Phone : 08514 - 276211, 276212
Fax : 08514 - 276213

Email : srcp07hc@gmail.com
srcn07hc@yahoo.com
Web : www.srcpnandyal.edu.in

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3.3.1

Number of research papers per teacher in the journals notified on UGC care list during the last five years

(ACADEMIC YEAR 2020-21)

Phone : 08514 - 276211, 276212
Fax : 08514 - 276213

Email : srcp07hc@gmail.com
srcn07hc@yahoo.com
Web : www.srcpnandyal.edu.in

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Approved by AICTE & PCI, New Delhi - Affiliated to JNTUA, Anantapur
NH - 18, Nandyal, Kurnool District, Andhra Pradesh - 518501.

Research papers published per teacher in the Journals notified on UGC care list during AY 2020-21

S.No	Title of paper	Name of the author/s	Department of the teacher	Name of journal	Year of publication	ISSN number	Link to the recognition in UGC enlistment of the Journal /Digital Object Identifier (doi) number		
							Link to website of the Journal	Link to article / paper / abstract of the article	Is it listed in UGC Care list
1	Assessing Pharmacotherapeutic Management of Anemia in Various Stages of Chronic Kidney Disease and Post Renal Transplant Patients	Pradeep Battula	Pharmacy Practice	International Journal of Pharmaceutical Sciences and Research	2021	0975-8232; P-2320-5148	https://ijpsr.com/bft-article/assessing-pharmacotherapeutic-management-of-anemia-in-various-stages-of-chronic-kidney-disease-and-post-renal-transplant-patients/	https://ijpsr.com/bft-article/assessing-pharmacotherapeutic-management-of-anemia-in-various-stages-of-chronic-kidney-disease-and-post-renal-transplant-patients/	Yes
2	A new cerebral ischemic injury model in rats, preventive effect of gallic acid and In silico approaches.	P Praveen Kumar	Pharmacology	Saudi Journal of Biological Sciences	2021	1319-562X	https://www.journals.elsevier.com/saudi-journal-of-biological-sciences	https://doi.org/10.1016/j.sjbs.2021.05.044	Yes
3	Cerebroprotective effect of Aloe Emodin: In silico and in vivo studies	P Praveen Kumar	Pharmacology	Saudi Journal of Biological Sciences	2021	1319-562X	https://www.journals.elsevier.com/saudi-journal-of-	https://doi.org/10.1016/j.sjbs.2021.09.077	Yes

Principal
Santhiram College of Pharmacy
NH-40, NANDYAL

Phone : 08514 - 276211, 276212
Fax : 08514 - 276213

Email : srcp07hc@gmail.com
srcn07hc@yahoo.com
Web : www.srcpnandyal.edu.in

SANTHIRAM COLLEGE OF PHARMACY

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NH - 18, Nandyal, Kurnool District, Andhra Pradesh - 518501.

							biological-sciences		
4	A rapid RP-HPLC method for the simultaneous estimation of Ivacaftor and Tezacaftor and in silico study of their metabolitic products	P Praveen Kumar	Pharmacology	Future Journal of Pharmaceutical Sciences	2021	2314-7253	https://fjps.springeropen.com/about	https://doi.org/10.1186/s43094-021-00254-y	Web of science
5	Development of Imidazoline-2-one Derivatives as Potential Antifungal and Anthelminthic Agents: in silico and in vitro Evaluation	Venu Simham	Pharmaceutical Chemistry	Indian Journal of Heterocyclic Chemistry	2021	0971-1627	https://connectjournals.com/	https://connectjournals.com/toc2.php?abstract=3408803H_13_IJHC_3874_423-433a.pdf&&bookmark=CJ-001644&&issue_id=03&&yaer=2020	Yes
6	Determination of Valacyclovir Hydrochloride in Pure and Pharmaceutical Dosage forms by Chromatography	N.Madana Gopal,	Pharmaceutical Analysis	Journal of Xidian University	2021	1001-2400	http://xadzkjdx.cn/	http://xadzkjdx.cn/Volume-15-Issue-12-December-21/	yes
7	Formulation and Evaluation of Fast Dissolving Buccal Patches of Tenofovir Disoproxil Fumarate	D. Maheswara Reddy	Pharmaceutics	Research J. Pharm. and Tech	2021	0974-360X	https://www.rjptonline.org/	https://www.rjptonline.org/HTMLPaper.aspx?Journal=Research%20Journal%20of%20Pharmacy%20and%20Te	scopus

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Principal
Santhiram College of Pharmacy
NH-40, NANDYAL

Phone : 08514 - 276211, 276212
Fax : 08514 - 276213

Email : srcp07hc@gmail.com
srcn07hc@yahoo.com
Web : www.srcpnandyal.edu.in

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								chnology;PID=2021-14-1-39	
8	Development and In-Vitro Characterization of Sustained Floating Hollow Microspheres Containing Labetalol Hcl for the Treatment of Hypertension	D. Mahes wara Reddy	Pharmac eutics	International Journal of Pharmaceutic al Sciences and Research	2021	0975-8232	https://ijpsr.com/	https://ijpsr.com/bft-article/development-and-in-vitro-characterization-of-sustained-floating-hollow-microspheres-containing-labetalol-hcl-for-the-treatment-of-hypertension/?view=fulltext	web of science
9	Development and Evaluation of Mouth Dissolving Tablets of Montelukast sodium using co processed excipients	K. Samapa th Kumar	Pharmac eutics	Journal of Pharmaceutic al research International	2021	2231-2919	https://journaljpri.com/	https://journaljpri.com/index.php/JPRI/article/view/31271	Web of science
10	Formulation and Evaluation of Solid lipid nanoparticles of Ethanolic Extract of Allovera Leaf powder and its Neuropharmacological Effects in Mice	K. Samapa th Kumar	Pharmac eutics	High technology letters	2021	1006-6748	http://www.gjstx-e.cn/	http://www.gjstx-e.cn/gallery/30-feb2021.pdf	Scopus

Principal
Santhiram College of Pharmacy
NH-40, NANDYAL

Phone : 08514 - 276211, 276212
Fax : 08514 - 276213

Email : srcp07hc@gmail.com
srcn07hc@yahoo.com
Web : www.srcpnandyal.edu.in

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11	Extraction of clove oil by hydro distillation and to know the comparative diffusion study by using different polymers for the treatment of periodontitis	K. Samapath Kumar	Pharmaceutics	Journal of Xidian University	2021	1001-2400	http://xadzkjdx.cn/	https://drive.google.com/file/d/1qDeFO2hkpvOvmQGrSWi2ZhxwD-R9sjNh/view	Scopus
12	Stability Indicating Method Development and Validation for Estimation of Salbutamol Sulphate in Pure and its Tablet Dosage Form by Using RP-HPLC	Siva Sanker Reddy. L	Pharmaceutical Analysis	High Technology Letters	2021	1006-6748	http://www.gjstx-e.cn/	http://www.gjstx-e.cn/gallery/5-dec2021.pdf	Scopus
13	Characterization of Methyl and Ethyl Esters of Amino-Acids as Corneal Permeation Enhancers.	R.E.Ugandar	Pharmacy Practice	Malaysian Journal of Medicine and Health Sciences	2021	2636-9346	https://medic.upm.edu.my/upload/dokumen/20201230144248 13_MJMHS_0542.pdf	https://medic.upm.edu.my/upload/dokumen/20201230144248 13_MJMHS_0542.pdf	Scopus/ESCI/ISC, EBSCO host and Rubriq.
14	Evaluation Of Safety And Efficacy Of Selective Anti-Hypertensive Patients With Cardio Vascular Diseases At A Tertiary Care Hospital, India-An Observational Study.	R.E.Ugandar	Pharmacy Practice	Journal Of Pharmaceutical Research International	2021	2456-9119	https://journaljpri.com/index.php/JPRI/article/view/32629	https://doi.org/10.9734/jpri/2021/v33i44A32629	ESCI/Web of Science
15	Formulation and Evaluation of Quetiapine	R.E.Ugandar	Pharmacy Practice	High technology letters	2021	1006-6748	http://www.gjstx-e.cn/gallery/25-nov2021.pdf	https://doi.org/10.37896/HTL27.11/4624	YES/UGC CARE-

Principal
Santhiram College of Pharmacy
NH-18, NANDYAL

Phone : 08514 - 276211, 276212
Fax : 08514 - 276213

Email : srcp07hc@gmail.com
srcn07hc@yahoo.com
Web : www.srcpnandyal.edu.in

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	Fumarate Mouth Dissolving Tablets.								II/Scopus
16	Design,Development and Optimization of Acyclovir Transdermal Patches using 2 3 Factorial Design	R.E.Ugandar	Pharmacy Practice	High technology letters	2021	1006-6748	http://www.gjstx-e.cn/gallery/39-nov2021.pdf	https://doi.org/10.37896/HTL27.11/4638	YES/UGC CARE-II/Scopus
17	Formulation and evaluation of sustain release periodontal films containing erythromycin for periodontitis	R.E.Ugandar	Pharmacy Practice	High technology letters	2021	1006-6748	http://www.gjstx-e.cn/gallery/42-nov2021.pdf	https://doi.org/10.37896/HTL27.11/4641	YES/UGC CARE-II/Scopus
18	Design, Development and optimization of Labetalol Hydrochloride as pulsatile drug delivery system using central composite design	Y.Dastagiri Reddy	Pharmaceutics	High technology letters	2021	1006-6748	http://www.gjstx-e.cn/	http://www.gjstx-e.cn/gallery/17-dec2021.pdf	Scopus
19	Formulation and Evaluation of Effervescent Floating Tablets of Rioprostil	K.Pavankumar	Pharmaceutics	High technology letters	2021	1006-6748	http://www.gjstx-e.cn/gallery/26-nov2021.pdf	https://doi.org/10.37896/HTL27.11/4625	scopus
20	Formulation and Evaluation of colon targeted drug Delivery of Diloxanide furoate Tablets	K.Pavankumar	Pharmaceutics	Research J. Pharm. and Tech	2021	0974-360X	https://rjptonline.org/Home.aspx	https://doi: 10.52711/0974-360X.2021.01035	scopus

Principal
Santhiram College of Pharmacy
NH-40, NANDYAL

Phone : 08514 - 276211, 276212
Fax : 08514 - 276213

Email : srcp07hc@gmail.com
srcn07hc@yahoo.com
Web : www.srcpnandyal.edu.in

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	using pH Dependent Polymers								
21	Optimization, Development, Formulation of Lornoxicam Oral Dispersible Tablets using Central composite Experimental Design	K.Pavankumar	Pharmaceutics	Advances in BioResearch	2021	2277-1573	http://www.soeagra.com/abr.html	DOI: 10.15515/abr.0976-4585.12.4.249256	web of science
22	A Prospective Observational Study on Evaluation ofTherapeutic Efficacy of Antiplatelets in Coronary Artery Disease with Percutaneous Transluminal Coronary Angioplasty	Dr.C.Bhrgava Reddy	Pharmacy Practice	Journal of Pharmaceutical Research International	2021	2456-9119	https://journaljpri.com/	https://journaljpri.com/	Web of science ESCI
23	A Case Report on Coarctation of the Aorta	Dr.C.Bhrgava Reddy	Pharmacy Practice	International Journal of clinical pharmacokinetics and Medical sciences	2021	2583-0953	https://pharmasprings.com/ijcpms/	https://pharmasprings.com/ijcpms/	UGC
24	Method Development and validation for estimation of related substances in	B. Moham	Pharmaceutical analysis	Research journal of pharmacy	2021	0974-360X	https://www.rjptonline.org/Issues.aspx	https://rjptonline.org/search.aspx	Scopus

Principal
Santhiram College of Pharmacy
NH-40, NANDYAL

Phone : 08514 - 276211, 276212
Fax : 08514 - 276213

Email : srcp07hc@gmail.com
srcn07hc@yahoo.com
Web : www.srcpnandyal.edu.in

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	tilorone dihydrochloride using RP-HPLC	med Ishaq		and technology					
25	Analytical characterization of biomarkers in an optimized novel antidiabetic polyherbal formulation using high-performance thin-layer chromatography and liquid chromatography with tandem mass spectrometry	B. Mohammed Ishaq	Pharmaceutical analysis	Egyptian Pharmaceutical Journal	2021	1687-4315 (print), 2090-9853 (Online)	https://www.epj.eg.net	https://www.epj.eg.net/article.asp?issn=1687-4315;year=2021;volume=20;issue=4;spage=329;epage=338;aulast=Jayaraju	scopus
26	Evaluation of Antidiabetic Activity of a Novel Polyherbal Preparationagainst Streptozotocin Induced Diabetes Rat Model	B. Mohammed Ishaq	Pharmaceutical analysis	Journal of Pharmaceutical Research International	2021	2456-9119	https://journaljpri.com/index.php/JPRI	https://journaljpri.com/index.php/JPRI/article/view/31470	scopus

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ASSESSING PHARMACOTHERAPEUTIC MANAGEMENT OF ANEMIA IN VARIOUS STAGES OF CHRONIC KIDNEY DISEASE AND POST RENAL TRANSPLANT PATIENTS

Pradeep Battula [*1], P. Komala Priya [2], K. Nikitha [2], A. Pooja [2], M. Geervani [2], V. Siva Kumar [3] and Navaneetha Krishnan Subramanian [2]

Department of Pharmacy Practice [1], Santhiram College of Pharmacy, Nandyal - 518112, Andhra Pradesh, India.

Department of Pharmacy Practice [2], Sree Vidyanikethan College of Pharmacy, Tirupati - 517102, Andhra Pradesh, India.

Department of Nephrology [3], Sri Venkateswara Institute of Medical Sciences, Tirupati - 517507, Andhra Pradesh, India.

Keywords:

Chronic kidney disease, Anemia, SES, Karnofsky performance scale index, Transplantation, Dialysis

Correspondence to Author:
Dr. Battula Pradeep

Associate Professor,
Department of Pharmacy Practice,
Santhiram College of Pharmacy,
Nandyal - 518112, Andhra Pradesh,
India.

E-mail: doctorbattulapradeep@gmail.com

ABSTRACT: Introduction: Anemia in CKD occurs when the kidneys are damaged or diseased. They cannot make enough EPO, which stimulates the bone marrow to produce RBC. It is associated with increased cardiovascular diseases, hospitalization, reduced quality of life, cognitive impairment, and mortality. **Materials and Methods:** A prospective observational study was conducted on CKD patients. Demographic details, treatment information, SES, and performance of daily activities were collected from the patients. Anemia was confirmed in patients by observing laboratory investigations, SES was collected by using the Modified Kuppuswamy scale, and the performance of patients for the treatment was analyzed by using the Karnofsky performance index. **Results:** The majority of the patients affected with anemia belong to UL Class. The performance of patients was improved as well as an increase in hemoglobin levels and decreases in Serum Creatinine levels were observed. P-value calculated for Haemoglobin, and serum creatinine was < 0.0001, which indicates the treatment was statistically significant. **Conclusion:** The pharmacotherapeutic treatment prescribed for anemia in various categories of CKD patient's shows significant improvement in the levels of Haemoglobin and serum creatinine.

INTRODUCTION: Chronic kidney disease is a multifactorial disorder that is continuously increasing worldwide [1]. It is characterized by kidney damage or dysfunction as well as an increased risk of cardiovascular disease [2].

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Anemia is defined as Hemoglobin (Hb) level less than 13.5 g/dl for men and less than 12.0 g/dl for women [3]. Anemia is one of the complications in CKD, which develops gradually and increases in severity as kidney disease progresses [4].

The major causes of anemia in CKD patients are Iron and erythropoietin deficiencies and hypo-responsiveness to the actions of erythropoietin. Other causes for anemia are decreased Half-life of RBC, blood loss, Nutritional deficiency, inflammation, erythropoiesis Inhibition which occurs due to the accumulation of uremic toxins [5].

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Original article

A new cerebral ischemic injury model in rats, preventive effect of gallic acid and *in silico* approaches

P. Praveen Kumar [a,*], Madhuri D. [b], L. Siva Sankar Reddy [a], Y. Dastagiri Reddy [a], G. Somasekhar [c], N.V.L. Sirisha [d], K. Nagaraju [e], M.S. Shouib [b], A.S. Rizwaan [b]

[a] Santhiram College of Pharmacy, Nandyal, Kurnool, Andhra Pradesh, India
[b] Creative Educational Societys College of Pharmacy, Kurnool, Andhra Pradesh, India
[c] SKU College of Pharmaceutical Sciences, Anantapur, Andhra Pradesh, India
[d] Nitte College of Pharmaceutical Sciences, Banglaore, Karnataka, India
[e] C.R Reddy College of Pharmacy, Eluru, West Godavari, Andhra Pradesh, India

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Antioxidants
Inflammatory mediators

ABSTRACT

Current study was designed multiple occlusions and reperfusion of bilateral carotid arteries induced cerebral injury model and evaluated the protective effect of gallic acid on it. *In silico* study was involved to study gallic acid binding affinity on cerebrotonic proteins compared with standard drugs using *Autodoc vina tool*. Cerebral ischemia was induced by occlusion of bilateral common carotid arteries for 10 mins followed by 10 reperfusions (1 cycle), cycle was continued to 3 cycles (MO/RCA), then pathological changes were observed by estimation of brain antioxidants as superoxide dismutase, glutathione, catalase, oxidants like malonaldehyde, cerebral infarction area, histopathology, and study gallic acid treatment against cerebral injury. Gallic acid exhibited a strong binding affinity on targeted cerebrotoxic proteins. MO/RCA rat brain antioxidant levels were significantly decreased and increased MDA levels ($p < 0.0001$), Infarction size compared to sham rats. Gallic acid treatment rat brain MDA levels significantly decreased ($p < 0.4476$) and increased SOD ($p < 0.0001$), CAT ($p < 0.0001$), GSH ($p < 0.0001$), cerebral infarction area when compared to MO/RCA group. Developed model showed significant cerebral ischemic injury in rats, injury was ameliorated by Gallic acid treatment and in silico approaches also inhibit the cerebrotoxic protein function by targeting on active sites.

1. Introduction

Throughout the world, Currently Ischaemic stroke (IS) is a cerebrovascular disease with high range of severity in morbidity and mortality (Feigin et al., 2016). The occurrence of this disease is of 2 varieties i.e. focal & global. When the amount of blood flow is less or decrease in flow of blood to specific regions of brain-embolic middle cerebral artery occlusion (MCAO) is known as Focal ischemia. global ischemia happens when cerebral blood flow (CBF) is reduced throughout the parts of brain which in turn leads to cardiac arrest (Smith, 2004; Traystman, 2003). The tissue damage occurs when there is a back flow of blood to the tissues, Cerebral ischemia–reperfusion injury (CIRI) which is very common in ischemic stroke. CIRI persuades oxidative stress which in turn triggers neuronal loss and cognitive impairment, circulation regeneration results in inflammation, and harmful oxidation effects (Ritzel et al., 2015), hence inflammatory agents play a key role in damage of ischemic brain tissue (Liu et al., 2018) along with antioxidant enzymes to modulate and provoke neuronal cell defence against toxic reactive oxygen species (ROS) (Ding et al., 2015; Farrell-Dillon et al., 2017) with this justification antioxidants have been advised in vitro and in vivo for a desirable pursuit for CIRI therapy, as the crucial role was played by oxidative stress. Globally 11% of total deaths are happened due to stroke when compared to all life-threatening diseases, especially in India the main cause for death is stroke according to the epidemiological statistics (Banerjee and Das, 2016; Kamalakannan et al., 2017) and cerebrovascular diseases are considered the second most common cause of expected deaths in 2020 (Huang and McNamara, 2004).

* Corresponding author at: Head of the Department of Pharmacology, Santhiram College of Pharmacy, Nandyal, Kurnool, Andhra Pradesh, India.
E-mail address: praveenpharmaco@gmail.com (P. Praveen Kumar).

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Original article

Cerebroprotective effect of Aloe Emodin: *In silico* and *in vivo* studies

Praveen Kumar Pasala [a], Rizwaan Abbas Shaik [b], Mithun Rudrapal [c,*], Johra Khan [d,e], Mohammad A. Alaidarous [d,e], Shubham Jagdish Khairnar [f], Atul R. Bendale [g], Vaishali D. Naphade [h,i], Ranjan Kumar Sahoo [j], James H. Zothantluanga [k], Sanjay G. Walode [c]

[a] Santhiram College of Pharmacy, Nandyal 518501, Andhra Pradesh, India
[b] Creative Educational Society's College of Pharmacy, Kurnool 518003, Andhra Pradesh, India
[c] Rasiklal M. Dhariwal Institute of Pharmaceutical Education & Research, Pune 411019, Maharashtra, India
[d] Department of Medical Laboratory Sciences, College of Applied Medical Sciences, Majmaah University, Al Majmaah 11952, Saudi Arabia
[e] Health and Basic Sciences Research Center, Majmaah University, Al Majmaah 11952, Saudi Arabia
[f] MET Institute of Pharmacy, Bhujbal Knowledge City, Nashik 422003, Maharashtra, India
[g] Sandip Institute of Pharmaceutical Sciences, Nashik 422213, Maharashtra, India
[h] Department of Pharmacy, Oriental University, Indore 453555, Madhya Pradesh, India
[i] School of Pharmaceutical Sciences, Sandip University, Nashik 422213, Maharashtra, India
[j] School of Pharmacy and Life Sciences, Centurion University of Technology and Management, Bhubaneswar 752050, Odisha, India
[k] Department of Pharmaceutical Sciences, Faculty of Science and Engineering, Dibrugarh University, Dibrugarh 786004, Assam, India

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Antioxidants

ABSTRACT

This study involved cerebroprotective potential of aloe emodin (AE) by *in silico* molecular docking analysis against various cerebrotoxic proteins followed by *in vivo* activity on multiple occlusions and reperfusion of bilateral carotid arteries (MO/RCA) induced cerebral injury in experimental rats. Molecular docking studies were carried out to evaluate the binding affinity (or binding interaction) between AE and various proteins involved in apoptosis such as caspase-3 (CASP3) and Bcl-2-associated X protein (BAX), and proteins involved in inflammation such as interleukin-6 (IL-6), tumor necrosis factor α (TNF α), nitric oxide synthase (NOS), acid-sensing ion channel (ASIC) and glutamate receptor (GR) involved in cerebral stroke, and results were compared with that of standard drugs, minocycline, quercetin, and memantine. Cerebral ischemic reperfusion induced by MO/RCA was assessed for 10 mins reperfusion period as one cycle, and the experiment was conducted for up to 3 cycles in rats. After completion of 3 cycles, the rats were subjected to ethically acceptable animal euthanasia followed by isolation of the brains which were studied for the size of cerebral infarction, and biochemical parameters such as glutathione (GSH), malondialdehyde (MDA), catalase (CAT) were estimated from the brain homogenate. Further, histological studies were done to study neuronal contact. Results of molecular docking indicated that the AE exhibited interaction with active sites of cerebrotoxic proteins usually involved in protein functions or cerebrotoxicity. Biochemical results showed that in the untreated brain, MDA levels increased significantly, and decreased GSH and CAT levels were observed when compared to MO/RCA group, while treated rats showed a decrease in the levels of MDA and an increase in GSH and CAT levels as compared to MO/RCA rats. In comparison with sham rats and normal rats, histopathological analysis revealed neuronal damage in MO/RCA surgery rats which manifested as decreased intact neurons. However, treatment with AE 50 mg/kg b.wt. restored contact between neuronal cells. It can be concluded that AE showed cerebroprotective effect on RO/RCA with promising inhibition of cerebrotoxic proteins (apoptotic and

* Corresponding author.
E-mail addresses: praveenpharmaco@gmail.com (P.K. Pasala), rsmrpal@gmail.com (M. Rudrapal), j.khan@mu.edu.sa (J. Khan), m.alaidarous@mu.edu.sa (M.A. Alaidarous), sunnykhairnar62@gmail.com (S. Jagdish Khairnar), atulbendale123@gmail.com (A.R. Bendale), vaishalinaphade587@gmail.com (V.D. Naphade), ranjankumar.sahoo@cutm.ac.in (R. Kumar Sahoo), jameshztta@gmail.com (J.H. Zothantluanga), sanjuwalode@rediffmail.com (S.G. Walode).
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Future Journal of Pharmaceutical Sciences

RESEARCH Open Access

A rapid RP-HPLC method for the simultaneous estimation of Ivacaftor and Tezacaftor and in silico study of their metabolitic products

Madhuri Donakonda[1*], Srija Indrakanti[1], Praveen Kumar Pasala[2], Malleswari Desari[1] and Shireesha Kammari[1]

Abstract

Background: This study was designed to develop a reliable method for estimation of Ivacaftor and Tezacaftor in pure and its pharmaceutical dosage form by RP-HPLC in human plasma. Molecular docking studies were carried out and the results were visualized using PyMol and Discovery studio visualizer (Discovery studio visualizer ver. 2.5). The pharmacokinetic properties such as Swiss ADME and pKCSM of the Ivacaftor and its metabolites Ivacaftor M1, M6 and Tezacaftor and metabolites Tezacaftor M1, M2 were predicted. In admetSAR, web-based query tools incorporating a molecular built-in interface enable the database to be queried by SMILES.

Results: A simple, linear, precise, and accurate RP-HPLC method was developed and validated for the determination of Ivacaftor (IVA) and Tezacaftor (TEZ) in human plasma. Chromatographic separation was achieved isocratically on Inspire C18, (4.6 × 250 mm, 5 µm) column at 30 °C. Mobile phase consisting of methanol and 0.05% formic acid in ratio of 95:5 with flow rate of 1 mL/min with injection volume 20 µl detector used is PDA at 235 nm. The developed method was validated according to ICH guidelines and found to be linearity range was found to be for TEZ (10–50 µg/mL) and IVA (15–75 µg/mL). IVA and TEZ drugs and its metabolites were retrieved from the PubChem database and the 2D chemical structures were generated from SMILES notation by using the Chemsketch Software. The structure was viewed using Swiss-PDB Viewer to form a better understanding of the molecule for toxicity and biological activity prediction.

Conclusion: The results obtained by the proposed method from validation parameters and from assay confirmed that the determination of Tezacaftor (TEZ) and Ivacaftor (IVA) in their combined dosage form in human plasma was sensitive and selective method. In silico study has revealed that IVA and its metabolites IVA M1, IVA M6 are according to Lipinski rule. The oral bioactivity of IVA was found to be more when compared to its metabolites (Molinspiration) and TEZ and its metabolites TEZ M1, TEZ M2 even though they have the molecular weight > 500, but all other parameters from Molinspiration revealed better oral bioactivity of TEZ M2. Validation of the developed isocratic RP-HPLC procedure revealed that, regardless of how the sample was purified, the method was characterized by good linearity, sensitivity, reproducibility, specificity, and low values of LOD (0.090 µg/mL) and LOQ (0.275 µg/mL). From the in silico docking results, it is quite evident that metabolites of TEZ and IVA have the great potential against cystic fibrosis.

Keywords: Tezacaftor, Ivacaftor, In silico docking, Human plasma, RP-HPLC metabolites

* Correspondence: madhurisatyasai@gmail.com
[1]Department of Pharmaceutical Analysis and Quality Assurance, CES College of Pharmacy, Chinnatekur, NH-7, Kurnool, Andhra Pradesh 518218, India
Full list of author information is available at the end of the article

molecule pharmacokinetic and toxicity; GPCR: G-protein coupled receptor; ICM: Ion channel modulators; NRL: Nuclear receptor ligand; TPSA: Topographical polar surface area; IPA: Isopropyl alcohol; SD: Standard deviation; RSD: Relative standard deviation; RT: Retention time

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Authors' contributions
MD: plan and design of work. SI: experimental procedure for RP-HPLC method development and validation. PP: in silico docking studies and results of docking evaluation. M.R.D: experimental procedure for RP-HPLC method development and validation. S.K: in silico docking. All the authors have read and approved the final manuscript.

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Author details
[1]Department of Pharmaceutical Analysis and Quality Assurance, CES College of Pharmacy, Chinnatekur, NH-7, Kurnool, Andhra Pradesh 518218, India. [2]Department of Pharmacology, Santhiram College of Pharmacy, Kurnool, Andhra Pradesh 518501, India.

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Development of Imidazoline-2-one Derivatives as Potential Antifungal and Anthelminthic Agents: *in silico* and *in vitro* Evaluation

Vijaya Jyothi Mallela[1], Naresh Babu Chilamakuru[1], Shakir Basha Shaik[2], Venu Simham[3], Ramalingam Peraman[1], Triveni Singirisetty[1]*

[1]Molecular Modelling and Drug Discovery Division, RERDS – Centre for Pharmaceutical Research, Raghavendra Institute of Pharmaceutical Education and Research – Autonomous, Ananthapuramu, Andhra Pradesh, India
[2]Department of Pharmaceutical Quality Assurance, Raghavendra Institute of Pharmaceutical Education and Research, Ananthapuramu, Andhra Pradesh, India
[3]Department of Pharmaceutical Chemistry, Santhiram college of Pharmacy, Nandyal, Kurnool, Andhra Pradesh, India

ABSTRACT Based on appropriate values of synthetic accessibility concerning from ADMET properties and docking scores by docking against proteins 3OZU and 1OJ0, a series of 4,5-diphenyl-1*H*-imidazol-2-ones ($\mathbf{I}_{1\text{-}15}$) were synthesized. The key intermediate, 2-hydroxy-1,2-disubstitutedethanones ($\mathbf{E}_{1\text{-}15}$) were prepared by benzoin condensation using 2:1 ratio of aromatic aldehydes and thiamine in the presence of alkali. Further, these cyclized ethanones ($\mathbf{E}_{1\text{-}15}$) were treated with urea to yield 4,5-diphenyl-1*H*-imidazol-2-one derivatives ($\mathbf{I}_{1\text{-}15}$) and were characterized by IR, ^{1}H NMR, Mass spectra, and CHNO analysis. The synthesized compounds were screened for their anthelmintic potential on *Pheretima Posthuma* along with standard albendazole, and antifungal activity (minimum inhibitory concentration method) on *Candida albicans* and *Aspergillus niger* along with standard miconazole. The results revealed that among all the tested compounds $\mathbf{I}_3$, $\mathbf{I}_4$, and $\mathbf{I}_7$ show considerable synthetic accessibility, docking scores, anthelminthic, and antifungal activity.

KEYWORDS Molecular docking, ADMET studies, Imidazol-2-ones, Anthelmintic activity, Antifungal activity.

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INTRODUCTION

At present, several drugs are available for treating microbial infections, but due to the microbial resistance by microorganisms they are becoming less useful. So always there is an enormous necessity for the development of novel agents toward microbes to incredulous resistance and side effects.[1] New bioactive molecules development factually involves mostly with nitrogen-containing heterocyclic compounds owing to their wide spectrum and quite, a lot of biological targets.[2] Among nitrogen-containing heterocycles, azole containing pharmacophore occupies an influential role in the development of novel bioactive compounds. Imidazole scaffolds have a broad spectrum of activities, including antifungal, analgesic, pesticidal, antiparasitic, anti-inflammatory, anticancer, anticonvulsant, antiviral, cytotoxic, and antiarrhythmic activities.[3-7] As per the World Health Organization (WHO), soil-transmitted helminth infections are more prevailing and produce symptoms such as diarrhea, abdominal pain (intestinal manifestations), general malaise, and weakness. The latest estimates, specify that more than 880 million children need treatment for these parasites.[8] Even though helminth parasites are a noteworthy public health, the advance to treat helminthiasis is with new pharmacological agents has been delayed from decades, the existing anthelmintic is narrow.[9] Tribendimidine seems to be the only drug reported for anthelmintic from the past three decades.[10,11] This clear

*Corresponding author: E-mail: s.trivenipharma@gmail.com

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Determination of Valacyclovir Hydrochloride in Pure and Pharmaceutical Dosage forms by Chromatography

N.Madana Gopal*, A. Sireesha Bai, L.Siva sanker Reddy, D.China Babu, C.Madhusudan Chetty.
Department of Pharmaceutical Analysis, Santhiram college of Pharmacy, Nandyal, Andhra Pradesh, India

Abstract: Simple, precise and sensitive chromatographic method was developed for the determination of Valacyclovir Hydrochloride in pure and pharmaceutical dosage forms. Chromatogram was run through Shimadzu Shim-pack GIST C18 (250 × 4.6 mm, 5µ) column at a flow rate of 0.8 mL/min and Methanol: phosphoric acid (pH 4.2) (65:35%) was used in this method. Column oven temperature was maintained at 30 °C and the working wavelength was selected at 254 nm. Beer-Lambert's law revealed good correlation in the concentration range of 25-150 µg/mL. The retention time was 2.89 with RSD for interday precision, intraday Precision was 0.78 %, 0.17. The developed method was successfully applied to the determination of Valacyclovir Hydrochloride in commercially available dosage forms. Statistical comparison of the results showed insignificant difference between the proposed method and reference method. The proposed methods offered the advantages of simplicity and economy that can be applied without the need for expensive instrumentation and reagents in quality control analysis.

Keywords – ***HPLC, Valacyclovir Hydrochloride, method development, validation, formulation***

I. INTRODUCTION

Valacyclovir Hydrochloride (Figure-1) is (2-(6-hydroxy-2-imino-3,9-dihydro-2H-purin-9-yl)methoxy ethyl (2S)-2-amino-3-methylbutanoate hydrochloride)[11] belongs to Antiviral category. Basically, it is a Antiviral agent and act by convert to acyclovir to triphosphate form Acyclovir triphosphate (ACV-TP),again it inhibits viral DNA polymerase, incorporates into and terminates the growing viral DNA chain to inactivates viral DNA polymerase[12].It is used for herpes viruses, cold sores and shingles.

A through literature survey revealed that various analytical and few bioanalytical methods [5,8] were published to describe the quantification of Valacyclovir Hydrochloride in active pharmaceutical ingredient and pharmaceutical dosage forms to study the purity, degradation products by UV-Spectrophotometric method[1-3] and HPLC[4,6,7-10]. Our literature survey also revealed simple, precise, good resolution and sensitive method lower quantification and identification concentration for these principle components within the short period of time with the good resolution and peak shape. We attempted to develop a method with all those prerequisites and validated our method .The developed method succeeded in the quantification.

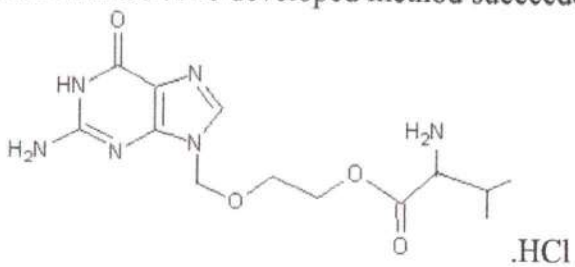

Figure 1: Structure of Valacyclovir Hydrochloride

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RESEARCH ARTICLE

Formulation and Evaluation of Fast Dissolving Buccal Patches of Tenofovir Disoproxil Fumarate

D. Maheswara Reddy*, C. Madhusudhana Chetty, Y. Dastagiri Reddy, P. Komali, B. Sri Divya, S. Sandhya Rani

Santhiram College of Pharmacy, Nandyal 518501, AP, India.
*Corresponding Author E-mail: **dagadamahesh@gmail.com**

ABSTRACT:

Background and objectives: Tenofovir disoproxil fumarate is a anti-retroviral agent. It is used in the treatment of HIV-1 infection in adults and pediatric patients of 2 years of age and older. It is also indicated for the treatment of chronic hepatitis-B in adults and pediatric patients 12 years of age and older. The present work is designed to prepare and evaluate mucoadhesive buccal film of Tenofovir disoproxil fumarate as a novel form of fast releasing dosage form. The objective of this study was to develop oral drug delivery system in the form of fast dissolving film which overcomes first pass metabolism and the drug achieve to specific site, for greater therapeutic action. **Methods:** Buccal films of Tenofovir disoproxil fumarate were prepared by solvent casting method. The prepared films were evaluated for the various evaluation parameters like thickness, surface pH, weight uniformity, content uniformity, folding endurance, swelling index, in vitro drug release study. **Results:** All the formulations exhibited good results for physicochemical characterizations. In in vitro drug release study, the films exhibited fast release within 5 hours. The formulation F1 (containing HPMC3cps and croscarmellose) showed no irritant effect on buccal mucosa. It was revealed that Superdisintegrants composition had significant influence on drug release. Thus, conclusion can be made that stable dosage form can be developed for Tenofovir disoproxil fumarate for fast release by buccal patches.

KEYWORDS: Tenofovir disproxil fumarate, Buccal patches, Superdisintegrants, Hydroxy propyl methyl cellulose.

INTRODUCTION:

Oral route has been the commonly adopted and most convenient route for drug delivery. Oral route of administration has been received more attention in the pharmaceutical field because of the more flexibility in the designing of dosage form than drug delivery design for other routes, ease of administration as well as traditional belief that by oral administration the drug is well absorbed as the food stuffs that are ingested daily.[1]

The mucosa of the mouth is very different from the rest of the gastro intestinal tract and morphologically is more similar to skin.

Although the permeability of skin is widely regarded as poor, it is not generally appreciated that the oral mucosa lacks the good permeability demonstrated by the intestine.[2]

Tenofovir disoproxil fumarate, marketed by Gilead Sciences, belongs to a class of anti-retroviral drugs known as nucleoside analogue reverse transcriptase inhibitors (NRTI's), an enzyme crucial to viral production in HIV infected people. Tenofovir is indicated in combination with other anti-retroviral agents for the treatment of HIV-1 infection in adults and pediatric patients of 2 years of age and older. It is also indicated for the treatment of chronic hepatitis-B in adults and pediatric patients 12 years of age and older.[3,4,5]

MATERIALS:

Tenofovir disoproxil fumarate was obtained as gift sample from the Hetero drugs, Hyderabad. HPMC3cps, Superdisintegrants were obtained from Otto reagents,

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DEVELOPMENT AND *IN-VITRO* CHARACTERIZATION OF SUSTAINED FLOATING HOLLOW MICROSPHERES CONTAINING LABETALOL HCL FOR THE TREATMENT OF HYPERTENSION

D. Maheswara Reddy *, Y. Dastagiri Reddy, K. Sampath Kumar, P. Koushik Reddy and P. Santhi

Santhiram College of Pharmacy, Nandyal - 518112, Andhra Pradesh, India.

Keywords:

Floating hollow microspheres, Solvent evaporation techniques, Gastro retentive drug delivery system (GRDDS), Labetalol HCl

Correspondence to Author:
Mr. D. Maheswara Reddy

Associate Professor,
Department of Pharmaceutics,
Santhiram College of Pharmacy,
Nandyal - 518112, Andhra Pradesh,
India.

E-mail: dagadamahesh@gmail.com

ABSTRACT: Aim: The present work for the development and *in-vitro* evaluation of sustained floating hollow microspheres (SFHM). **Materials and methods:** Sustained floating hollow microspheres were prepared by means of HPMC K4M, ethylcellulose and sodium alginate in various concentrations by using the solvent evaporation method using dichloromethane as solvent. The floating hollow microspheres of Labetalol HCl were formulated by the solvent evaporation method. SFHM was characterized using surface morphology by scanning electron microscopy (SEM), buoyancy studies, *in-vitro* floating behavior, incorporation efficiency, drug loading, production yield *in-vitro* drug release, and drug release kinetics studies. **Results:** The mean particle size ranges from 74.36± 1.02 to 102.0 ± 2.87µm. The entrapment efficiency of the drug ranges between 74.23 ± 2.12 to 80.82 ± 2.23%. The drug loading varies between 105.8 ± 1.46 to 125.2 ± 1.36µg/mg. The prepared hollow microspheres are exhibit good flowability. The *in-vitro* studies show release up to 12 h. The release kinetics data showed the best fit to the non-fickian release (diffusion and swelling). **Conclusion:** The outcomes conclude that Labetalol HCl SFHM may represent to expected option for greater bioavailability and improve patient consistency.

INTRODUCTION: Drugs that might be easily held from the gastrointestinal tract and having a short half-life are cleared out quickly from the systemic circulation. To short these complications, oral controlled drug delivery dosages were preferred. They convey the drug slowed into the GIT and keep up a reliable medicine center in the serum for a more drawn-out time period. Attempt's to improve oral medicine bioavailability have been created about the pharmaceutical business.

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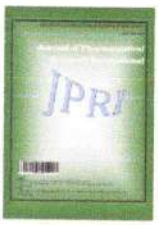
As the number and concoction, arranged assortment of prescriptions has extended, new strategies are needed to develop orally dynamic therapeutics. In this way, GRDDS, which improves the prolongation of the drug in the GIT and improve their bioavailability, has been developed [1].

One of the most potent approaches for achieving a prolonged and obvious medicine transport profile in the GI package is to control the GRDFs.

Increased blood pressure is related to a linear increase in the endanger of CV disease. Starting with BP of 115/75 mm Hg, every 20mmHg increase in SBP and/or every 10mmHg increase in DBP doubles the chance of demise due to stroke, coronary heart ailment, or different vascular diseases Disease [2].



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Development and Evaluation of Mouth Dissolving Tablets of Montelukast Sodium Using Co-processed Excipients

K. Sampath Kumar[1*], D. Maheswara Reddy[1], Y. Dastagiri Reddy[1], J. Balanarasimha Goud[1] and Abdul Basith[1]

[1]Santhiram College of Pharmacy, Nandyal, A. P. India.

Authors' contributions

This work was carried out in collaboration among all authors. Author KSK designed the study, wrote the first protocol and wrote the first draft of the manuscript. Authors DMR, YDR, JNG and AB managed the analyses of the study and review literature. All authors read and approved the final manuscript.

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ABSTRACT

Background: The concept of formulating ODT containing montelukast sodium offers an appropriate, practical approach to accomplish fast release of the drug. Absorption of these tablets takes place directly into the systemic circulation which bipass the hepatic first-pass metabolism of montelukast sodium which ultimately results in the improvement in the bioavailability.
Method: In the present study ODT tablets of montelukast sodium were prepared by using different Superdisintegrants like natural and synthetic (tulasi, hibiscus, orange peel powder, Ispaghula, banana peel powder, Crospovidone). Thirteen formulations were designed, using a two level of Superdisintegrants (minimum and maximum concentration) and employing two Superdisintegrants at a time by using the co-processed technique.
Results: No significant drug and excipients interaction was observed. The prepared tablets were evaluated by weight variation, thickness, hardness, friability, drug content uniformity, disintegration

**Corresponding author: E-mail: sampathkatakam@gmail.com;*

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FORMULATION AND EVALUATION OF SOLID LIPID NANOPARTICLES(SLNs) OF ETHANOLIC EXTRACT OF *ALOE VERA* LEAF POWDER AND ITS NEUROPHARMACOLOGICAL EFFECTS IN MICE

Corresponding Author: K. Sampath Kumar, M. Pharmacy(Ph.D)(Department of Pharmaceutics),Assoc.Professor, sampathkatakam@gmail.com

Co-Author: 1. B.V Ramana M.Pharm., (Ph.D) (Department of Pharmacology), Assoc.Professor,
2. N. Srinivas Reddy , M.Pharm., (Department of Pharmacognosy), Assoc.Professor.

3. D. Maheswar Reddy, M.Pharm.,(Ph.D)(Department of Pharmaceutics), Assoc.Professor.

4. S. Usha Rani, M. Pharmacy (Department of Pharmaceutics), raniusharani0024@gmail.com

ABSTRACT:

Solid lipid nanoparticles are typically spherical with an average diameter between 1 and 1000 nm. It is an alternative carrier system to tradition colloidal carriers, such as, emulsions, liposomes, and polymeric micro and nanoparticles. *Aloe Vera* (Aloe barbandensis Miller) , of liliaceous family is having high potential medicinal values and mostly preferred for the traditional medication. Ethanolic leaf extract of *Aloe vera*was prepared and it is formulated in the form of Solid Lipid Nanoparticles (SLNs).four formulations of SLNs were prepared (SLNs1-SLNs4) with varying percentages of steric acid (4% & 6% w/v) as a lipid, and two varying amounts of Ethanolic extract of *Aloe vera*leaf. All prepared formulations were subjected to *in-vitro*release studies, and *in-vivo* studies for neuropharmacological studies in mice.

KEY WORDS: Nanoparticles, Aloe Vera, Neuropharmacology, Ethanolic extract,

INTRODUCTION

Aloe Vera (Aloe barbandensis Miller) , of liliaceous family is having high potential medicinal values and mostly preferred for the traditional medication ,which originally found in Asian countries like, Pakistan ,Bangladesh ,India and in few parts of south African(1).So it is a tropical and subtropical succulent plant with lance shaped leaves along with jagged edges with sharp points(2).The plant contains flowers and fruits which contains numerous seeds. It contains active substances such as vitamins, enzymes, amino acids, lignin, saponins, minerals, anthraquinone glycosides, sugar, saccharide, fatty acids etc. (3). *Aloe vera* plant extract is affordable and cheap, in order to treat different types of diseases and conditions(4).According to WHO the fast growing disorder is type2 diabetes mellitus which have the prevalence to cause severe complications even disabilities ,where as an *Aloe vera* has shown significant results over Hypoglycemic condition(5).*Aloe vera* extract is used to treat type 2 Streptozocin induced diabetes mellitus which shown better effect than glimepiride by decreasing malondialdehyde and superoxide dismutase ,by increasing the blood glutathione. And also used to control the hypoglycemic effect with early metabolism in women, have significant effect by decreasing HbA1c levels. (6-7). Alloxan induced diabetes mellitus In Adult male Wister albino rats treated by *Aloe vera* extract which shown more activity than metformin (8-9). High molecular fractions of *Aloe vera* having more Hypoglycemic effect than Glibenclamide for the treatment of

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FORMULATION AND EVALUATION OF SOLID LIPID NANOPARTICLES(SLNs) OF ETHANOLIC EXTRACT OF *ALOE VERA* LEAF POWDER AND ITS NEUROPHARMACOLOGICAL EFFECTS IN MICE

Corresponding Author: K. Sampath Kumar, M. Pharmacy(Ph.D)(Department of Pharmaceutics),Assoc.Professor, sampathkatakam@gmail.com

Co-Author: 1. B.V Ramana M.Pharm., (Ph.D) (Department of Pharmacology), Assoc.Professor,
2. N. Srinivas Reddy , M.Pharm., (Department of Pharmacognosy), Assoc.Professor.

3. D. Maheswar Reddy, M.Pharm.,(Ph.D)(Department of Pharmaceutics), Assoc.Professor.

4. S. Usha Rani, M. Pharmacy (Department of Pharmaceutics), raniusharani0024@gmail.com

ABSTRACT:

Solid lipid nanoparticles are typically spherical with an average diameter between 1 and 1000 nm. It is an alternative carrier system to tradition colloidal carriers, such as, emulsions, liposomes, and polymeric micro and nanoparticles. *Aloe Vera* (Aloe barbandensis Miller) , of liliaceous family is having high potential medicinal values and mostly preferred for the traditional medication. Ethanolic leaf extract of *Aloe vera*was prepared and it is formulated in the form of Solid Lipid Nanoparticles (SLNs).four formulations of SLNs were prepared (SLNs1-SLNs4) with varying percentages of steric acid (4% & 6% w/v) as a lipid, and two varying amounts of Ethanolic extract of *Aloe vera*leaf. All prepared formulations were subjected to *in-vitro*release studies, and *in-vivo* studies for neuropharmacological studies in mice.

KEY WORDS: Nanoparticles, Aloe Vera, Neuropharmacology, Ethanolic extract,

INTRODUCTION

Aloe Vera (Aloe barbandensis Miller) , of liliaceous family is having high potential medicinal values and mostly preferred for the traditional medication ,which originally found in Asian countries like, Pakistan ,Bangladesh ,India and in few parts of south African(1).So it is a tropical and subtropical succulent plant with lance shaped leaves along with jagged edges with sharp points(2).The plant contains flowers and fruits which contains numerous seeds. It contains active substances such as vitamins, enzymes, amino acids, lignin, saponins, minerals, anthraquinone glycosides, sugar, saccharide, fatty acids etc. (3). *Aloe vera* plant extract is affordable and cheap, in order to treat different types of diseases and conditions(4).According to WHO the fast growing disorder is type2 diabetes mellitus which have the prevalence to cause severe complications even disabilities ,where as an *Aloe vera* has shown significant results over Hypoglycemic condition(5).*Aloe vera* extract is used to treat type 2 Streptozocin induced diabetes mellitus which shown better effect than glimepiride by decreasing malondialdehyde and superoxide dismutase ,by increasing the blood glutathione. And also used to control the hypoglycemic effect with early metabolism in women, have significant effect by decreasing HbA1c levels. (6-7). Alloxan induced diabetes mellitus In Adult male Wister albino rats treated by *Aloe vera* extract which shown more activity than metformin (8-9). High molecular fractions of *Aloe vera* having more Hypoglycemic effect than Glibenclamide for the treatment of

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Stability Indicating Method Development and Validation for Estimation of Salbutamol Sulphate in Pure and its Tablet Dosage Form by Using RP-HPLC

L. Siva Shankar Reddy*[1], SK.Ruksar[1], D.Chinababu[2], C. Madhusudhana Chetty[3], N. Madan Gopal[4]

Santhiram College of Pharmacy, Nandyal, Kurnool, AP, India

Co-Author

L.Sivashankar Reddy, Santhiram College of Pharmacy, Mail Id: shiva_s_rl@yahoo.co.in

ABSTRACT

Salbutamol comes under the category of anti- asthmatic and belongs to a class of drugs knows as bronchodilator, it is a model short acting ß2- receptor agonist used as a bronchodilator to manage asthma and other chronic obstructive airway diseases. The objective of this study was to develop a simple and fast stability indicating method for the determination of Salbutamol in bulk and tablets. Salbutamol was eluted on a Waters C18 Column with 250 mm × 4.6 mm i.d and 5 µm Particle size with a mobile phase of Methanol and HPLC Water (70:30) v/v in isocratic mode at a flow rate of 1.0 ml/min. The analyte was quantified using a 225 nm PDA detector. The chromatograms of Salbutamol obtained with this method showed a well resolved retention time at 2.98 min of its excipients and degradation products. The area of the peak with respect to the concentration calibration curves, which were linear from 2.5-15µg/ml, had a regression coefficient (r^2) greater than 0.999. Accuracy and precision have been determined and perfectly matched to the ICH standards. The study showed that the proposed RP-HPLC method was simple, fast, robust and reproducible, which can be used for the evaluation of the purity and stability of the drug without interference from excipients or decomposition products of active pharmaceutical ingredients.

Keywords: Salbutamol Sulphate, Methanol, HPLC Water

ORIGINAL ARTICLE

Characterization of Methyl and Ethyl Esters of Amino-Acids as Corneal Permeation Enhancers

Rajan Ethiraj Ugandar[1,4], Voleti Vijay Kumar[1], C.Madhusudhana Chetty[1], Dinesh Kumar Sharma[2], Kiran C Nilugal[3], Sandeep Poddar[4]

[1] Department of Pharmaceutics, Faculty of Pharmacy, Santhiram College of Pharmacy, Nandyal, 518501,Kurnool District, Andhra Pradesh, India.
[2] Department of Pharmaceutics, Faculty of Pharmacy, Himalayan Institute of Pharmacy and Research, Dehra Dun,248001, Uttara Khand, India
[3] Department of Pharmacology, School of Pharmacy, Management and Science University, Shah Alam,40100, Malaysia
[4] Lincoln University College, Petaling Jaya, 47301, Malaysia

ABSTRACT

Introduction: Amino acids are important role-playing components in the maintenance of the normal functions of parts of eye like retina and conjunctiva. In the current study the methyl and ethyl esters of amino acids such as lysine, phenyl alanine and valine were used to enhance the corneal permeation of ketorolac tromethamine. **Methods:** The amino-acid esters were coupled with the drug ketorolac tromethamine to obtain the test products and were characterized by various analytical techniques. The characterized test products were used to formulate the test ophthalmic solutions of Ketorolac tromethamine such as KPD-1, KPD-1A, KPD-2, KPD-2A, KPD-3 and KPD-3A with methyl and ethyl esters of corresponding amino-acids. These test products were subjected percentage corneal hydration and to permeation studies by using Franz diffusion cell mounted with freshly isolated goat cornea. **Results:** All the test results were compared with those of the standard Ketorolac tromethamine ophthalmic solution and observed that all the test solutions have exhibited less percentage corneal hydration and enhanced corneal permeation of ketorolac tromethamine. **Conclusion:** From all the results it can be concluded that the NonsteroidalAnti-Inflammatory Ketorolac has enhanced trans-corneal permeation and reduced corneal hydration when formulated with amino acid transporters by the pro-drug approach in ophthalmic solutions as the formulated pro-drugs have revealed high vitreal drug concentration.

Keywords: Amino-acid esters, Characterization, Permeation, Enhancer

Corresponding Author:
Rajan Ethiraj Ugandar, PhD
Email: reugandar@gmail.com
Tel: +918618910930

INTRODUCTION

Ocular administration of drugs is primarily associated with the need to treat ophthalmic disease and is not regarded as a means of gaining systemic drug action. The corneal permeation of a drug from an administered ophthalmic preparation will be around 5% or less while remainder is lost by pre-corneal constrains (1). Pre-corneal constraints include spillage of a drug by overflow, dilution of a drug by tears turnover, naso-lacrimal drainage/systemic drug absorption, non-productive conjunctival drug absorption and enzymatic metabolism and binding of the drug to proteins (2). The most effective method for drug targeting is believed to be to amino acids and peptide transporter as these transporters have the enormous range of substrates and direction of transport from epithelium to endothelium providing a possible task in the permeation of substrate molecule (3). The presence of LATI, ATB0+, ASCTI in cornea are acting as transporters (4, 5) and were involved in the transport of different components to the posterior segment. This has been conceptual and formed the rationale to use the methyl and ethyl esters of amino acids such as arginine, phenylalanine, and alanine to be transporters on parts of the cornea.

MATERIALS AND METHODS

Chemicals & reagents: l-lysine, l-phenyl alanine and l-valine (SAS Chemicals Co., Mumbai). Thionyl chloride (SD fine chem. Ltd., Mumbai). Methanol (SD fine Chemicals Limited). Ethanol (Jiangsu Huaxsi Ltd. China). Ketorolac tromethamine (Unisule Pvt. India Ltd., Sonepat). Tetrahydrofuran (RFCL Limited, New Delhi). Hydroxybenzotriazole (Spectrochem Pvt. Ltd., Mumbai). Dicyclohexylcarbodimide (Spectrochem Pvt. Ltd. Mumbai). Sodium bicarbonate (CDH (P) Ltd., New

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Evaluation on Safety and Efficacy of Selective Anti-Hypertensive Drugs in Patients with Cardiovascular Disease at a Tertiary Care Hospital, India-an Observational Study

R. E. Ugandar[1*], Umadevi Iluru[1], Mariamma Bethe[1], C. Bhargava Reddy[1] and Kiran C. Nilugal[2]

[1]Department of Pharmacy Practice, Santhiram College of Pharmacy, Nandyal-518501, Kurnool District, Andhra Pradesh, India.

[2]School of Pharmacy, Management and Science University, Shah Alam-40100, Selangor Darul Ehsan, Malaysia.

Authors' contributions

This work was carried out in collaboration among all authors. Author REU had done the designing of study and had provided the facilities for the study. Author UI had done the protocol preparation, data collection, data management, data analysis and determination of final conclusion. Author MB had done the data collection, data management and data handling. Author CBR had obtained the Institutional ethics committee approval. Author KCN had done the review of the study. All authors read and approved the final manuscript.

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Original Research Article

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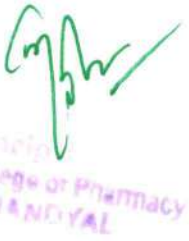
ABSTRACT

Background: Hypertension means persistent elevation of Blood Pressure in arteries. It is the second leading cause of death. The symptoms include Severe Headache, Drowsiness, Vision problem, Nose bleed, fatigue, Confusion. It may lead to various types of Cardiovascular disorders such as Myocardial Infarction, Coronary Artery Disease, Heart Failure. The treatment of Hypertension can be done by Anti-Hypertensive Drugs which include Angiotensin -II Receptor Blockers, Beta Blockers, Angiotensin Converting Enzyme Inhibitors etc.

**Corresponding author: E-mail: ugandarsrcp@gmail.com;*



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FORMULATION AND EVALUATION OF QUETIAPINE FUMARATE MOUTH DISSOLVING TABLETS

R.E Ugandar[1*], S.Suresh Reddy[2].

[1]Department of Pharmaceutics, Santhiram college of pharmacy, Nandyal, Andhrapradesh, India.

[2]Department of Pharmaceutics, Santhiram college of pharmacy, Nandyal, Andhrapradesh, India.

[*]Corresponding author: R.E Ugandar[1].

ABSTRACT

The objective of present study was to formulate directly compressible orodispersible tablets of Quetiapine Fumarate by direct compression method with a view to enhance patient compliance. Plantago Asiatica (3-5 % w/w) was used as superdisintegrant and T.corniculata the kasuri (3-5 % w/w) as disintegrating agent. The tablets were evaluated for thickness, weight variation, hardness, friability, content uniformity, wetting time, porosity, in vitro disintegration time and in vitro drug release. The formulation containing combination of sodium starch glycolate and croscarmellose sodium was emerged as promising based on evaluation parameters. The disintegration time for optimized formulation was 22sec. Fourier transform infrared spectroscopy study did not indicate any drug excipient incompatibility, either during mixing or after compression. Short-term stability studies on the optimized formulation indicated no significant changes in drug content and in vitro disintegration time. The directly compressible orodispersible tablets of Quetiapine Fumarate with lower friability, greater drug release and shorter disintegration times were obtained using croscarmellose sodium and sodium starch glycolate at optimum concentrations.

Keywords: Psychosis, Mouth dissolving tablet, Quetiapine fumarate, super disintegrants, Direct compression technique.

I. INTRODUCTION:

Strong oral dose structures offers resistance to patient inferable from issues like dysphasia, hazard of gagging, and hand quakes. Strong measurements frames likewise present generous hardships in patients like youngsters, slow-witted, uncooperative and patient on decreased liquid diet [1]. In addition, paediatric patients might have ingestion issues inferable from immature solid and apprehensive control [2,3]. Likewise utility of orally directed customary tablets is restricted in states of water unavailability[4].Several creative medication conveyance frameworks have been reported to vanquish the issue of regular tablets. Novel strong oral dose structure, which deteriorates and breaks up quickly in salivation without need for drinking water is orodispersible tablet. These tablets ordinarily break up inside 15 s to 2 min. A few medications are retained from the mouth, pharynx and throat as the salivation passes down into the stomach and produce quick beginning of activity. Subsequently, bioavailability of such medication is essentially more noteworthy than customary tablet dose

High Technology Letters

Design, Development and Optimization of Acyclovir Transdermal Patches using 2^3 Factorial Designs

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P. Komali[*1], Dr.R.E.Ugandar[1], Dr. Y. Dastagiri Reddy[1]

1. Santhiram College of Pharmacy, Nandyal, Kurnool dist., Andhra Pradesh

Corresponding author: P. Komali, Department of Pharmaceutics, Santhiram College of Pharmacy, Nandyal, Kurnool dist., Andhra Pradesh

Abstract: Purpose: The goal of current study is to develop, optimize and evaluate acyclovir transdermal patches. Due to its low oral bioavailability, first pass metabolism and the need of prolonged release; the drug was fabricated as sustained release transdermal patches. Method: Acyclovir transdermal patches were formulated using solvent evaporation technique. A 2^3 factorial method was implemented to develop different transdermal patches formulations by varying the factors like Ethyl cellulose concentration X_1(100-300mg), Sonication time X_2(5-20minutes), DMSO concentration X_3(1-3%) which was used to verify the performance of these parameters on the responses like % drug release (Y_1) and folding endurance (Y_2). FTIR and DSC studies were carried out to determine compatibility studies. Results: The compatibility studies revealed that there was no interaction between the drug and excipients. The prepared patches were evaluated for various parameters. The formulation containing 100 mg of Ethyl Cellulose and 3% DMSO showed better sustained release of Acyclovir when compared with other formulations. After fitting the values into the Design expert software, the formulation composed of 290.05 mg of ethyl cellulose and 2.91% of DMSO has been designated as optimized formulation. Conclusion: The optimized formulation showed the responses of 84.56 % drug release (Y_1) and 239 folding endurance (Y2). Kinetic studies revealed that the optimized formula follows first order model and exhibited Case-II diffusion mechanism. Statistical analysis was used to determine the significant difference between predicted and experimental values.

Key words: Acyclovir, Ethyl cellulose, DMSO, 2^3factorial design.

1. INTRODUCTION

The fundamental goal of a transdermal medication delivery system is to transfer pharmaceuticals into systemic circulation through the skin at a controlled rate with little variance between and between patients. Transdermal delivery is now one of the most promising drug delivery modalities.(1)Transderm-Scop, the first transdermal drug delivery (TDD) system developed in 1980, contained the drug Scopolamine for the treatment of motion sickness. Transdermal technology is a membrane-mediated system. This system's membrane is a microporous polypropylene film. The drug reservoir is a drug solution in a mineral oil/polyisobutylene mixture. This study's release will be maintained for three days.(2)

At present, numerous diseases such as motion diseases, cardiovascular diseases, and hormonal abnormalities are being treated using this technique. The treatment of many other diseases like skin cancer, sexual and menstrual dysfunctions in women, anxiety, stress, etc. are yet to be treated by using this technique in future. The products of the transdermal system generate handsome revenue in the international pharmaceutical markets too.(3) Polymers, enhancers, plasticizers and solvent systems are given due consideration while fabricating polymers, which are believed to be the key ingredients of the transdermal drug delivery system because the frequency of drug penetration and its release depends upon polymers.(4)

Acyclovir is a nucleotide antiviral used to treat herpes simplex, Varicella zoster, herpes zoster, herpes labialis, and intense herpetic keratitis. Acyclovir becomes acyclovir monophosphate because of the activity of viral thymidine kinase. Acyclovir monophosphate is changed over to the diphosphate structure by guanylate kinase. Acyclovir diphosphate is changed over to acyclovir triphosphate by nucleoside diphosphate kinase. Acyclovir has low oral bioavailability and half-life of 3hrs. Hence, the drug must be administered multiple times a day there by resulting in toxic effects. So, to tackle this problem novel transdermal drug delivery system is used.(5)

II. MATERIALS AND METHODS

Materials

Acyclovir, is an anti-viral drug which is a gift sample from Hetero drugs (Hyd.). Ethyl cellulose is obtained from Otto reagents. Glycerin, DMSO and methanol were obtained through SD fine chem. Ltd., Mumbai.

Experimental Design

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Formulation and evaluation of sustain release periodontal films containing erythromycin for periodontitis

Talloju.Sravani*[1], Dr.R.E.Ugandar[1], Dr.Y.Dastagiri Reddy[1], Shaik.Shafi[1]

1. Santhiram College of Pharmacy, Nandyal, Kurnool District, Andhra Pradesh

Corresponding author: T. Sravani, Department of Pharmaceutics, Santhiram College of Pharmacy, Nandyal, Kurnool District, Andhra Pradesh

Email.ID:sravanitalloju958@gmail.com, Cell No: 9533066099

Abstract: purpose: The purpose of the existing work is to formulate and evaluate the sustained release periodontal films containing erythromycin and various polymers in different concentrations for local delivery into periodontal pockets and thus prolonging the action of drug release with dose. Method: The periodontal films were prepared using the solvent casting technique. Nine formulations were prepared with ethyl cellulose as the main polymer and copolymers like HPC, SCMC in different concentrations the prepared films were evaluated for various parameters like weight variation, thickness, folding endurance, %moisture loss, swelling index, surface pH, drug content uniformity, antibacterial activity, invitro diffusion studies. Results: The compatibility studies showed that there was no interaction between drug and excipients. The evaluated results were within the limits. The formulation F2 was found to be the best periodontal film which is prepared with ethyl cellulose. Hence, it was considered as an optimized formulation. The in-vitro drug release studies showed maximum drug release in formulation F2 (94.66%). The antibacterial studies were carried out using disc diffusion method to study the antibacterial activity of erythromycin against staphylococcus aureus. Conclusion: The formulation F2 containing ethyl cellulose (150mg), glycerin, pr lene glycol, tween 80 showed sustain release of erythromycin when compared to other formulation. From the korsmeyer it was concluded that the mechanism of drug release from the film followed the Non-Fickian diffusion mechanism. In vitro antibacterial studies which were carried out using erythromycin against staphylococcus aureus showed inhibitory effect after 12 hrs.

Key words: Erythromycin, Periodontitis, Ethyl cellulose, sodium carboxy methyl cellulose, hydroxyl propyl cellulose, staphylococcus aureus.

I. INTRODUCTION

The introduction of a local drug delivery system in the periodontal pocket is a promising therapeutic modality for achieving better clinical outcomes when used as an adjunct to conventional and non-surgical periodontal therapy this route provides one of the potential routes for typically large, hydrophilic and unstable proteins, oligonucleotides and polysaccharides as well as conventional small drug molecules. This cavity has been used as a site for local and systemic drug delivery (1). Some of the advantages of periodontal drug delivery or it bypasses the gastrointestinal tract and the hepatic portal system improved patient compliance due to elimination of associated pain with injections, the convenience of administration as compared to injections or oral medications. Lower inter subject variability as compared to transdermal films. Novel periodontal dosage forms includes fibers, films, gels, injectable system, micro particulate system, strips and compacts (2).

Films are the most recently developed dosage forms for buccal administration. Buccal films may be preferred over adhesive tablets in terms of flexibility and comfort. In addition, they can circumvent the relatively short residence time of oral gels on the mucosa, which are easily washed away and removed by saliva moreover, in the case of local delivery for oral diseases, the films also help to protect the wound surface, thus helping to reduce pain and treat the disease more effectively (3).

An ideal film should be flexible, elastic and soft yet adequately strong to withstand breakage due to stress from mouth movements it can be rapidly inserted into the base of the pocket with minimal discomfort to the patient. If the thickness of the film doesn't exceeds 400mm,and it has sufficient adhesiveness, it will remain submerged without any noticeable interference with the patients oral hygiene habits. Films that release drugs by diffusion alone or prepared using the patient oral hygiene habits. For a given drug the release kinetics from the polymer matrix could governed predominantly by the polymer morphology and excipients present in the system drug release from a polymeric material takes place either by diffusion or by polymer degradation or by a combination of both. Polymer degradation generally takes place by enzymes or hydrolysis either in the form of bulk erosion or surface erosion (4).

Periodontal diseases are mainly the result of infections and inflammation of gums and bones that surround and support the teeth. In its early stage, called gingivitis, the gums can become swollen and red, and they may bleed. In tits more serious form, called periodontitis, the gums can pull away from the tooth bone can be lost, and teeth may loosen or even fall out. Periodontal disease, including diseases such as chronic periodontitis, aggressive periodontitis systemic disease, in the context of periodontitis, and necrotizing periodontal disease. This terms and conditions are characterized by destruction of periodontal ligament, and the resorption of the alveolar bone, and migration of the junctional epithelium along the surface of the tooth. There is a local inflammatory response caused by bacterial infection from a periodontal pocket associated with subgingival plaque (5)

Erythromycin is a bacteriostatic antibiotic drug produced by a strain of saccharopolyspora erythraea (formerly Streptomyces erythraeus) and belongs to the macrolide group of antibiotics which consists of azithromycin, clarithromycin, spiramycin, and others it was originally discovered in 1952 (6). Erythromycin is widley used for treating variety of infections, including those caused by gram positive and gram negative bacteria it is available for administration in various forms, including intravenous, topical, and eye drop preparations. To replicate, bacteria require a specific process of protein synthesis, enable by ribosomal protein's. erythromycin acts by inhibition of protein synthesis by binding to the 23s ribosomal RNA molecule in the 50s subunit of ribosomes in susceptible bacterial organisms it stops bacterial protein

Design, Development and optimization of Labetalol Hydrochloride as pulsatile drug delivery system using central composite design

B. Sri divya*[1], Y. Dastagiri ReddY[1], Siva Sankar Reddy.L[1],D.MaheshwarReddy[1],K.Sampath kumar[1], Madhusudhana chetty.C[1]

1. Santhiram College of Pharmacy, Nandyal, Kurnool District Andhra Pradesh

Corresponding author: B. Sri divya, Department of Pharmaceutics, Santhiram College of Pharmacy, Nandyal, Kurnool District, Andhra Pradesh

Abstract:

Objective:

The main objective of the present work is to design, development and optimization of labetalol hydrochloride as pulsatile drug delivery system using central composite design. Labetalol hydrochloride is an antihypertensive drug belongs to BCS-1 but the oral bioavailability is low to increase the oral bioavailability of labetalol hydrochloride can be designed as pulsatile system.

Methods:

By using central composite design, the formulation table can be obtained and then the pulsatile tablets were prepared by using Carbopol 934P and $HPMCK_4M$ polymers in different concentrations. The prepared tablets were subjected to pre-compression and post-compression parameters. The evaluation results are within specified limits as per I.P. Compatibility studies were performed by using FTIR Spectroscopy and DSC studies.

Results:

All the evaluation parameters exhibit good results and the optimized formulation shows better results i.e., hardness (6.30 kg/cm^2) and drug release (90.62%). The optimized formulation was subjected for first order, zero order, higuchi model and Korsmeyer-Peppas model. It was found to be adherent to first order release and exhibits non-fickian mechanism.

Key words: Central composite design, Carbopol 934P, $HPMCK_4M$, pulsatile tablets.

INTRODUCTION:

Pulsatile drug delivery systems arethe systems that can delivers the drug within a short period after a programmable lag time. These systems can be designed according to the circadian rhythm or biological clock that can delivers the drug at right time and at right place and in right amount that improves patient compliance (1). In these systems there is no drug release at initially, but there is an immediate or controlled release of drug whenever the patient is at risk. These controlled releases of drug can also be utilizing for enhancing absorption, reducing side effects, increasing and decreasing dose.(2)

In the present study compressed tablets of pulsatile drug delivery systems were involved. Compressed tablets consist of core and backing layer in which core is prepared by wet granulation method and backing layer is prepared by dry granulation method. After compression these pulsatile tablets were coated by using coating solutions of Eudragit RL-100.

Labetalol is an anti-hypertensive drug which is used for the treatment of high blood pressure. Labetalol belongs to BCS class-I with high permeability and high solubility but the oral bioavailability of labetalol is very poor i.e., 25% due to insufficient absorption when administered in conventional dosage form.

The main objective of the present study is to Design, Development and Optimization of Labetalol as Pulsatile drug delivery systems by using Central composite design in order to maintains the lag time of 4-5 hrs after oral administration such that it reaches maximum plasma levels occurs in early morning hours whenever the patient is at more risk.

MATERIALS AND METHODS:

Materials:

FORMULATION AND EVALUATION OF EFFERVESCENT FLOATING TABLETS OF RIOPROSTIL

Author names: Pavankumar Krosuri*[1], Syed Saba Mehdi[1], N.Pavani[1], M.Gladys[1], Y. Divya sri[1]

1. Department of Pharmaceutics, Santhiram College of Pharmacy, NH40, Nerrawada, Nandyal, Kurnool (dt.)-518501, Andhrapradesh

ABSTRACT

Rioprostil an antiulcer drug has poor bioavailability and has low elimination half-life which makes it an ideal candidate for gastro retentive floating drug delivery system. The Floating tablets of Rioprostil were prepared to increase the gastric retention and to improve the bioavailability of the drug .The floating tablets were formulated using HPMC E 15M, Ethyl Cellulose, Eudragit S 100 as polymers. Lauric acid, sodium bicarbonate, magnesium stearate, talc and MCC are used as excipients. The tablets were prepared by wet granulation method. The formulated tablets were evaluated for the quality control tests: weight variation, hardness, friability, swelling index, floating lag time and total floating time, The *in vitro* drug release of the tablets was evaluated in 0.1NHCL.The drug release from the optimized formulation F9 subjected to curve fit

ing analysis showed to best fit zero order kinetics indicating drug release does not depend on its concentration and the 'n' value in korsmeyer-peppas model is > 0.5 and followed non-fickian diffusion mechanism.

Key words: Rioprostil, Antiulcer drug, HPMC E 15M, Micro Crystalline Cellulose, Ethyl Cellulose, Eudragit S 100.

INTRODUCTION:

Different routes of drug administration together with enteral and epithelial duct area unit utilized in follow, however; oral route of drug administration is most popular due to compliance.

On opposite hand, oral route has several disadvantages that embody variable canal transit that disturbs the uniform absorption of the drug, incomplete unharness of drug from dose form and shorter viscus duration. These disadvantages result into poor bioavailability of sure medicine significantly that have floating tablets of Flagyl, composed of metal alginate, low substituted hydroxypropyl polysaccharide and hydrogen carbonate, to extend native action of metronidazole against H. pylori.

appropriate candidates for formulating GRDDS area unit those that have slender absorption window restricted to higher digestive tract, that area unit meant for native action in abdomen, that area unit unstable or less soluble at high pH scale of internal organ fluid and which might cause serious facet effects once passing in lower digestive tract. However, GRDDS isn't appropriate for such medicine that area unit unstable at low pH scale of viscus fluid, that area

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RESEARCH ARTICLE

Formulation and Evaluation of colon targeted drug Delivery of Diloxanide furoate Tablets using pH Dependent Polymers

Pavankumar Krosuri*, K.Ravikumar, S.N.Priyanka, G.Anjana Devi, S.Lakshmiprasanna, A.Sujatha, A.Akhila

Department of Pharmaceutics.Santhiram College of Pharmacy, Nandyal, Andhrapradesh, India.

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

ABSTRACT:

Diloxanide Furoate is a Dichloroacetamide derivative utilized for the treatment of various protozoal infections like amoebiasis. Colon targeted tablets were designed using pH sensitive polymers like Eudragit S100, Eudragit L 100,Cellulose acetate phthallate at different concentrations. All the matrix,compression coated formulations showed the desired physicochemical properties as per the official limits. The drug release studies were performed according to the USP paddle method by using 0.1N HCL for 2 hours, pH 7.4 phosphate buffer for 3 hours and pH 6.8 phosphate buffer upto 18 hours. A better controlled drug release was shown for Eudragit L 100. Based on the comparative drug release studies among different Formulations F9 with Eudragit L 100 polymer showed better control drug release. The release kinetics for the Optimised Formulation F9 was calculated and "r^2" value was more for Zero order kinetics i.e.,0.970 indicating that the formulation doesnot depend upon its concentration and from the Korsmeyer peppas model the diffusion exponent value "n" is > 1 indicating that it follows super case II transport mechanism. The accelerated stability studies conducted for optimised formulation F9 for 3 months have no significant variation.

KEYWORDS: Diloxanide furoate, amoebiasis, supercase II transport, Accelearated Stability studies.

INTRODUCTION:

Protzoal and helminthic infections are a major cause of disease in many parts of the world. It includes infectio ns like Amoebiasis, Giardiasis and Trichomoniasis.

Amoebiasis :

It is caused by *Entamoeba histolytica*, which is spread between humans by its cysts. It has a worldwide distribu tion, but is endemic in most parts of India and other developing countries. Poor environmental sanitation is the main cause for the spread of the disease[1].

Colon targeted drug delivery system :

Historically, oral ingestion has been the most convenient and commonly used method of drug delivery. For sustained as well as controlled release systems, the oral route of administration has received the most attention. This is because of greater flexibility indosage form design for the oral rather than the parenteral route.

Patient acceptance of colon would therefore ensure direct treatment at the disease site, lower dosing rate and reduce the systemic side effects. In addition to local therapy, the colon can also beutilized as a portal for the entry of drugs into the systemic circulation[2].

The Drug Diloxanide Furoate used in the present Research investigation is a Dichloroacetamide derivative which acts as a antiprotozoal, luminal amebicide that is used for the treatment of intestinal amoebiasis caused by Entamoeba histolytica. It destroys the trophozites of Entamoeba histolytica that finally convert in to cyst forms[3].

MATERIALS AND METHODS:

Chemicals & Reagents:

Diloxanide furoate was obtained from KP Lbs Hyderabad, Eudragit S-100, Eudragit L-100, Cellulose acetate phthalate, PVP K30, Micro crystalline cellulose,

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Advances in Bioresearch

ORIGINAL ARTICLE

Optimization, Development, Formulation of Lornoxicam Oral Dispersible Tablets using Central composite Experimental Design

Pavankumar Krosuri*, Y.Dastagiri Reddy, K.Madhavi, J.Sunayana
1. Department of Pharmaceutics, Santhiram College of Pharmacy, Nandyal, Andhra Pradesh, India.

ABSTRACT

The Present Research investigation was designed to formulate and optimize Oral disintegrating formulations of Lornoxicam by using Qbd approach. To evaluate the input variables and output variables scientifically central composite design was used. Different concentrations of superdisintegrants were taken as predicted variables. In vitro dispersion time,% Drug release were taken as response variables. The quantitative effect at different levels of independent variables on response variables were predicted by utilizing polynomial equations. There is significance in curvature effect and the Design was nonlinear, therefore composite design study was adopted to optimization of the Formulation. FTIR and Differential scanning colorimetric studies concluded that no incompatibility exists among Drug and Excipients. Precompression and post compression parameters were within specified values. As concentration levels of CP and SSG increases % drug release was increased and in vitro dispersion time was decreased. From the Kinetic studies, the release of drug from the formulations obeyed first order, dependent variables and independent variables were demonstrated by utilizing contour plots. By using this statistical model the Predicted, Experimental values were found to be close to each other relatively. The results concluded that the design proposed for the formulation of Lornoxicam oral disintegrating tablets showed better optimized properties.

Key words: Lornoxicam, Superdisintegrants, Central composite design.

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INTRODUCTION

The oral form of administration is the most common preferable way of administering the dosage form . Among different dosage forms tablets are more convenient because of its easy to manufacture, patient compliance , precised dosing, stability compared with capsules and oral liquids [1]. In order to avoid patient discomfort and promote the administration by all age groups orodispersible tablets promotes better patient compliance which disintegrates under salivary pH without the need of drinking water especially in bed ridden conditions and in travelling [2, 3]. Orodispersible tablets were also known as fast dissolving tablets.

Lornoxicam comes under the category of cox2 inhibitor used to cure inflammation, pain occurred by rheumatoid arthritis and osteoarthritis and also post surgical pains. Superdisintegrants provide faster disintegration by water absorption by capillary action and swelling of the formulation which further promotes better disintegration and dissolution properties.

Depending on factorial numbers, levels, their interaction possibilities experimental designs were designed [5]. Box and Wilson design is a better design that has a combined advantages of star design and factorial design or fractional factorial design. This model is validated by using Analysis of variance. There is multidimensional interaction with the design space and combination of input variables and process parameters have been proved to provide the quality of proof based on ICH Q8 (R2)guidelines. In the present research investigation, A Trail was made to prepare oral disintegrating tablets of Lornoxicam by using Box and wilson design to identify activity of superdisintegrants on % drug release .

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A Prospective Observational Study on Evaluation of Therapeutic Efficacy of Antiplatelets in Coronary Artery Disease with Percutaneous Transluminal Coronary Angioplasty

C. Bhargava Reddy[1*], T. Akhila Saila Sree[1], K. Samyuktha[1], D. Kranthi chaitanya[2], R. E. Ugandar[1] and C. Madhusudhana Chetty[3]

[1]Department of Pharmacy Practice, Santhiram College of Pharmacy, Nandyal, Kurnool (dt), Andhra Pradesh, India.
[2]Department of Cardiology, Santhiram Medical College and General Hospital, Nandyal, Kurnool (dt), Andhra Pradesh, India.
[3]Principal of Santhiram college of Pharmacy, Nandyal, Kurnool (dt), Andhra Pradesh, India.

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Coronary artery disease otherwise named as Coronary heart disease. Coronary Artery Disease means narrowing of the coronary arteries. This narrowing causes reduction of blood flow to the heart muscle by buildup of plaque in the arteries of heart. A common symptom of Coronary artery disease is chest pain or chest discomfort which can travel to the shoulder, arm, back, neck or jaws. Other symptoms may include Shortness of breath, palpitations and even fatigue. Majorly antiplatelets are given in the treatment of CAD and followed by angioplasty for the clearing of plaques in the coronary artery. Collected a sample size of 200 patients, among them 126 are males and 74 are females. Patient with age group of 51-60 are more prone to CAD in both males and females. Chest pain is majorly seen in males compared to females. Chest pain, Sweating and shortness of breath is seen in both males and females and the number of male patients are more

**Corresponding author: E-mail: akhilasailasree@gmail.com;*

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A Case Report on Coarctation of the Aorta

Akhila saila sree T*[1], Samyuktha K[2], Nandini Pandey[2], Bhargav reddy C[2]

[1]Santhiram College of Pharmacy, Nandyal, Kurnool Dist, Andhra Pradesh, India

[2]Santhiram Medical College and General Hospital, Nandyal, Kurnool Dist, Andhra Pradesh, India

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Keywords:

Coarctation of the Aorta, Congenital Heart Disease, Transcatheter Therapy, Aberrant Aperture

ABSTRACT

Coarctation of the aorta is described as an innate cardiac anomaly comprising the narrow aortic section consisting medial stiffen with a bit in folding of the media and fortuitous neo tissue layer membrane (intimal). Coarctation of the aorta is the 6th most familiar lesion in hereditary/innate heart disease. Here, the localized constriction forms shelf like formation with an aberrant aperture or membranous curtain like formation with a central or aberrant aperture, though in spite of consolation of the anatomical restraint, the succeeding risk of premature morbidity and death keep on. The present study figures the ideal guidance of a disease from neonatal to adult life. It also includes the treatment of coarctation of the aorta by the evolution of transcatheter treatment for either the native and peculiarly repetitive coarctation of the aorta. Late obstacles, even after the proper fortunate treatment, are not common. So, lifelong follow-up is more vital in coarctation of aorta patients.

*Corresponding Author

Name: Akhila saila sree T
Phone: 8008609502
Email: akhilasailasree@gmail.com

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INTRODUCTION

The word coarctation referred as constrict/tighten and is originated from the latin coatare, i.e., to tightening inturn the stemming from co-and arctare and to repair vigorously. From artus, close, tight-coarctation of aorta (Co A) is a relatively common innate cardiac defect. In Coarctation of the aorta, a portion of the artery constricts, usually in nearer to the ductus arteriosus or the ligamentum arteriosum following the blockage. But the narrow area of the aorta may differ in location and also in the structure, wideness and length. Its incidence ranges from 5 - 8% of all the innate cardiac defects. This state is most frequently diagnosed because of heart sounds or HTN found on general auscultation. Aortic blockage may be restored by the surgery or by the transcatheter operating procedures, the later it mainly go through the balloon angioplasty and stent installation. In back days, surgery has been widely used, but due to the death rate and extremely obstacles correlated with surgery, catheter operating procedure are exclusively used for the therapeutic outcome [1]. Balloon angioplasty in infants and stents in teens are fetching early choice of treatment for the management of coarctation of the aorta [2]. Classification of coarctation of aorta includes the:

1. Native coarctation of the aorta
2. Recurrent coarctation of the aorta

It also includes preductus, ductus and post ductus coarctation of the aorta. Native coarctation of the aorta defines the detached tapering of the subsiding aorta that ensures from ridge-like stiffen of the media of aortic wall that projects into lumen facing the insertion of the ductus arteriosus. The beginning of the subclavian artery can be intricate with post-stenotic expansion of the aorta commonly encountered.

Recoarctation of the aorta is defined as restenosis succeeding of an inceptive triumphant surgical or

Method Development and Validation for Estimation of related Substances in Tilorone Dihydrochloride using RP-HPLC

M. Zeba Baktiyar, B. Mohammed Ishaq*, Siva Sanker Reddy L, M. Sreenivasulu

Department of Pharmaceutical Analysis, Santhiram College of Pharmacy, Nandyal, Kurnool, Dist. A.P. India. 518501.

*Corresponding Author E-mail: **bmdishaq@yahoo.com**

ABSTRACT:

A simple, precise and reproducible RP-HPLC method was developed for the estimation of related substances in tilorone dihydrochloride. Quantification was performed using a Zorbax SB-phenyl column (150 × 4.6mm, 5µ) with mobile phase A: 20mM potassium dihydro phosphate + 2ml of triethylamine, pH 2.30 and mobile phase B: acetonitrile, methanol and water 60: 20: 20% v/v. A gradient program was followed with a run time of 55 minutes at a flow rate of 1.0 ml/min. The column temperature was maintained at 40°C, the injection volume was 10 µl and the detection was performed at 269nm using a PDA detector. The retention time of Tilorone dihydrochloride was found to be 10.36 minutes. The proposed method has been validated according to the ICH guidelines for Linearity, Precision, Accuracy, LOD, and LOQ. The method was linear from 0.157 - 3.934µg/ml for standard, 0.153-3.820µg/ml and 0.166 - 4.140µg/ml for impurities, TLHC01 and TLHC02 respectively. The impurities TLHC01 and TLHC02 have been mapped in all stress conditions. The LOD and LOQ of TLHC01 were found at 1.757µg/ml and 5.857µg/ml and 1.919µg/ml and 6.396µg/ml respectively for TLHC02 respectively. Statistical analysis showed that the method was precision, reproducible, selective, specific and accurate for the analysis of Tilorone dihydrochloride and its impurities. The wide range of linearity, sensitivity, precision, short retention times and simple mobile phase have shown that the method is suitable for the routine quantification of mass impurities of tilorone hydrochloride and its dosage pharmaceutical forms with high precision and accuracy.

KEYWORDS: Tilorone Dihydrochloride, RP-HPLC, Degradation studies, Validation.

INTRODUCTION:

Silicosis is a fibrous lung disease caused by the inhalation of crystalline silica dust[1,2]. It is a debilitating, progressive, non-reversible and sometimes fatal lung disease. The great damage of silicosis has been gradually recognized and many drugs have been synthesized for the treatment of silicosis.[3] Tiloronoxim is a derivative of Tilorone recently synthesized for the treatment of silicosis. The preclinical study demonstrated the efficacy of tiloronoxim with low chronic toxicity.[4] It is rapidly and widely distributed in the body and is excreted in the urine. It is metabolized in different metabolites in humans and among these Tilorone (Figure 1) is pharmacologically active[5].

Figure 1: Chemical structure of Tilorone dihydrochloride

Tilorone is a new class of antiviral drugs, approved by the FDA. It is an orally active inducer of interferon.[6] Specifically induces a prolonged and unusual response to prolonged interferon that is uncommon compared to other synthetic inducers.[7-10] Tilorone is an orange powder that is freely soluble in methanol, water and moderately soluble in ethanol, dimethylsulfoxide, and dimethylformamide. Chemically, it is 2,7-bis- [2 (dimethylamino) -ethoxy] -fluorene-9-one with molecular formula $C_{25}H_{34}N_2O_3$ (molecular weight: 410.55g/mol).

Few articles have been published for the determination of tiloronoxim or Tilorone in biofluids. The determination of Tilorone in human urine has been reported by HPLC-MS/MS[11] and a spectrophotometric derived method.[12] No document has been reported to quantify impurities related to the tilorone process to date. This document describes a sensitive, specific and rapid HPLC method for the determination of Tilorone impurities and the methods have been validated according to the ICH guidelines.[13]

EXPERIMENTAL:

Chemicals and solvents:

The pure drug Tilorone was obtained as a gift sample from MSN Laboratories, Hyderabad, India. Tilorone tablets were purchased at the local pharmacy. Methanol, acetonitrile and HPLC grade water were purchased from SD Fine Chem, Mumbai, India. All other chemicals used were of AR grade.

HPLC–PDA instrumentation and chromatographic conditions:

The HPLC system was an LC Waters (Waters, Milford, MA, USA) composed of a quaternary gradient system (600 controllers), in-line degasser (Waters, model AF), photodiode array detector (water, model 2998) and automatic sampler (Waters, model 717 plus). The data was processed with the Empower Pro software (Waters, Milford, MA, USA). The chromatographic separation test was performed with a Zorbax SB-phenyl analytical column (internal diameter 150mm × 4.6mm, particle size 5µm) maintained at 40°C. mobile phase A: 20mM potassium dihydro phosphate + 2ml of triethylamine, pH 2.30 and mobile phase B: acetonitrile, methanol and water 60: 20: 20% v/v. A gradient program was followed with a run time of 55 minutes at a flow rate of 1.0 ml/min. The detection wavelength was 269nm. 20mM potassium dihydro phosphate buffer and methanol in the ratio of 70:30 %v/v were used as diluent.

Preparation of Mobile phase:

Mobile phase A:

4.76g of potassium dihydrogen phosphate was carefully weighed and dissolved in 500ml of distilled water, sonicated for 10 minutes to dissolve and the volume was made up to 1000ml with distilled water. 2ml of triethylamine were added, the pH of the solution was adjusted to 2.30±0.05 with a solution of diluted orthophosphoric acid. The solution was filtered through a 0.22µm membrane filter.

Analytical characterization of biomarkers in an optimized novel antidiabetic polyherbal formulation using high-performance thin-layer chromatography and liquid chromatography with tandem mass spectrometry

Kummu Jyothsna Jayaraju[a], Beludari Mohammed Ishaq[b]

[a]Research Scholar, Faculty of Pharmaceutical Sciences, Jawaharlal Nehru Technological University Anantapur, Ananthapuramu, Andhra Pradesh, India, [b]Department of Pharmaceutical Analysis, Santhiram College of Pharmacy, Nandyal, Kurnool, Andhra Pradesh, India

Correspondence to B. Mohammed Ishaq, M.Pharm, PhD, Flat No. 306, Aditya Towers, Beside National PG College NGO's Colony, Nandyal, Kurnool District, Andhra Pradesh, India.
Tel: +91 779 941 2060;
e-mail: drbmdishaq@gmail.com

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Background
Diabetes mellitus is a chronic health issue that requires novel approaches to treatment and a multimodal approach to prevention. In the treatment of diabetes, a polyherbal formulation is the finest alternative medicine. A polyherbal formulation was developed in-house and evaluated for its antidiabetic potential on streptozotocin-induced diabetes rat. The same extract was now characterized analytically utilizing a variety of methods.

Objective
The goal of this study was to quantify the biomarkers in a novel antidiabetic polyherbal formulation made in-house with *Cinnamonum zeylanicium* bark, *Eugenia jambolana* seeds, *Vinca rosea* whole plant, and *Gymnema sylvestre* (GS) leaves, using high-performance thin-layer chromatography (HPTLC) and liquid chromatography with tandem mass spectrometry (LC–MS/MS).

Materials and methods
Cinnamaldehyde (CIN), gallic acid (GLA), vincristine (VC), vinblastine (VB), and gymnemic acid (GYA) were identified as bioactive components of polyherbal formulation hydroalcoholic extract utilizing HPTLC and LC–MS/MS. Acetonitrile, methanol, and 0.1 percent formic acid was used as mobile phase, chromatographic separation was accomplished in 30 min using a gradient system and a SUNFIRE C18, 250×4.6, 5-µm analytical column with a flow rate of 1.0 ml/min in LC–MS/MS research. Scanned in a positive mode with a scan speed of 100–2000 AMU/s over a mass range of 20–1974 Da. The electron-spray ionization mode was used, with a source temperature of 150°C and a desolvation temperature of 350°C. The HPTLC separation was performed using ethyl acetate/acetonitrile/water/formic acid/N-dimethyl formamide 5.5 : 2.5 : 0.5 : 1.0 : 0.5 (v/v) as the mobile phase on precoated silica gel 60 GF254 plates. At room temperature, the plates were developed to a distance of 9.0 cm. CIN, GLA, VC, VB, and GYA plates were scanned and measured at wavelengths of maximum absorption of 259, 287, 342, 355, and 387 nm, respectively. Band size, chamber-saturation duration, migration of the solvent front, slit width, and other experimental parameters were carefully examined, and the optimized chromatographic conditions were chosen.

Results
LC–MS analysis of the hydroalcoholic extract of the polyherbal formulation revealed the presence of all the five bioactive chemical constituents, CIN, GLA, VC, VB, and GYA. Similarly, the drug samples were satisfactorily resolved with Rf 1.81±0.01, 0.05±0.01, 0.02±0.01, 0.09±0.01, and 0.04±0.01 for CIN, GLA, VC, VB, and GYA respectively, using HPTLC.

Conclusion
The importance of combining Ayurvedic formulations with contemporary high-throughput screening techniques will spark new interest in more powerful biocompatible drug leads. The findings of this study lend scientific credence to the therapeutic applications of the polyherbal formulation.

Keywords:
cinnamaldehyde, gallic acid, high-performance thin-layer chromatography, liquid chromatography with tandem mass spectrometry, vinblastine and gymnemic acid, vincristine

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Introduction

Ayurveda is an Indian medical system [1] and is an ancient system of traditional medicine that has been used on the Indian peninsula from 5000 BC to provide natural solutions to cure ailments and improve health

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Evaluation of Antidiabetic Activity of a Novel Polyherbal Preparationagainst Streptozotocin Induced Diabetes Rat Model

K. Jyothsna Jayaraju[1] and B. Mohammed Ishaq[2*]

[1]Faculty of Pharmaceutical Sciences, Jawaharlal Nehru Technological University Anantapur, Ananthapuramu. A. P. India.
[2]Santhiram College of Pharmacy, Nandyal, Kurnool Dist. A.P. India.

Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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ABSTRACT

Background: Diabetes Mellitus is a chronic disorder characterised by abnormally elevated glucose levels in the blood. Diabetes is caused by one of two mechanisms: insufficient insulin synthesis (which is produced by the pancreas and reduces blood glucose) or insufficient response of cells to insulin action. The current aim of this research project was to formulate and evaluate the Polyherbal preparation (PHP) of the plants constituted with Cinnamonum zeylanicium (CJ) bark, *Eugenia jambolana* (EJ) seeds, *Vinca rosea* (VR) whole plant, *Gymnema sylvestre* (GS) leaves and determination of the anti-diabetic potential of the formulation in the animal model induced by Streptozotocin.

Methods: Plant components in the current study used were Cinnamonum zeylanicium (CJ) bark, *Eugenia jambolana* (EJ) seeds, *Vinca rosea* (VR) whole plant, *Gymnema sylvestre* (GS) leaves were collected.Using a hydroalcoholic solvent, physico-chemical parameters and active chemical constituents were evaluated. The active components present in the extracts were identified by Preliminary phytochemical screening. The PHP acute toxicity analysis was conducted in compliance with OECD Guideline 423, with 200 mg/kg and 4000 mg/kg administered orally to rats over 28 days.

**Corresponding author: E-mail: drbmdishaq@gmail.com;*

Principal
Santhiram College of Pharmacy
NH-40, NANDYAL