosage form. Validation results assured that the recommended method was specific, rapid, reliable and reproducible. Good percent recoveries and low % RSD reveals the suitability of the present method for analysis of Sitagliptin phosphate and Simvastatin in quality control laboratories.

Keywords: Sitagliptin; Simvastatin; RP-HPLC; Estimation.

Introduction

Sitagliptin phosphate (Fig. 1) is an oral dipeptidyl peptidase-4 (DPP-4) reversible inhibitor [1]. Chemically Sitagliptin is (3R)-3-amino-1-[3-(trifluoromethyl)-5,6 dihydro [1,2,4] triazolo [4,3-a] pyrazin-7(8*H*)-yl]-4-(2,4,5-trifluorophenyl)-1-butanone. It acts as DPP-4 inhibitorwhich exerts its action by slowing the inactivation of the incretin

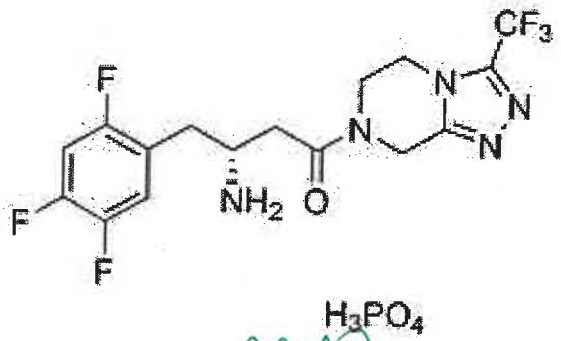

Fig. 1: Chemical structure of Sitagliptin phosphate

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RP-HPLC Method Development and Validation for Estimation of Dalfampridine in Pure and Tablet Dosage Form

T. Prasanthi[1], A. Lakshmana Rao[2], Shabana Begum[3], S. Tejaswini[4], T. Krishna[5], TNSD Prathima[6]

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T. Prasanthi, A. Lakshmana Rao, Shabana Begum et al. RP-HPLC Method Development and Validation for Estimation of Dalfampridine in Pure and Tablet Dosage Form. J Pharmaceut Med Chem. 2019;5(1):41-46.

Abstract

A simple, economic, rapid, accurate and stability indicating RP-HPLC method was developed for the estimation of amount of of Dalfampridine in pure and tablet dosage form. The method was performed on Phenomenex C18 (125 X 4.6 mm, 5 µm) using the mobile phase composed of buffer (0.01M sodium acetate pH 4.5): methanol in the ratio of 60:40 v/v. Th flow rate was maintained at 0.8 mL/min. The retention time for Dalfampridine was found to be 1.713 min. The method was found to be linear in the range of 5-25 µg/mL and the regression equation was found to be y=14691x-12844. For intra- and inter-day precision the %RSD for Dalfampridine was found to be 0.218 and 0.622%. Percentage mean recovery was found to be 98.36%. LOD and LOQ values obtained for Dalfampridine were found to be 0.107 µg/mL and 0.323 µg/mL respectively. Acid, alkali, oxidative, thermal and neutral degradation studies were performed. The results are analysed statistically and are found to be satisfactory. Hence this method can be routinely applicable for analysis of Dalfampridine in pure and tablet dosage form.

Keywords: Dalfampridine, RP-HPLC, Recovery, Dosage form.

Introduction

Dalfampridine (Fig. 1), is a potassium channel blocker prescribed for the treatment of multiple sclerosis. It is chemically pyiridine 4-amine or 4-Amino pyridine. It is also useful as an antagonist or non-depolarising neuro muscular blocking agents such as d-tubocurarine, gallamine, pancuroniun. Dalfampridine (DFP) which acts as at central and peripheral nervous system enhances conduction in demylinated axons and improve walking ability of multiple sclerosis patients [1]. It strengthens brain signals through the nerves that have been damaged by multiple sclerosis [2]. The use of Dalfampridine is to stimulate the demylinated axons that are exposed in multiple sclerosis patients.

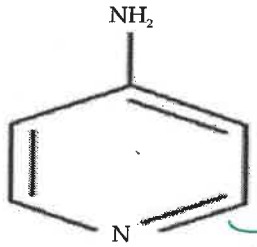

Fig. 1: Structure of Dalfampridine

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RP-HPLC Method Development and Validation for Estimation of Dalfampridine in Pure and Tablet Dosage Form

T. Prasanthi[1], A. Lakshmana Rao[2], Shabana Begum[3], S. Tejaswini[4], T. Krishna[5], TNSD Prathima[6]

[1]Associate Professor, [2]Professor & Principal, [3-6]Students, Department of Pharmaceutical Analysis, V.V. Institute of Pharmaceutical Sciences, Gudlavalleru, Krishna, Andhra Pradesh 521356, India.

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Abstract

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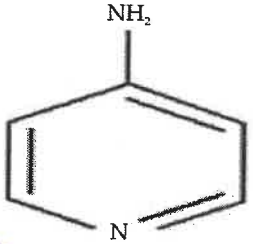

Fig. 1: Structure of Dalfampridine

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Research Article

DEVELOPMENT AND VALIDATION OF HPTLC METHOD FOR THE ANALYSIS OF TOLPERISONE HYDROCHLORIDE IN PHARMACEUTICAL DOSAGE FORM

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Keywords:
Tolperisone, HPTLC, Formulation, Estimation.

ABSTRACT

A simple, sensitive, rapid and precise high performance thin layer chromatographic method has been developed and validated for the estimation of Tolperisone hydrochloride in bulk and pharmaceutical dosage form. The stationary phase used was silica gel precoated aluminum plate $60F_{254}$ plates. The mobile phase used was a mixture of chloroform:acetone:toluene (6:2:2, v/v/v). The detection of spots was carried out at 265 nm. The method was validated in terms of specificity, linearity, precision and accuracy. The calibration curve was found to be linear between 50-600 ng/band. The developed method was subjected for forced degradation studies like acid, alkali, peroxide and thermal stress conditions were performed as per ICH guidelines. The proposed method was suitable for routine quality control analysis of Tolperisone hydrochloride in bulk and pharmaceutical formulation.

INTRODUCTION

Tolperisone hydrochloride (Fig. 1) is a skeletal muscle relaxant, acts at the level of spinal cord by blocking sodium channels and calcium channels [1-2]. Chemically it is 2-methyl-1-(4-methylphenyl)-3-(1-piperidinyl)-1-propanone hydrochloride [3]. Tolperisone hydrochloride exerts its spinal reflex inhibitory action predominantly via pre-synaptic inhibition of the transmitter release from the primary afferent endings via combined action on voltage-gated sodium and calcium channels [4]. Tolperisone hydrochloride increases the blood supply to skeletal muscle and antinociceptive activity against thermal stimulation that is likely to be attributed to its local anesthetic action [5].

Literature survey revealed that few HPTLC methods [6-7] were reported for the estimation of Tolperisone hydrochloride. Hence the objective of this method is to develop and validate a simple, precise and rapid HPTLC method in accordance with ICH guidelines [8-9] for the estimation of Tolperisone hydrochloride in bulk sample and its pharmaceutical formulation.

EXPERIMENTAL

Instrumentation

To develop a high performance thin layer chromatographic method for quantitative determination of Tolperisone hydrochloride using computerized Camag HPTLC system (Camag, Muttenz, Switzerland) consisting of a Camag 100 microlitre sample syringe (Hamilton, Bonded, Switzerland) on silica gel precoated aluminum plate $60F_{254}$ plates, [20 m × 20cm width 200µm thickness; E. Merck, Darmstadt, Germany] using a Camag Linomat V (Switzerland) sample applicator. Densitometric scanning was performed using a Camag TLC scanner III in the reflectance absorbance mode at 265 nm and operated by CATS software (V 3.15, Camag). The source of radiation used was deuterium lamp emitting a continuous UV spectrum between 190 nm and 400 nm. A Camag glass twin-trough development chamber, different size pipettes, volumetric flasks, measuring cylinders, micro syringes and ruler were used.

Chemicals and solvents

The reference samples of Tolperisone hydrochloride was obtained as gift sample from Spectrum Pharma Research Solutions, Hyderabad, India. Commercially available tablet formulation claimed to contain 150 mg of Tolperisone hydrochloride was purchased from local market. Chloroform, acetone and toluene purchased from Merck Chemicals, Mumbai, India.