



SREE DATTHA INSTITUTE OF PHARMACY

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Sagar Road, Sheriguda, Ibrahimpatnam, R.R.Dist.-501510

Ph.:08414-202206, 320919, 9393808082

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College Code: SDIP

LIST OF RESEARCH PUBLICATIONS BY FACULTY IN THE YEAR 2014- 2015

Title of the paper	Name/s of the author/s	Department of the teacher	Name of the journal	ISSN number	Link of the recognition in UGC enlistment of the Journal	Name of the indexing database
A Review On Dried Nanosuspensions- A Novel Formulation To Enhance Solubility Of Poorly Aqueous Soluble Drugs	S Raja Shekhar, P Vijaya Lakshmi	Department of Pharmaceutics	International Journal Of Pharmacy	2249-1848	http://www.pharmascholars.com/abstractview/a-review-on-dried-nanosuspensions-a-novel-formulation-to-enhance-solubility-of-poorly-aqueous-soluble-drugs	Copernicus - UGC CARE 64220
Chemoprotective effect of ethanolic extract of Morinda citrifolia against Cisplatin induced nephrotoxicity	Seshachary Anusha Karamcheti, D. Satyavati N.Siva Subramanian, Pradeep H.A, C. Pradeep kumar,G.D eepika Sri Prashanthi	Department of Pharmacology	The Pharma Innovation – Journal	2277-7695	http://www.thepharmajournal.com/vol3Issue1/Issue mar 2014/16.1.pdf	google Scholar
Challenges And Opportunity in Encapsulation of Liquid Filled in Hard Gelatin Over Soft Gelatin Capsules - An Innovative Technology.	Naresh Thamada, D. Satyavathi, Sunil Gupta, Dinesh kumar	Department of Pharmaceutics	International Journal of Institutional Pharmacy and Life Sciences	2249-6807	http://www.ijipls.com/uploaded/journal_files/140524020549.pdf	Pharma web
Development and validation of RP-HPLC method for the analysis of Cobicistat and related impurities in bulk and pharmaceutical dosage forms	D. Satyavathi, Ganji Shiny	Department of Pharmaceutical Analysis	Asian Journal of Pharmaceutical Analysis	2231-5675	http://www.indianjournals.com/ijor.aspx?target=ijor:ajpa&volume=5&issue=1&article=001	google Scholar
Design And Evaluation Of Chitosan	Naresh Kshirasagar *, Naresh	Department of Pharmaceutics	International Journal of	2250-3153	https://www.researchgate.net/profile/Naresh_Kshirasagar3/publications	Research Gate

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Containing Mucoadhesive Buccal Patch Of Fluxotone HCL	Thamada, V.N.Balaji Kumar Naik, M.Sushma Gopal	ics	Scientific and Research Publication s,		tion/329555524 DESI GN AND EVALUATI ON OF CHITOSAN CONTAINING MUCO ADHESIVE BUCCAL PATCH OF FLUXO TINE HCL/links/5c0f3 f4292851c39ebe4499 b/DESIGN-AND- EVALUATION-OF- CHITOSAN- CONTAINING- MUCOADHESIVE- BUCCAL-PATCH-OF- FLUXOTINE-HCL.pdf	
ANTIDIABETIC ACTIVITY AND ANTI-OXIDANT ACTIVITY OF NIDDWIN, A POLYHERBAL FORMULATION IN ALLOXAN INDUCED DIABETIC RATS	T. SRUTHI, D. SATYAVA TI, K. UPENDAR , C. PRADEEP KUMAR	Department of Pharmacolo gy	Internation al Journal of Pharmacy and Pharmaceut ical Sciences	0975- 1491	https://pdfs.semanticscholar.org/95dc/de9757d29bffeefa71d29c65d4265248b545.pdf	Academic Sciences
Evaluation Of Azadirachta Indica Extracts Against Helicobacter Pylori 26695 Lipopolysaccharide Induced Gastric Ulcer In Rats	Kiranmai Mandava , Mohamme d Ibrahim Mahendra Kumar	Department of Pharmacolo gy	Internation al Journal of Indegenous Medicinal Plants	2051- 4263	https://www.researchgate.net/publication/272182523_Evaluation_of_Azadirachta_indica_Extracts_against_Helicobacter_Pylori_26695_Lipopolysaccharide_Induced_Gastric_Ulcer_in_Rats	Research Gate
Evaluation of nootropic activity of smriti: a polyherbal formulation	Jyothi Vadthya, Satyavati. D, Pradeep Kumar .C, Ch. Maheshwar a Reddy	Department of Pharmacolo gy	The Pharma Innovation - Journal	2277- 7695	http://www.thepharmajournal.com/archives/?year=2014&vol=3&issue=3&ArticleId=341	Copernicus - UGC CARE 64220
DESIGN AND DEVELOPMENT OF BILAYERED TABLETS OF AMLODIPINE BESYLATE AND METOPROLOL SUCCINATE	Dr.B.Venk ateswara Reddy, K.Navaneet ha ,K.Venkata Ramana Reddy	Department of Pharmaceut ics	World journal of pharmaceut ical research	2277 - 7105	file:///C:/Users/My%20Lappy/Downloads/article_wjpr_1402740630.pdf	WJPR

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	J.Poli Reddy					
Formulation And Evaluation Of Rosuvastatin Nanosuspensions	S Raja Shekhar And P Vijaya Lakshmi	Department of Pharmaceutics	International Journal Of Pharmacy	2249-1848	http://www.pharmascience.com/abstractview/formulation-and-evaluation-of-rosvastatin-nanosuspensions	Copernicus - UGC CARE 64220
Formulation And In Vitro Studies Of Carvedilol Microspheres With Its Characterization	K.Venkata Ramana Reddy, Pratap Kumar Patra, K.Divakar, B.Venkateswara Reddy	Department of Pharmaceutics	International Journal Of Pharmacy And Pharmaceutical Sciences	0975-1491	https://www.researchgate.net/publication/275406996_Formulation_and_In_Vitro_Studies_of_Carvedilol_Microspheres_with_its_Characterization	Academic Sciences
Molecular Aspects Of Bbb	K. Venkata Ramana Reddy, Dr.Venkateshwar Reddy, Poonam Chandra Loya	Department of Pharmacology	Research Journal Of Pharmaceutical Dosage Forms And Technology	0975-234X	file:///C:/Users/My%20Lappy/Downloads/Molecular Aspects of B BB.pdf	any publication
Evaluation of Anti Depressant and MAO Inhibitory Activity of Rhodiola rhodantha rhizome methanolic extract	J.Anantha Lakshmi, Dr. D. Satyavati	Department of Pharmacognosy	Research Journal of Pharmacy and Technology	0974-360X	http://www.indianjournals.com/ijor.aspx?target=ijor:rjpt&volume=8&issue=3&article=013	Research Gate
Process Development And Optimization For Moisture Activated Dry Granulation Method For Losartan Potassium Tablets	B.Venkateswara Reddy, K.Navaneetha, K.Venkata Ramana Reddy	Department of Pharmaceutics	International Journal Of Pharmacy And Pharmaceutical Sciences	0975-1491	https://www.researchgate.net/publication/275407151_Process_development_and_optimization_for_moisture_activated_dry_granulation_method_for_losartan_potassium_tablets	Research Gate
Rapid Green Synthesis Of Silver Nano Particles From Root Bark Extract Of Azadirachta Indica A.Juss And Their Application	Aravind K, Tasneem Mohammed, Kiranmai M	Department of Pharmacognosy	Annals of Drug Discovery And Biomedical Research	2349-736x	https://www.researchgate.net/publication/325011697_Rapid_green_synthesis_of_silver_nano_particles_from_root_bark_extract_of_azadirachta_indica_a_juss_and_their_application	Research Gate

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In Clinical Ultra Sound Gel					cation in clinical ultra sound gel Ann Dr ug disc Biomed Res 12 144-154	
Synthesis And Anti-Inflammatory Activity Screening Of Some Novel Pyrazole Derivatives	Pratap Kumar Patra, Ch. Niranjana Patra, Subasini Pattnaik	Department of Pharmaceutical Chemistry	World Journal Of Pharmacy And Pharmaceutical Sciences	2278 – 4357	file:///C:/Users/My%20Lappy/Downloads/article_wjpps_1396444206.pdf	WJPPS
Synthesis, Spectral And Microbial Studies Of Some Novel Metal (II) Complexes With Quinoline Derived Schiff Bases	Tasneem Mohammad And Kiranmai M	Department of Pharmaceutical Chemistry	Annals Of Drug Discovery And Biomedical Research	2349-736x	https://www.researchgate.net/publication/285739813_Synthesis_Spectral_and_Microbial_Studies_of_Some_Novel_Metal_II_Complexes_with_Quinoline_Derived_Schiff_Bases	Research Gate
Hypoglycemic Activity Of Niddwin, A Polyherbal Formulation In Normal Rats	T.Sruthi, Dr.D.Satyavati, Rajneekar Dasari, V.Jyothi, P.Roshan Ali	Department of Pharmacology	Asian Journal of Pharmaceutical and Clinical Research	0974-2441	file:///C:/Users/My%20Lappy/Downloads/648-Article%20Text-3033-1-10-20131229.pdf	Copernicus - UGC CARE 64220
Formulation and evaluation of intraorally rapid disintegrating tablets of olanzapine	Y. Ganesh Kumar, D. Satyavati, Ch. Anil kumar and N. Soujanya	Department of Pharmaceutics	Der Pharmacia Lettre	0975-5071	https://www.scholarsresearchlibrary.com/articles/formulation-and-evaluation-of-intraorally-rapid-disintegrating-tablets-of-olanzapine.pdf	Scholars research library
Antifungal and Anthelmintic Activity of Some Novel Pyrazole Derivatives	Pratap Kumar Patra, Ch.Niranjana Patra and Subasini Pattnaik	Department of Pharmaceutical Chemistry	Asian Journal of Research in chemistry	0974-4169	http://ajrconline.org/AbstractView.aspx?PID=2014-7-1-18	Semanticscholar
Synthesis and Screening of analgesic activity of some novel pyrazole	Pratap Kumar Patra, Ch.Niranjana Patra and Subasini Pattnaik	Department of Pharmaceutical Chemistry	International journal of pharmaceutical sciences and research	0975-8232	http://ijpsr.com/bft-article/synthesis-and-screening-of-analgesic-activity-of-some-novel-pyrazole/?view=fulltext	Web of Science (Thomson Reuters) - UGC CARE 41111

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Synthesis and Antibacterial activity screening of Some Novel Pyrazole Derivatives	Pratap Kumar Patra, ChNiranjan Patra, SubasiniPattnaik	Department of Pharmaceutical Chemistry	International Journal of Pharmacy and Pharmaceutical Sciences	0975-1491	https://pdfs.semanticscholar.org/6a99/fc10e5d3b5b41826f31c3481a051b4124c14.pdf?ga=2.75655765.1305906400.1566546979-1432223459.1566379098	Academic Sciences
Evaluation of Anti-Diarrhoeal activity of methanolic rhizome extract of PicrorrhizakurroaR oyle ex. Benth	M.VishnuVardhan Reddy, Sk.Arifa Begum,K. Hemamalin i, M.Swathi	Department of Pharmacology	Asian Journal of Pharmaceutical and Clinical research	0974-2441	http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.866.5139&rep=rep1&type=pdf	Academic Sciences
Antidiabetic and Antihyperlipidemic Activity of Alcoholic and Hydroalcoholic Extracts of Cocculusorbiculatusin Streptozotocin Induced Diabetic Rats	DamayanthiDalu and Satyavati Dhulipala	Department of Pharmacology	AJPCT	2321 - 2748	http://www.imedpub.com/abstract/antidiabetic-and-antihyperlipidemicactivity-of-alcoholic-and-hydroalcoholicextracts-of-cocculus-orbiculatus-in-streptozotocin-induced-diabetic-rats-10378.html	Research Gate
Evaluation Of Anti Depressant And Nootropic Activity Of CalophyllumInophyllum	Silpa Sundur, Inayat Ali, Dr. A. Venkateshwar Reddy, Dr. D. Satyavathi	Department of Pharmacology	Indo American Journal of Pharmaceutical Research	2231-6876	file:///C:/Users/My%20Lappy/Downloads/150535_7660.pdf	Copernicus - UGC CARE 64220



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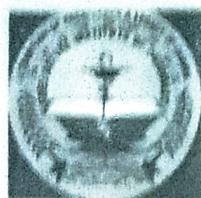
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LIST OF RESEARCH PUBLICATIONS BY FACULTY IN THE YEAR 2015- 2016

Title of the paper	Name/s of the author/s	Department of the teacher	Name of the journal	ISSN number	Link of the recognition in UGC enlistment of the Journal	Name of the indexing database
Formulation and evaluation of Gastroretentive Doxofylline tablets	L. Rajesh Patro, J. Geethanjali, K. Harish, K. Raju and E. Umadevi	Department of Pharmaceutics	Der Pharmacia Lettre	0975-5071	https://pdfs.semanticscholar.org/fe3/03765b091455ae81bb6abca9544cad335692.pdf	Scholars research library
Antitumor And Antioxidant Potential Of Zizyphus jujuba Mill Root Extract In Aspirin And Ethanol Induced Gastric Ulcers	Sameena Alam, Madhavi K Reddy, MV Reddy	Department of Pharmacology	International Journal of Phytomedicine	0975-0185	https://www.arjournals.org/index.php/ijpm/article/view/1811	Elsevier EMBASE - UGC CARE 43652
Factors Affecting Microspheres Formation	P. Shruti, K. Venkata Ramana Reddy, P. Srikanth Chowdary, Eslavath Ravindar Naik	Department of Pharmaceutics	Am. J. PharmTech Res	2249-3387	file:///C:/Users/My%20Lappy/Downloads/AJPTR-52001_4893.pdf	Academic scientific journals
Formulation And Evaluation Fast Dissolving Tablets Of Natriptan Using Super Disintegrants	L. Rajesh Patro, C. Ramesh, D. Ravi, G. Nithin Kumar and K. Raghuvaram Reddy	Department of Pharmaceutics	WJPPS	2278 – 4357	file:///C:/Users/My%20Lappy/Downloads/article_wjpps_1454141831.pdf	WJPPS
Formulation And Evaluation Of BuccalMucoadhesive Tablets Of Glipizide	B. Venkateswara Reddy and K. V. Ramana Reddy	Department of Pharmaceutics	WJPPS	2278 – 4357	file:///C:/Users/My%20Lappy/Downloads/article_wjpps_1436162956.pdf	WJPPS
Formulation characterization and in-vitro/in-vivo evaluation of orodispersible tablets of	Vijayanand P., J. S. Patil and M. Venkata Reddy	Department of Pharmaceutics	Der Pharmacia Sinica	0976-8688	http://www.imedpub.com/articles/formation-characterization-and-invitroin-vivo-evaluation-of-	Pelagia Research Library

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Nebivolol HCl					orodispersible-tablets-of-nebivolol-hcl.pdf	
Formulation, characterization and in vivo evaluation of novel edible dosage form containing nebivololHCl	Pujari Vijayana nd, JagadevappaPatil, MandaVenkata Reddy	Department of Pharmaceutics	Brazilian Journal of Pharmaceutical Sciences On-line version	2175-9790	http://www.scielo.br/scielo.php?script=sci_arttext&pid=S1984-82502016000100020	Research Gate
Formulation and Evaluation of Didanosine Enteric Coated Sustained Release Tablet	B Arunprasath, S A Sreenivas, K V Subrahmanya m , Ashwini , Harika	Department of Pharmaceutics	International Journal of Pharma Research and Health Sciences	2348-6465	http://www.pharmaceuticalhealthsciences.net/pdfs/volume3-issue4/2-vol3-issue4-formulation-and-evaluation-of-didanosine-enteric-coated-sustained-release-tablet.pdf	Pharma health sciences



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LIST OF RESEARCH PUBLICATIONS BY FACULTY IN YEAR 2016 – 2017

Title of the paper	Name/s of the author/s	Department of the teacher	Name of the journal	ISSN number	Link of the recognition in UGC enlistment of the Journal	Name of the indexing database
Design And Characterization Of Ofloxacin And Dexamethasone Ocular Inserts Using Combination Of Hydrophobic And Hydrophilic Polymers	E. Sravanthi Reddy, Himansu Bhusan Samal, S. A. Sreenivas	Department of Pharmaceutics	Asian Journal Of Pharmaceutics	0973-8398	https://www.asiapharmaceutics.info/index.php/ajp/article/view/1089/601https://www.asiapharmaceutics.info/index.php/ajp/article/view/1089/601	semantic scholar
A New Validated Rp-Hplc Method For The Determination Of Metformin Hcl And Empagliflozin In Its Bulk And Pharmaceutical Dosage Forms	S. K. Godasu And S. A. Sreenivas	Department of Pharmaceutical Analysis	International Journal Of Pharmaceutical Sciences And Research	2320-5148	http://ijpsr.com/bft-article/a-new-validated-rp-hplc-method-for-the-determination-of-metformin-hcl-and-empagliflozin-in-its-bulk-and-pharmaceutical-dosage-forms/?view=fulltext	Web of Science (Thomson Reuters) - UGC CARE 41111
Herbal Effect Of Green Tea In Treatment Of Chronic Periodontitis : A Clinical & Microbiological Study	PrernaShukla Clinician, Roopaadinarayan, Shrinkhala Singh, Dr. S.A.Sreenivas	Department of Pharmacognosy	University Journal Of Dental Sciences, An Official Publication Of Aligarh Muslim University	2278:2648	https://www.amu.ac.in/pdf/dentjour/HERBAL%20EFFE%20CT%20OF%20GREEN%20TEA%20IN.pdf	semantic scholar
Phytochemical Investigation and	Pratap Patra,	Department of	International	0975-8232	http://ijpsr.com/bft-article/phytochemic	web of Science (

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Hepatoprotective Effect of Scopariadulcis against carbon tetrachloride induced liver damage in rats	Shivkumar Shete, Shital Dange	Pharmacology	Journal of Pharmaceutical sciences and Research		al-investigation-and-hepatoprotective-effect-of-scoparia-dulcis-against-carbon-tetrachloride-induced-liver-damage-in-rats/	Thomson Reuters) - UGC CARE 41111
ANALYSIS OF PATIENT ADMISSIONS IN HOSPITAL DUE TO ADVERSE DRUG REACTION	Dr. Shivkumar Kashinath Shete, Dr. K.Sattanathan	Department of Pharmacy Practice	Journal of Drug Delivery and Therapeutics	2250-1177	file:///C:/Users/My%20Lappy/Downloads/1866-Article%20Text-5345-2-10-20180909.pdf	JDDTOnline
Formulation and Evaluation of Herbal Eye Gel from Heliotropium indium linn leaf extract for Conjunctivitis	Jasmin Sajini , V. Sivajothi, A. Geethalakshmi*, Anusha N Raj	Department of Pharmaceutics	Journal of Innovation in Pharmaceutical Sciences		https://www.innovationjournals.com/psv1i2-2.pdf	Semantic scholar
Evaluation of the clinical use of nebulization therapy and antibiotics in inpatients with chronic obstructive pulmonary disease: A randomized prospective study at a tertiary care teaching hospital	Asfia Fatima*, Falak Naaz, Amatul Ali Sameera, Najiya Fatima, Mohd Mohiuddin Shareef, Musa Khan, Javed Akhtar Ansar	Department of Pharmaceutics	Int J Adv Pharmacy Med Bioallied Sci		https://www.researchgate.net/publication/318902118_Evaluation_of_the_clinical_use_of_nebulization_therapy_and_antibiotics_in_inpatients_with_chronic_obstructive_pulmonary_disease_A_randomized_prospective_study_at_a_tertiary_care_teaching_hospital	Research Gate



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LIST OF RESEARCH PUBLICATIONS BY FACULTY IN YEAR 2017 – 2018

Title of the paper	Name/s of the author/s	Department of the teacher	Name of the journal	ISSN number	Link of the recognition in UGC enlistment of the Journal	Name of the indexing database
RP-HPLC Method Development and Validation of Regorafenib in pure Form and Pharmaceutical Dosage Form	Jitendra Debata , Pratap Kumar Patra, P. Suresh	Department of Pharmaceutical Analysis	Asian J. Research Chem	0974-4169	http://ajrconline.org/AbstractView.aspx?PID=2018-11-4-12	google Scholar
In Vitro Antioxidant Potency Studies Of Hydro Alcoholic Leaf Extract Of Cassia Uniflora	Jitendra Debata*, Pratap Kumar Patra, P. Suresh	Department of Pharmacology	Indo American journal of pharmaceutical research	2349-7750	file:///C:/Users/My%20Laptop/Downloads/171233.pdf	google Scholar
The study of prescription pattern in respiratory tract infection diseases in a tertiary care hospital	R Ragini*, Shivkumar Shete, K Anoocha, P Anees , Afshan Shadab baig	Department of Pharmacy Practice	International Journal of Research in Pharmacology & Pharmacotherapeutics	2278-2656	http://www.ijrpp.com/sites/default/files/articles/IJRP_P_17_407_12-19.pdf	google Scholar
In Vitro Antioxidant Activity On Ethanolic Extract Of Black Grapes (Vitis	Shital Dange*, K. Janaki, D. Deepika, V. Kavya Sri, D. Karthik	Department of Pharmacology	Panacea Journal of Pharmacy and Pharmaceutical	2349-7025	https://pdfs.semanticscholar.org/1ffc/b5c354aad6f3042986ab68ccf5d42a8e26b8.pdf?_ga=2.1	Semanticscholar

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Vinifera) And Preliminary Phytochemical Screening			Sciences		14122786.13 05759409.12 66146117 1412223459 1566119078	
Comparison Of Analytical Parameter of Genetically Transformed Hairy Roots Of Withania somnifera With Normal Roots	Rupali Gawande, Parag Kale, Shital Dange, Shivakumar Shete, Dr A G Namde o, Dr S A Sreenivas	Department of Pharmacognosy	International Journal Of Pharmac y And Analytic al Research	2320- 2831	http://www.ijpar.com/sites/default/files/articles/IJAR_17_206-289-295.pdf	IJPAB



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LIST OF RESEARCH PUBLICATIONS BY FACULTY IN YEAR 2018 – 2019

Title of the paper	Name/s of the author/s	Department of the teacher	Name of the journal	ISSN number	Link of the recognition in UGC enlistment of the Journal	Name of the indexing database
Synthetic Novel Flavanoid derivatives act as potential Antidiabetic agent against Streptozocin induced in diabetic Rats	G. Babu, Asish Bhaumik, K. Krishnama chary, P. Kalyani	Department of Pharmaceutic al Analysis	Asian J. Research h Chem	0974-4150	http://ajrconline.org/HTML_Papers/Asian%20Journal%20of%20Research%20in%20Chemistry_PID_2018-11-5-6.html	ajrconline
Pharmacokinetic and Pharmacodynamic studies of etodolac loaded vesicular gels on rats by transdermal delivery	N Madhavi	Department of Pharmaceutic s	Daru Journal of Pharma ceutical science s	2008-2231	https://www.ncbi.nlm.nih.gov/pubmed/30206897	PubMed

**A REVIEW ON DRIED NANOSUSPENSIONS- A NOVEL FORMULATION TO ENHANCE SOLUBILITY OF POORLY AQUEOUS SOLUBLE DRUGS**S Raja Shekhar*¹ and P Vijaya Lakshmi²¹CMR College of Pharmacy, Kandlakoya (v), Medchal road, Hyderabad- 501401²Sri Datta Institute of Pharmacy, Sheriguda(v) Ibraimpatnam(M), Nagarjuna Sagar road, Rangareddy Dist-501510***Corresponding author e-mail:** s.rajashekhar2@gmail.com**ABSTRACT**

Solubility is most important and crucial factor for drug effectiveness. Large proportions of newly discovered drugs are water insoluble, and therefore poorly bioavailable. Nanosuspensions are one of the promising drug delivery systems proved to be very effective in eliminating the solubility problems and increasing the bioavailability of poorly soluble drugs. Nanosuspensions are very finely colloid, biphasic, dispersed, solid drug particles in an aqueous vehicle. These are prepared by using wet mill, high pressure homogenizer, emulsion-solvent evaporation, melt emulsification method and super critical fluid techniques. The most recent advancement in Nanosuspensions is Dried Nanosuspension which is prepared by freeze drying or spray drying of the formulated Nanosuspensions. It has higher stability and solubility properties than nanosuspensions. These can be delivered by oral, parenteral, pulmonary and ocular routes. Nanosuspensions can also be used for targeted drug delivery when incorporated in the ocular inserts and mucoadhesive hydrogels.

Key Words: Nanosuspensions, High Pressure Homogenizer, bioavailability, freeze drying.**INTRODUCTION**

More than 40 percent of the drugs coming from High-throughput screening are poorly soluble in water. Obviously poorly water-soluble drugs show many problems in formulating them in conventional dosage forms. One of the critical problems associated with poorly soluble drugs is too low bioavailability and or erratic absorption. Nanosuspensions are promising strategy for the efficient delivery of hydrophobic drugs. To date, nanoscale systems for drug delivery have gained much interest as a way to improve the solubility problems. The reduction of drug particles into the sub-micron range leads to a significant increase in the dissolution rate and therefore enhances bioavailability. Nanosuspensions are promising candidates that can be used for enhancing the dissolution of poorly water soluble drugs. Nanosuspensions contain submicron colloidal

dispersion of pharmaceutical active ingredient particles in a liquid phase stabilized by surfactants^[1]. Present review is emphasised on dried nanosuspensions. Nanosuspensions of a poorly soluble drug could be spray dried or lyophilised to obtain flowable powders that could be easily redispersed. These optimized powders significantly improve dissolution rates as compared to the micronized drug, or unoptimized nanosuspensions^[2].

Potential Benefits of Nanosuspension Technology for Poorly Soluble Drugs

- Reduced particle size, increased drug dissolution rate, increased rate and extent of absorption, increased bioavailability of drug, onset time, peak drug level, reduced variability and reduced fed/fasted effects.
- Nanosuspensions can be used for compounds that are water insoluble but which are soluble in oil. On the other hand, Nanosuspensions can be used

THE PHARMA INNOVATION - JOURNAL

Chemoprotective effect of ethanolic extract of *Morinda citrifolia* against Cisplatin induced nephrotoxicity

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The present study was aimed to evaluate the ethanolic extract of *Morinda citrifolia* (EEMC) fruits for chemoprotective effect in Cisplatin-induced nephrotoxicity in rats. Nephrotoxicity was induced in Wistar rats by intraperitoneal administration of Cisplatin 5 mg/kg. Effect of concurrent administration of ethanolic extract of *Morinda citrifolia* fruits at dose of 100 and 200 mg/kg b.w. were given for respective animal groups by oral route was determined using serum creatinine, serum protein and serum urea as indicators of kidney damage. Both the doses produced significant ($P<0.01$) protective activity in Cisplatin induced nephrotoxicity models as evident by decrease in serum creatinine, serum urea, serum protein in extract treated groups which was elevated by Cisplatin, which was further confirmed by histopathological study. Cisplatin induced glomerular atrophy, infiltration of cells and tubular congestion of the kidney cells were found to be reduced in the groups receiving EEMC along with cisplatin.

Keyword: Chemoprotective, *Morinda citrifolia*, Cisplatin.

1. Introduction

Nephrotoxicity is one of the most common kidney problems and occurs when body is exposed to a drug or toxin. When kidney damage occurs, body unable to rid of excess urine and wastes from the body and blood electrolytes will

all become elevated. A number of therapeutic agents can adversely affect the kidney resulting in acute renal failure, chronic interstitial nephritis and nephritic syndrome because increasing number of potent therapeutic drugs like aminoglycoside antibiotics, chemotherapeutic

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CHALLENGES AND OPPORTUNITY IN ENCAPSULATION OF LIQUID FILLED IN HARD GELATIN OVER SOFT GELATIN CAPSULES - AN INNOVATIVE TECHNOLOGY

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Keywords:

Hard gelatin capsules, Low
dose & High Potency, Liquid
Filling, Sealing Technology

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ABSTRACT

The encapsulation of liquids provide solutions for convenient delivery through improved oral absorption of poorly water-soluble drugs. In addition, low dose (content uniformity), highly potent (containment), low melting point drugs, those with a critical stability profile and those for which a delayed release is required are candidates for liquids. The choice of a hard or soft capsule will depend primarily on the components of the formulation which provide the best absorption characteristics as well as on the physical characteristics, such as the viscosity of the formulation and the temperature at which the product needs to be filled. Numerous excipients are available for formulation of lipid-based systems and their compatibilities with hard gelatin capsules have been tested. The availability of new enhanced manufacturing equipment has brought new opportunities for liquid-filled hard capsules. Filling and sealing technologies for hard capsules, provides the formulator with the flexibility of developing formulations in-house from small scale, as required for Phase I studies, up to production. **Liquid-fill hard capsule technology** is becoming increasingly accepted by the pharmaceutical industry and – while it can hardly be expected to replace more conventional dosage forms such as tablets and powder-filled capsules – it will become a mainstream alternative for those products with particular processing or clinical needs. Liquid filled hard gelatin capsule are well established as a solid dosage form for convenient administration of drugs orally in a liquid form in two piece HPMC capsule. This technology is more adopted for insoluble hydrophobic and potent drugs. And there are also many advantages in giving the drug in liquid form. Hence drug compounds are solubilised inside the hard gelatin capsules such that on subsequent dissolution of LFHGC in the gastro intestinal tract, the drug remains in solution, and contribute for good bioavailability of drugs.

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Development and validation of RP-HPLC method for the analysis of Cobicistat and related impurities in bulk and pharmaceutical dosage forms

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Abstract

The prime aim of the current work is to develop and validate a novel, specific, sensitive, precise, rapid and faster isocratic elution, RP HPLC method for estimation of Cobicistat and related impurities in bulk and pharmaceutical dosage forms. Chromatographic separation was achieved on Inertsil ODS – 3V column (250 mm X 4.6 mm, 5µ) using an isocratic mode with mobile phase composed of potassium dihydrogen phosphate buffer (PH 2.5) and acetonitrile in the ratio of 30:70 v/v. The flow rate was 1.0ml/min, temperature is maintained at ambient and detection was made at 240 nm. The run time was 15 min. The developed method was validated according to the ICH guide lines and different analytical parameters such as linearity, precision, accuracy, specificity, limit of detection, limit of quantitation were determined. The linearity of calibration curve for each analyte in concentration range of 400 µg/ml -1200µg/ml. is good. There exists good correlation between peak area and analyte concentration. Relative standard deviation values for cobicistat is 0.099 and impurity is 0.6636. LOD for drug and impurity is 0.02% and 0.20% respectively. LOQ for drug and impurity is 0.06% and 0.60% respectively. Hence the proposed method is highly sensitive, precise, accurate, robust and fast. The short retention time allows the analysis of large number of samples in short period of time and it is cost effective, so it can be successfully applied for routine analysis of active pharmaceutical ingredient and related impurities in bulk and pharmaceutical dosage forms.

Keywords

Cobicistat, Tybost, method validation, RP-HPLC method.

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DESIGN AND EVALUATION OF CHITOSAN CONTAINING MUCOADHESIVE BUCCAL PATCH OF FLUXOTINE HCL

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Abstract- The main objective of present study was to design and evaluate the Muco adhesive buccal patch. The buccal region is an attractive route of administration for systemic drug delivery. To provide prolonged desire state concentration of Fluxotine Hydrochloride with minimal fluctuation and improved bioavailability, a mucoadhesive buccal patch is designed in the present study that Fluxotine hydrochloride is an antidepressant with selective serotonin reuptake inhibitor, its oral bioavailability is 80% because of first pass metabolism.

In this study Mucoadhesive buccal patches were prepared with chitosan dissolved in glacial acetic acid and glycerol as plasticizer. Mucoadhesive patch containing 20mg of Fluxotine Hcl were evaluated with respect to their *invitro* drug permeation through goat buccal mucosa in 3 hr by using Franz diffusion cell, weight variation, uniformity of film, Area of the film, determination of % yield of buccal patch, percentage moisture loss, Mucoadhesive strength, folding endurance, drug content uniformity, swelling behaviour and surface pH were obtained. The physicochemical interaction between drug and polymer were investigated by FTIR spectroscopy revealed that there is no interaction.

Then the formula could be promising for the fabrication of buccal patches.

Index Terms- Fluxotine Hcl, buccal patches, invitro release, evaluation

I. INTRODUCTION

Recent years have seen an increasing interest in the development of novel mucoadhesive buccal dosage forms. These are useful for the systemic delivery of drug as well as for local targeting of drug to a particular region of the body. Buccal delivery for the transmucosal absorption of the drug into the systemic circulation offers number of advantages for those drugs that suffer from first pass metabolism in the liver, poor oral bioavailability. Conceivably buccal delivery systems provide easy administration, thereby increasing patient compliance.[1],[2]. FLUXOTINE HCL is an **SSRI** (selective serotonin reuptake inhibitor) used mainly as an antidepressant to treat major depression, bipolar disorder, obsessive compulsive disorder, bulimia nervosa, panic disorder and premenstrual dysphoric disorder. Fluxotine hydrochloride was selected as the model drug for the investigation because it has got certain characteristics that a drug should possess to get absorbed through

buccal route viz., biphasic solubility and low molecular weight (309.33 g/mol). Moreover it undergoes first-pass metabolism, so its bioavailability may be improved when delivered through buccal route.[3]

The main aim was to prepare mucoadhesive buccal patches by using different concentration of mucoadhesive polymer to drug ratio in order to obtain desired concentration of the drug when compared to conventional dosage forms. As the bioavailability of conventional dosage form is less than 80%

II. MATERIALS AND METHODS

Materials

FLUXOTINE HCL was obtained as a gift sample from NATCO PHARMA LTD. Hyderabad. Chitosan was provided from Hi Media Laboratories Pvt. Ltd Mumbai. PVP K-30, glycerol, glacial acetic acid were obtained from S.D. Fine Chemicals, India. All other reagent and chemicals were of analytical grade.

Methods

SOLVENT CASTING METHOD: *Preparation of mucoadhesive buccal patches:*

1%,2%(m/V) of chitosan was dissolved in 10 mL 1.5% (V/V) acetic acid under occasional stirring for 12 hr. The resulting viscous chitosan solution was filtered through nylon gauze to remove debris and suspended particles. To improve patch performance and release characteristics, a water-soluble hydrophilic additive, PVP K-30, was added in different concentrations. The drug and PVP K-30 were added into the chitosan solution under constant stirring. PEG 6000 was added into the solution as plasticizer under constant stirring. This viscous solution was left overnight at room temperature to ensure a clear, bubble-free solution. The solution was poured into a glass Petri dish (16 cm diameter) and allowed to dry at ambient temperature till a flexible film was formed. Dried films were carefully removed, checked for any imperfections or air bubbles and cut into patches of 16 mm in diameter, containing 20 mg of drug per patch.[4],[5]. The patches were packed in aluminum foil and stored in an airtight glass container to maintain the integrity and elasticity of the patches. **TABLE 1** contains the compositions of different formulations.

ANTIDIABETIC ACTIVITY AND ANTI-OXIDANT ACTIVITY OF NIDDWIN, A POLYHERBAL FORMULATION IN ALLOXAN INDUCED DIABETIC RATS

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ABSTRACT

Objective: The present study was focused to evaluate the antidiabetic activity and antioxidant activity of NIDDWIN, a polyherbal formulation in alloxan induced diabetic rats.

Methods: Alloxan induced diabetic rats were divided into four groups of five each. Group-I was given aqueous suspension of 2% gum acacia, Group-II and III was given aqueous suspension of NIDDWIN 50mg/kg and 100mg/kg, Group-IV was given aqueous suspension of Glibenclamide 10mg/kg were given orally for 10days. The blood samples were collected before and after administration of drugs at 0, 2, 4, 6, and 8hrs on 1st, 5th, and 10th day from retro-orbital sinus, serum was separated and estimated for glucose, cholesterol and triglycerides levels. On 10th day pancreas were isolated from all the groups and subjected for histopathological studies. Diabetic rats were evaluated for anti-oxidant activity by using NIDDWIN.

Results: NIDDWIN showed significant antidiabetic activity at 4th hr on 1st, 5th and 10th day was found to be effect in comparable with standard Glibenclamide 10mg/kg. Histopathological results of NIDDWIN showed positive results when compared with standard Glibenclamide 10mg/kg. NIDDWIN significantly showed the percentage reduction of lipid per-oxidation levels in diabetic rats.

Conclusion: NIDDWIN a polyherbal formulation concluded that it possesses antidiabetic activity and anti-oxidant activity in diabetic rats and further NIDDWIN should be evaluated to develop probable mechanism of action.

Keywords: NIDDWIN, Glibenclamide, Alloxan monohydrate, Glucose Kit, Cholesterol Kit, Triglycerides Kit, Alpha-tocopherol, Thiobarbituric acid, UV-spectrophotometer.

INTRODUCTION

Diabetes is a heterogeneous metabolic disorder characterized by altered carbohydrate, lipid and protein metabolism which causes hyperglycemia resulting from insufficient insulin secretion, insulin action or both [1, 2]. It is one of the refractory diseases identified by Indian council of medical research for which an alternative medicine is a need for the treatment. Diabetes mellitus has become a growing problem in the contemporary world [3]. Today India has become the diabetic capital of the world with over 20million diabetic patients and this number is likely to increase to 57million by 2025[4]. This astronomical increase in the prevalence of diabetes has made diabetes a major public health challenge for India and is become important human ailment afflicting many from various walks of life in different countries and once again the whole world being looked upon ayurvedic the oldest healing system of medicine for the treatment of diabetes [2]. Although there are many synthetic medicines developed for patients, but it is the fact that it has never been reported that someone had recovered that totally from diabetes [5]. The modern oral hypoglycemic agents showed undesirable side effects thus in the recent years considerable attention has been directed towards the antidiabetic potential of medicinal plants and their herbal formulation in the management of disease. The concept of polyherbalism is peculiar to ayurveda although it is difficult to explain in term of modern parameters. It is evident that there are many herbal formulations of varying potency since these preparation act by different mechanism, it is theoretically possible that different combination of these extract will do better job in reducing blood glucose. In the traditional system of plant medicine it is usual to use plant formulation and combined extract of plant are used as a drug of choice rather than individual ones [6] to get the benefit of synergism. Some of the polyherbal formulations which are in the market are: Diabet, Diasol, Diasulin, Dia-care, ESF/AY/500, EFPT/09, Karmin plus, Okudibet, 5EPHF.

NIDDWIN a polyherbal formulation which include 11 antidiabetic herbs and 1 mineral the 12 constituents of NIDDWIN were individually proved to have antidiabetic activity but the combination of these 12 constituents called NIDDWIN for its antidiabetic activity was not yet reported. Each 500mg of NIDDWIN consists of following formulation: *Tinospora*

cordifolia – 50mg, *Gymnema sylvestre* – 50mg, *Terminalia tomentosa* – 50mg, *Asphaltum* – 50mg, *Tribulus terrestris* – 50mg, *Emblica officinalis* – 58mg, *Mucuna pruriens* – 50mg, *Sida cordifolia* – 50mg, *Withania somnifera* – 25mg, *Terminalia bellerica* – 8mg, *Terminalia chebula* – 8mg, *Momordica charantia* – 10mg.

Therefore, the present study was focused to evaluate the antidiabetic activity and antioxidant activity of NIDDWIN in alloxan induced diabetic rats.

MATERIALS AND METHODS

Chemicals and standard drugs

Glibenclamide, Alloxan monohydrate, Gum acacia, Alpha-tocopherol (cipla), Thiobarbituric acid, sodium do decyl sulphate, potassium chloride, n-butanol, pyridine, glucose kit, cholesterol kit, triglycerides kit chemicals are purchased from SD Fine chemicals Ltd., India. All the chemicals used were of analytical grade.

Plant Material

NIDDWIN a polyherbal formulation containing 11antidiabetic herbs and 1mineral was manufactured by IMIS pharmaceuticals Pvt Ltd., Vijayawada is evaluated for antidiabetic activity.

Animals

Male albino wistar rats weighing 180-200gms were obtained from authorized animal house (Albino research center, Hyderabad). Animals were housed at room temperature 25°C with a 12hrs light and 12hrs dark cycle.

The animals had free access to standard rat pellet diet and tap water.

After one week of acclimatization, the animals were considered for suitable study and the experiments were conducted according to CPCSEA guidelines no GNIP(TKR)/CPCSEA/IAEC/2013/11.

Acute toxicity study

The animals were divided into four groups each containing 5animals NIDDWIN a polyherbal formulation was given orally in logarithmic doses 30, 100, 300 and 1000mg/kg. The rats were observed

Evaluation of *Azadirachta indica* Extracts against *Helicobacter Pylori* 26695 Lipopolysaccharide Induced Gastric Ulcer in Rats

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ABSTRACT

The association between *Helicobacter pylori* and gastric pathology is well established. Lipopolysaccharide is a major membrane component of *H.pylori*. *Helicobacter pylori* lipopolysaccharide (HP-LPS) is a potent virulence factor in the causation of gastric ulcer and other gastrointestinal disorders. Globally *H.pylori* is developing multidrug resistance making the life span of any drug limited, there is an urgent need to search for alternative medicines, which seem to lie in medicinal plants. The present study aimed to evaluate the anti-ulcer effect of *Azadirachta indica* extracts against HP-LPS induced gastric ulcer in rats. A daily dose of 50µg/animal for three days was selected as fixed dose to induce gastric ulcers. The effectiveness of plant extracts was assessed by ulcer index and gastric parameters such as volume of gastric juice, free acidity, total acidity, acid output and pepsin concentration. The protective effect of *A.indica* was also confirmed by histopathological examination of rat's stomachs. *A.indica* extracts were also subjected to HPLC and GC-MS analysis. HP-LPS induced alterations in gastric secretory parameters were altered significantly in rats treated with *A.indica* extracts, suggesting that it has an anti-secretory role. This result reveals that cellular damage and pathological changes caused by HP-LPS were mitigated by *A.indica* extracts. The anti-ulcer activity of *A.indica* extracts may be due to presence of flavonoids, tannins and other antioxidant principles which were responsible for combating the gastric mucosal offensive factors.

Keywords- *Helicobacter pylori* lipopolysaccharide (HP-LPS), *Azadirachta indica*, gastric ulcer, anti-ulcer activity.

1. INTRODUCTION

Helicobacter pylori is a spiral shaped gram-negative bacterium that lives in the stomach and duodenum. Greater than 50% of the world populations are suffering from gastritis which is the result of chronic infection of gastric mucosa by *H.pylori*. The infection may lead to the development of peptic ulcer [1]. Further leads to gastric mucosa associated lymphoid tissue lymphoma [2] and increase the risk of gastric cancer in humans [3]. In developing countries, 70-90% of population carries *H.pylori*; whereas the prevalence of infection in developed

countries is lower, ranging from 25-50% [4]. In recent studies, *H.pylori* infection is also suspected to be associated with coronary artery and ischemic heart disease [5-6].

It is well known that lipopolysaccharide is a very common and important component in outer most membrane of Gram negative bacterium responsible for toxicity of endotoxin. Lipopolysaccharide present in cell walls of *H.pylori* is involved in its virulence actions [7-8]. Antigenicity of *Helicobacter pylori*-lipopolysaccharide (HP-LPS) was reported by Mills SD *et al* [9]. Lipopolysaccharide is composed of lipid A, inner core oligosaccharide and oligosaccharide chains termed O antigen chains. *H.pylori* lipopolysaccharide has lower immunological activities compared with those of other Gram negative bacteria, but it was shown to stimulate histamine release and DNA synthesis in rat enterochromaffin-like cells more effectively than *E.coli* lipopolysaccharide [10-11]. It is also reported that, HP-LPS could enhance the production of reactive oxygen species from primary cultures of guinea pig gastric mucosa [12]. These findings strongly suggest that HP-LPS have the ability to trigger gastric mucosal cell responses. HP-LPS shows acute mucosal inflammatory responses within two days, associated with mucus epithelial cell apoptosis, increase in mucosal expression of endothelin-1, stimulation of TNF- α , increase in NOS-2, excessive nitric oxide generation, apoptotic caspase activation and marked enhancement in gastric epithelial cell apoptosis [8, 13-16]. Other relevant pathogenic factors of HP-LPS are the progression of the mucosal inflammation process, and disturbances in nitrogen-activated protein kinase cascades [17-18]. Maastricht Consensus report has recommended *H.pylori* eradication in many diseases and conditions [19]. The combination of a proton pump inhibitor (e.g.omeprazole) and antibiotics (e.g.amoxicillin, ampicillin, tetracyclins, Clarithromycin) is curative in patients suffering from *H.pylori* infections [20].

Azadirachta indica (*Meliaceae*) popularly known as neem, is a medicinal plant and has a role in the treatment of disorders like microbial infections, skin diseases, dental disorders, malaria, syphilis, leprosy and has antiseptic properties [21]. More than 135 compounds of diverse

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UPDATES

Vol. 3, Issue 3 (2014)**Evaluation of nootropic activity of smrithi: a polyherbal formulation****AUTHOR(S):**

Jyothi Vadthya, Satyavati. D, Pradeep Kumar .C, Ch. Maheshwara Reddy

ABSTRACT:

In the present study 'Smrithi' selected for evaluation of its nootropic activity in different experimental animal models like Scopolamine induced cognitive deficits in mice on Elevated plus maze (EPM) and Morris water maze (MWM) tasks. Smrithi was administered for seven days at the dose of 100 and 200 mg/kg body weight, scopolamine (0.3 mg/kg) was used to induce amnesia, piracetam (50 mg/kg) and Mentat (1 and 2 ml/kg) served as reference standards. Smrithi treated animals significantly ($p < 0.01$) reduce the Transfer latency on Elevated plus maze and Escape latency in Morris water maze when compared with that of standard nootropic Piracetam, standard polyherbal formulation Mentat and a control group of animals. The probable mechanism of action of Smrithi might be due to its ability to elevate Acetylcholine levels by significant reduction of Acetylcholinesterase enzyme activity in the brain and ultimately improved memory. In the light of above, it may be worthwhile to explore the potential of this formulation in the management of Alzheimer's patients.


 Effect of test drugs on spatial memory in elevated plus-maze * $p < 0.05$ and ** $p < 0.01$ control Vs treated groups using one way ANOVA followed by Dunnett's test

Fig.: Effect of test drugs on spatial memory in elevated plus-maze * $p < 0.05$ and ** $p < 0.01$ control Vs treated groups using one way ANOVA followed by Dunnett's test

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**DESIGN AND DEVELOPMENT OF BILAYERED TABLETS OF
AMLODIPINE BESYLATE AND METOPROLOL SUCCINATE****Dr.B.Venkateswara Reddy^{*1}, K.Navaneetha¹,K.Venkata Ramana Reddy²,P.Poli Reddy³**¹Department of Pharmaceutics, St.Pauls College of Pharmacy, Turkayamjal (V), Hayathnagar
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(M), R.R. India.**ABSTRACT**

The present work aims to develop a bilayer dosage form containing one immediate release drug amlodipine besylate and another extended release drug metoprolol succinate. The immediate release layer was prepared by using micro crystalline cellulose, sodium starch glycolate, croscopolvidone and dicalcium phosphate. The sustain release layer was prepared by using HPMC K15, Sodium CMC, Carbopol. FTIR studies for the drug and polymers shows that they are compatible. The optimized formulations from both layers are used to prepare the bilayer tablet. The prepared tablets are evaluated for various properties. Release of Metoprolol Succinate from the tablets formulated by employing Carbopol and PEO showed that the drug release was as per within the USP limits. So formulation M7 is concluded as optimized

formulation for sustained release. Amlodipine besylate from the tablets formulated by employing dicalcium phosphate, MCC and sodium starch glycolate showed that the drug release was as per within the USP limits. So formulation A8 is concluded as optimized formulation for immediate release. And for further study batch A8 and M7 were used for tableting a bilayered formulation which is subjected to post compression and *In-Vitro* dissolution studies by HPLC. The release kinetics of optimized formula (A8M7) showed non-fickian transport and followed Higuchi model. Thus it can be concluded that the combination therapy uses lower doses of drug to reduce the patient's blood pressure.

**FORMULATION AND EVALUATION OF ROSUVASTATIN NANOSUSPENSIONS**S Raja Shekhar*¹ and P Vijaya Lakshmi²¹CMR College of Pharmacy, Kandlakoya (v), Medchal road, Hyderabad- 501401.²Sri Datta Institute of Pharmacy, Sheriguda(v) Ibraimpatnam(M), Nagarjuna Sagar road, Rangareddy Dist-501510.***Corresponding author e-mail:** s.rajashekhar2@gmail.com**ABSTRACT**

The objective of the present study was to formulate and evaluate nanosuspensions of rosuvastatin, a poorly soluble drug in order to enhance its solubility and dissolution characteristics. Rosuvastatin is a Biopharmaceutical Classification System (BCS) Class II drug having very low solubility therefore low oral bioavailability. In this study rosuvastatin nanosuspensions were prepared by precipitation technique followed by high frequency sonication by using a combination of stabilizers like PVP K90 and LUTROL F127 in different ratios. The formulated nanosuspensions were characterised by Scanning Electron Microscope (SEM) and FTIR. The formulations were evaluated for drug content, entrapment efficacy, Zetapotential and In-Vitro dissolution. SEM results showed the particle size of the formulated nanosuspensions in nanosize. FTIR spectrum revealed that there are no interactions between drug and carriers. The effect of particle size was found to be significant on the saturation solubility of the drug and *in-vitro* drug release studies showed significant increase in the dissolution rate of nanosuspensions as compared with pure drug.

Key Words: Nanosuspensions, High Pressure Homogenizer, bioavailability, freeze drying, PVP K90, dissolution.**INTRODUCTION**

Nanosuspensions are colloidal dispersions of nanosized drug particles stabilized by surfactants. They can also be defined as a biphasic system consisting of pure drug particles dispersed in an aqueous vehicle in which the diameter of the suspended particle is less than 1µm in size^[1]. Reduction of drug particles to nanometer range leads to an enhanced dissolution rate not only because of increased surface area but also because of saturation solubility. The increase in the saturation solubility and solution velocity of nanoparticle is due to increase of vapour pressure of the particles. More than 40 percent of the drugs coming from High-throughput screening are poorly soluble in water^[2]. Obviously poorly water-soluble drugs show many problems in formulating them in conventional dosage forms. One of the critical problems associated with poorly soluble drugs is too low bioavailability and or erratic absorption^[3]. Nanosuspensions are promising

strategy for the efficient delivery of hydrophobic drugs.

Potential Benefits of Nanosuspension Technology for Poorly Soluble Drugs

- Reduced particle size, increased drug dissolution rate, increased rate and extent of absorption, increased bioavailability of drug, onset time, peak drug level, reduced variability and reduced fed/fasted effects.
- Nanosuspensions can be used for compounds that are water insoluble but which are soluble in oil. On the other hand, Nanosuspensions can be used in contrast with lipidic systems, successfully formulate compounds that are insoluble in both water and oils^[4].
- Nanoparticles can adhere to the gastrointestinal mucosa, prolonging the contact time of the drug and thereby enhancing its absorption.
- A pronounced advantage of Nanosuspension is that there are many administration routes for

Original Article

FORMULATION AND IN VITRO STUDIES OF CARVEDILOL MICROSPHERES WITH ITS CHARACTERIZATION

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ABSTRACT

Objective: Carvedilol is a non-selective beta blocker was formulated as microspheres by using Ethyl cellulose as a carrier.

Methods: These ethyl cellulose microspheres were prepared by the solvent evaporation method. The prepared microspheres were subjected to various evaluation parameters and in vitro release studies. Highest percentage of entrapment was obtained by increasing the amount of polymer with respect to uniformity of drug. The particle sizes of the prepared microspheres were determined by optical microscopy method and morphology by SEM analysis.

Results: The prepared microspheres have gained good spherical geometry with smooth surface as evidence by SEM studies. The entrapment efficiency for F₃ was found to be 97.5±0.1527 % with maximum drug loading of 45.26 around. The best-fit release kinetics was achieved with Korsmeyer-Peppas plot followed by zero order and first order kinetics. The release of drug was influenced by the drug to polymer ratio and particle size and was found to be both diffusion and dissolution controlled.

Conclusion: The study showed that Carvedilol microspheres of 1:2 (F₃ batch) ratios got better sustained effect over a period of 12 hours. Finding of all this investigation conclusively demonstrate prolongation of drug release at a constant and controlled rate.

Keywords: Carvedilol, Ethyl cellulose, Entrapment efficiency, SEM, *in vitro*-profile.

INTRODUCTION

The primary objective of zero-order release is to up-hold constant drug concentration in blood for a prolonged period of time. Microspheres have played a vital role in the development of controlled/sustained release drug delivery systems [1-2].

It blocks beta-1 and beta-2 adrenergic receptors as well as the alpha-1 adrenergic receptors. Carvedilol is a non-selective beta blocker indicated in the treatment of mild to moderate congestive heart failure (CHF).

Microspheres have been of particular interest from the pharmaceutical point of view providing the possibility to achieve sustained and controlled drug release. Different kinds of controlled drug delivery systems have been developed for various routes of administration, since they require less frequent drug administration, provide more efficient therapeutic effects, and reduce the incidence of side effects. To develop a drug delivery system for oral administration, the preferred route of administration, it is necessary to optimize the release rate of an active ingredient from the system. One of the most extensively studied methods is microsphere [3].

The overall aim and objective of project was the formulation of carvedilol microspheres and their evaluation of microspheres with their release kinetics.

MATERIALS AND METHODS

Drugs and Chemicals

Carvedilol was a gift sample obtained from Chandra labs, Hyderabad, Ethyl cellulose, Dichloro methane, Poly vinyl alcohol was supplied from Research Fine Chem. Industries, Mumbai.

Drug and excipients compatibility studies

To investigate any possible interactions between the drug and excipients used, the FTIR spectra of Carvedilol and its physical mixture with ethyl cellulose, ethanol, dichloromethane and polyvinyl

alcohol were carried out using Bomem FTIR MB-II spectro photometer. The samples were prepared as KBr (potassium bromide) discs compressed under a pressure of 10 Ton/nm². The wave number selected ranged between 400 and 4800 cm⁻¹. The results were summarized in and discussion made in table 1. The Fourier Transform Infra red analysis was conducted for the structure characterization. FTIR spectra of the formulated microspheres and drug were recorded. Microspheres were taken in a KBr pellet using Bomem FTIR MB-II instrument. Approximately 5mg samples were mixed with 50mg of spectroscopic grade KBr, samples were scanned in the IR range from 500-3500cm⁻¹, with a resolution of 4cm⁻¹.

Fourier Transform Infrared Spectroscopy

FTIR spectroscopy was used to ensure that no chemical interactions between the drugs and polymer has occurred. The wave numbers of final formulation and individual ingredients were compared, hence it was conclude that there was no chemical interactions were found among excipients and the drug.

Solvent Evaporation Method [4-7]

Carvedilol microspheres were prepared by solvent evaporation technique. For this carvedilol was dissolved in dichloromethane and then polymer was dissolved in ethanolic solution. Both drug and polymer solutions were mixed well to form a uniform solution. The obtained drug and polymer solution was added drop wise to the PVA solution under constant stirring at 1500 rpm by using homogenizer. The beaker and its content were heated to 80° c with constant stirring for 1hr until the aqueous phase was completely removed by evaporation. The microspheres formed were collected by whattman filter paper and washed 3 times with distilled water and dried at a room temperature for one day.

Surface morphology

The surface morphology and structure were visualized by scanning electron microscopy (SEM).The samples were prepared by lightly

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REVIEW ARTICLE

Molecular Aspects of BBB

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ABSTRACT:

The function of the BBB is dynamically regulated by various cells present at the level of the BBB. This realization implies better understanding of the relationship of at the BBB to drug structure and physicochemical properties. The physical barrier naming BBB is characterized by tight junctions between endothelial cells, by the absence of fenestrations and low occurrence of pinocytotic activity. Penetration of chemicals to the BBB occurs using a combination of intra and intercellular passages. The main factors that limit the penetration of lipophilic membranes by any molecule are its molecular weight and its ability to form hydrogen bonds and so bind to circulating plasma proteins. Tight junctions regulate the intracellular passage of molecules according to their physico-chemical properties (e.g. lipophilicity, ionization and polarity), where inter cellular penetration is regulated by influx and efflux transporters, endocytosis and passive diffusion.

KEYWORDS: Pharmacokinetic and pharmacodynamic parameters affecting BBB. Fundamental principles.

INTRODUCTION:

Poor pharmacokinetic properties (absorption, distribution, metabolism and excretion) and toxicity are responsible for most of the failures in drug discovery projects. In this chapter it gathers all information about fundamentals of BBB. The main characteristics of this cellular membrane are which covers like uniform thickness, no fenestrae, low pinocytotic activity, continuous basement membrane and negative surface charge. A study of 27 substances by Levin found that the four drugs in this group with molecular weights over 400 Da had no measurable brain uptake. However, it is now known that these substances are all substrates for P-glycoprotein, a major brain-to-blood, or efflux, pump located at the BBB that prevents or greatly retards a large number of small, lipid soluble molecules from entering the CNS. The BMVECs are surrounded by a basement membrane which composed of structural proteins (collagen and elastin), specialized proteins (fibronectin and laminin) and proteoglycans. This structural specificity gives the basement membrane cell establishment role penetration measurement methods and penetration prediction methods are discussed.

Structurally tight junctions formed by interaction of integral trans membrane proteins with neighbouring plasma membrane. In addition to the contribution in the barrier function some other events such as adhesion of BMVECs to each other, the contact inhibition during vascular growth, the initiation of cell polarity and the regulation of paracellular permeability have been suggested for adherence junctions. A dynamic interaction between tight junctions and adherence junctions through signalling pathways regulate the permeability of BBB. In addition to the proteins with enzymatic activities, there are other specific proteins (drug efflux transporters, multi drug resistance proteins, organic anion transporting polypeptides) work as BBB transporters which are responsible for rapid efflux of xenobiotics from the CNS (Losscher and Potschka, 2005) and delivery of the essential nutrients and transmitters to the brain.

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Evaluation of Anti Depressant and MAO Inhibitory Activity of *Rhodiola rhodantha* rhizome methanolic extract

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Online published on 2 May, 2015.

Abstract

The objective of the present study was to evaluate the antidepressant activity of methanolic extract for the rhizomes of *Rhodiola rhodantha*. Depression is the most common feature and it may range from a very mild condition to even severe depression which is called as psychotic depression. In the traditional systems of medicine many plants and formulations have been used to treat depression for thousands of years. The present study was undertaken to assess the antidepressant effect of crude methanolic extract of *Rhodiola rhodantha* at doses 100mg/kg, 200mg/kg and 400mg/kg using parameters forced induced swimming test (FST), tail suspension test (TST). Significant dose dependent decline in immobility time was observed in all the three doses in FST and TST and the extract showed dose dependent relation of immobility reduction in mice. In order to understand the probable mechanism of antidepressantlike activity in FST and TST, the levels of 5-hydroxy indole acetic acid in urine was taken as basis for biochemical assessment of anti depressant activity.

The antidepressant activity of extract was comparable to that of standard drug imipramine. The results of the present study indicate the potential for use of RRMS as an adjuvant in the treatment of depression.

[Top](#)

Keywords

Forced swim test, Tail suspension test, Depression, *Rhodiola rhodantha*, imipramine.[Top](#)

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Original Article

PROCESS DEVELOPMENT AND OPTIMIZATION FOR MOISTURE ACTIVATED DRY GRANULATION METHOD FOR LOSARTAN POTASSIUM TABLETS

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ABSTRACT

Objective: The present study deals with the formulation and process development of Losartan potassium tablets by moisture activated dry granulation (MADG) process and optimization of granulating fluid uptake concentration.

Methods: Losartan potassium was selected as a model drug and Micro crystalline cellulose (MCC) as a binder. Losartan potassium tablets prepared by MADG process were found to be a simple, clean and robust process. Losartan potassium tablets were manufactured for the Seven batches **F-I to F-VII** using different concentrations of granulating fluid, keeping the total weight (75 mg) of the tablet constant in all the formulations.

Results: The results from the evaluation of the effects of the granulating binder level, binder type suggest that the MADG process is robust and creates granulation with good physical properties and finished products with satisfactory quality attributes. The process is applicable for accomplishing most of the granulation need for solid dosage-form development as practiced in the pharmaceutical industry. It is essentially a one-step granulation process. It is also an economical, energy-saving and efficient manufacturing process.

Conclusion: The losartan potassium tablets prepared by MADG process had advantages such as short manufacturing time and process variables when compared with convention wet granulation process.

Keywords: Moisture activated, Optimization, Robust, Quality attributes, Pharmaceutical industry.

INTRODUCTION

Tablets are solid dosage forms containing medicinal substances with or without suitable diluents. They are most preferred form of medication both by pharmaceutical manufacturer as well as physicians and patients. Tablets are safe and convenient dosage form for administration of active pharmaceutical ingredients (API) with excellent physicochemical stability by comparison to some other dosage forms and also provide means of accurate dosing. However the process of manufacturing of tablets is complex. Hence, careful consideration has to be given to selection of right process and right excipients ultimately give a robust, high productivity and regulatory compliant product of good quality [1].

Granulation is one of the most important unit operations in the production of pharmaceutical oral dosage forms like tablets [2].

Granulation is one of the most important unit operations in the production of pharmaceutical oral dosage forms. Granulation process is defined as "any process whereby small particles are gathered into larger, permanent masses in which the original particles can still be identified." The term "granulated" material is derived from the Latin word "**granulatum**" meaning 'grained'. Pharmaceutical granules typically have a size range between 0.2 and 4.0 mm, depending on their subsequent use [3]. In modern times, granulation technology has been widely used by a wide range of industries such as coal, mining and agrochemical. These industries employ agglomeration techniques to reduce dust, provide ease of handling and enhance the material's ultimate utility [4].

Granulation methods can be divided into two major types: wet methods which utilize some form of liquid to bind the primary particles and dry methods which do not utilize any liquid. The classical granulation process using either wet or dry methods is employed in the process industries [5]. Pharmaceutical granulation process is used for tablet and sometimes capsule dosage forms; however, in some applications the process is used to produce spherical granules for the modified release indications or to prepare granules as sprinkles to be used by pediatric patients. In some countries like Japan, having granulated product in a "sachet" is acceptable where a large dose of the drug product is not suitable for swallowing [6].

A simple and novel granulation process called moisture-activated dry granulation (MADG) is that granulation process, in which a small amount of water is used to activate the granule formation (i.e., perform agglomeration) without requiring hot air drying of the granules [7]. After creating the moist agglomerates, this process uses stepwise addition and blending of common pharmaceutical ingredients that absorb and distribute moisture, thus resulting in a uniform, free-flowing and compatible granulation [8].

MADG is a very simple and innovative process where granules are created with water and a granulating binder, as in wet granulation but are not heat dried or milled. This process helps to minimize endpoint sensitivity [9].

MADG also offers energy savings, a short manufacturing time, and fewer critical formulation and process variables which makes it an easier candidate than conventional wet or dry granulation processes with which to implement the FDA's Quality by Design concepts [10,11].

MADG also offers energy savings short manufacturing time, fewer critical formulation and process variables which make it an easier candidate than conventional wet or dry granulation processes with which to implement the FDA's Quality by Design concepts [12]. Applicable to more than 90% of the granulation needs for pharmaceutical, food and nutritional industry, very few variables, resulting in less need for expensive process analytical technology (PAT), applicable to a number of formulations including high and low drug load formulations [13]. Polymer matrix type controlled release formulations, water soluble and insoluble drug formulations suitable for continuous processing. It uses very little energy so it is a green process, reproducible and scalable.

Now-a-days among all granulating techniques, MADG technology is widely employed in granulation of moisture sensitive active pharmaceutical ingredients.

The present study will be carried out with the Losartan potassium as ideal drug candidate for the preparation of granules by innovative MADG technology & optimization of water content, concentration of granulating binder and moisture absorbents along with other excipients.

Research article

Rapid green synthesis of silver nano particles from root bark extract of *azadirachta indica* a.juss and their application in clinical ultra sound gel

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Abstract

Objective: To synthesize and characterize silver nano particles (AgNPs) from the root bark extract of *Azadirachta indica* through green synthesis and prepare clinical ultrasound gel and evaluate the same for its antibacterial property. **Methodology:** Root bark extract of *Azadirachta indica* (RBAI) was prepared by using 80% ethanol. Different molar concentrations of plant extract and silver nitrate have been employed to synthesize AgNPs. The so formed AgNPs were confirmed by colour change, and further characterized by Ultraviolet-Visible spectroscopy. The RBAI was qualitatively analyzed for various phytochemical constituents. The size and morphology of the particles were characterized by scanning electron microscopy (SEM) followed by x-ray diffraction studies. Clinical ultrasound gel containing AgNPs was prepared and tested for its antibacterial potential. **Results:** The qualitative phytochemical screening of RBAI indicated the presence of flavonoids, glycosides and terpenoids suggesting that these compounds act as reducing and stabilizing agents. UV-Visible spectroscopic results exhibited a characteristic band at 430 nm. Scanning electron microscopy (SEM) showed spherical shapes and sizes of NPs that ranged between 29.7 to 97.7 nm. The most optimal combination of 5% extract and 1M silver nitrate was identified from SEM results and subjected for further evaluation by x-ray diffraction as they exhibited phase centered cubic symmetry. Clinical ultrasound gel containing AgNPs was prepared and tested for its antibacterial potential. Further investigations are recommended to establish commercial value of this gel. **Conclusion:** The present work reports a simple; cost effective and eco friendly method for the synthesis of water soluble silver nanoparticles (AgNPs) using root bark extract of *Azadirachta indica* (RBAI). Clinical ultrasound gel prepared from these NPs proved to be effective with significant antibacterial activity.

Key Words: Silver nanoparticles, *Azadirachta indica*, root bark extract, Scanning electron microscopy, Ultra sound gel, Antibacterial activity.

Research article

Synthesis, Spectral and Microbial Studies of Some Novel Metal (II) Complexes with Quinoline Derived Schiff Bases

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Abstract

Quinoline derived Schiff bases complex with metals Zinc, Cobalt and Copper and exhibit remarkable biological activity against *Escherichia coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Bacillus subtilis*. Tentative structures have been proposed on the basis of analytical and spectral data.

Key words: Quinoline derivatives, Schiff base, metal complex, anti bacterial activity, Minimum Inhibitory Concentration.

Introduction

The quinoline skeleton is often used for the design of many synthetic compounds with diverse pharmacological proquinoline containing drugs particularly 4-aminoquinoline which has a long and successful history as antimalarials. The quinoline ring system occurs in various natural products, especially in alkaloids. Quinoline skeleton is often used for the design of many synthetic compounds with diverse pharmacological properties. In 1880, quinine was isolated as active ingredient from the bark of cinchona tree for the treatment of malaria.¹ Chimanine alkaloids,

simple quinolines, isolated from the bark of *Gilipea longiflora* trees of the *Rutaceae* family, are effective against the parasite *Leishmania* sp. Cryptolepine an indoquinoline alkaloid isolated from decoction of the roots of shrub *Cryptolepis sanguinolenta*²⁻⁴ is used in traditional medicine for the treatment of other diseases⁵. Dynemicin A and streptonigrin anti tumor antibiotics, are synthesized from preformed quinoline derivatives^{6,7}. The 8-(diethylaminohexylamino)-6-methoxy-4-methylquinoline is highly effective against the protozoan parasite *Trypanosoma cruzi*, which is the agent of chagas' disease⁸ and the 2-(2-methylquinoline-4-ylamino)-N-

HYPOGLYCEMIC ACTIVITY OF NIDDWIN, A POLYHERBAL FORMULATION IN NORMAL RATS

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ABSTRACT

Objective: The present study was focused to evaluate the hypoglycemic activity of NIDDWIN, a polyherbal formulation in normal rats.

Methods: Male Albino Wistar Rats (180-200gms) were divided into four groups of five animals each. Group-I was given aqueous suspension of 2% gum acacia, Group-II was given aqueous suspension of NIDDWIN 50mg/kg, Group-III was given aqueous suspension of NIDDWIN 100mg/kg, Group-IV was given aqueous suspension of Glibenclamide 10mg/kg were given orally for 10days. The blood samples were collected before and after administration drugs at 0hrs, 2hrs, 4hrs, 6hrs, and 8hrs on 1st, 5th, and 10th days from retro-orbital sinus and serum was separated and estimated for glucose, cholesterol and triglycerides by using analytical method[1,2].

Results: NIDDWIN showed significant hypoglycemic activity at 4hrs on 1st, 5th, and 10th days was found to be effect in comparable with standard Glibenclamide 10mg/kg.

Conclusion: NIDDWIN a polyherbal formulation concluded that it possesses hypoglycemic activity in normal rats and should be evaluated for its antidiabetic activity

Keywords: NIDDWIN, Glibenclamide, Glucose Kit, Cholesterol kit, Triglyceride Kit, UV-Spectrophotometer.

INTRODUCTION

Diabetes is a heterogeneous metabolic disorder characterized by altered carbohydrate, lipid and protein metabolism which causes hyperglycemia resulting from insufficient insulin secretion, insulin action or both [3, 4]. It is one of the refractory diseases identified by Indian council of medical research for which an alternative medicine is a need for the treatment. Diabetes mellitus has become a growing problem in the contemporary world [5]. Today India has become the diabetic capital of the world with over 20million diabetic patients and this number is likely to increase to 57million by 2025[6]. This astronomic increase in the prevalence of diabetes has made diabetes a major public health challenge for India and is become important human ailment afflicting many from various walks of life in different countries and once again the whole world being looked upon ayurvedic the oldest healing system of medicine for the treatment of diabetes [3]. Although there are many synthetic medicines developed for patients, but it is the fact that it has never been reported that someone had recovered that totally from diabetes [7]. The modern oral hypoglycemic agents procedure undesirable side effects thus in the recent years considerable attention has been directed towards the antidiabetic potential of medicinal plants and their herbal formulation in the management of disease.

The concept of polyherbalism is peculiar to ayurveda although it is difficult to explain in term of modern parameters. It is evident that there are many herbal formulations of varying potency since these preparation act by different mechanism, it is theoretically possible that different combination of these extract will do better job in reducing blood glucose. In the traditional system of plant medicine it is usual to use plant formulation and combined extract of plant are used as a drug of choice rather than individual ones[8] to get the benefit of synergism and to find suitable antidiabetic and antioxidant combination therapy. Polyherbal formulation which appear to be most effective relatively nontoxic and have substantial documentation of efficacy.

NIDDWIN a polyherbal formulation which include 11 antidiabetic herbs and 1 mineral the 12 constituents of NIDDWIN were individually proved to be having antidiabetic activity but the combination of these 12 constituents called NIDDWIN for its antidiabetic activity was not yet reported in the market.

Hypoglycemic polyherbal formulations:

Some of the polyherbal formulations which are in the market are: Diabet, Dianex, DRF/AY/5001, Diabrid, Diakyur, Diasulin, Diabecure, EFPTT/09, 5EPHF, Karmin plus, Okudiabet,

Formulation of NIDDWIN

Tinospora cordifolia – 50mg, *Gymnema sylvestre* – 50mg, *Terminalia tomentosa* – 50mg, *Asphaltum* – 50mg, *Tribulus terrestris* – 50mg, *Emblca officinalis* – 58mg, *Mucuna pruriens* – 50mg, *Sida cordifolia* – 50mg, *Withania somnifera* – 25mg, *Terminalia belerica* – 8mg, *Terminalia chebula* – 8mg, *Momordica charantia* – 10mg.

Therefore, the present study was focused to evaluate the hypoglycemic activity in normal rats of the polyherbal formulation NIDDWIN.

MATERIALS AND METHODS

Plant Material

NIDDWIN a polyherbal formulation containing 11antidiabetic herbs and 1mineral was manufactured by IMIS pharmaceuticals Pvt ltd., Vijayawada is evaluated for hypoglycemic activity.

Animals

Male albino wistar rats weighing 180-200gms were obtained from authorized animal house (Albino research center, Hyderabad). Animals were housed at room temperature 25°C with a 12hrs light and 12hrs dark cycle. The animals had free access to standard rat pellet diet and tap water. After one week of acclimatization, the animals were considered for suitable study and the experiments were conducted according to CPCSEA guidelines.

Acute toxicity study

The animals were divided into four groups each containing 5animals NIDDWIN a polyherbal formulation was given orally in increasing dose 30, 100, 300 and 1000mg/kg. The rats were observed continuously for 2hrs for behavioural, neurological and autonomic profiles and after 24hours and 72hours for any lethality [9, 10].



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Formulation and evaluation of intraorally rapid disintegrating tablets of olanzapine

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ABSTRACT

Olanzapine is an atypical antipsychotic, FDA for the treatment of schizophrenia and bipolar disorder. Olanzapine is structurally similar to clozapine and quetiapine. The present research work is aimed at developing a Formulate and Evaluated of a Rapid disintegrating tablet dosage form of Olanzapine. Who have little or no access to water are also good candidates for Rapid disintegrating tablets of Direct Compression method was employed for blending of drug with polymers in the given ratio as a nine formulations. The prepared powder blends were then compressed into tablets using the necessary Superdisintegrants like CCS, CP, and SSG and Excipients. The tablets were evaluated for Weight variation, thickness, hardness, friability, Drug Content and Disintegrating Time (Sec) were subjected to a 40 minutes in vitro drug release studies (USP dissolution rate test apparatus II, 50 rpm, 37°C ±0.5°C) using phosphate buffer, pH 6.8 as a dissolution medium (900ml). The amount of Olanzapine released from the tablet formulations at different time intervals was estimated using a UV spectroscopy method. The formulations that showed a considerable retardation of the drug release are considered promising. Among the nine formulations, F5 formulation containing Drug to Crospovidone (CP) in ratio 1:0.25 is optimized based on its ability to till 40 mins of invitro dissolution time, and its % Cumulative Drug Release Of The 96.09% of dissolution study.

Key words: Olanzapine, schizophrenia, direct compression, Crospovidone

INTRODUCTION

Rapid dissolving tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva. The faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form¹.

The major advantage of the ODT formulation is that it combines the advantages of both liquid and conventional tablet formulations, and also offering advantages over both traditional dosage forms. It provides the convenience of a tablet formulation, and also allowing the ease of swallowing provided by the liquid formulation. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient



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Antifungal and Anthelmintic Activity of Some Novel Pyrazole Derivative

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ABSTRACT:

Various Quinazolinone clubbed Pyrazole derivative compounds (7a1,7a2,7b1,7b2) were synthesized as per standard chemical procedure and characterized by physical and spectral analysis. Quinazolinone nucleus was synthesized using anthranilic acid as starting material and then it clubbed with Pyrazole moiety. The antimicrobial activity of all the synthesized compounds was evaluated separately for the possible antifungal activity against common pathogenic microorganisms *Candida albicans* and *Aspergillus niger* by cup plate method and anthelmintic activity by using common Indian earthworm *Pheretima posthuma*. Ketokonazole was used as a standard antifungal drug and albendazole, piperazine citrate as standard anthelmintic drug in this study.

KEY WORDS: Pyrazole, Quinazolinone, Antifungal, Anthelmintic, Ketokonazole.

INTRODUCTION:

Pyrazoles are five member ring heterocyclic compounds, have some structural features with two nitrogen atoms in adjacent position and are also called as Azoles¹. Recently Pyrazole derivatives have been found in nature, β- [1-pyrazolyl]alanine was isolated from the seeds of water melons [*Citrullus lanatus*]. The best described property of almost every group of pyrazoles is in the treatment of inflammation and inflammation associated disorders, such as arthritis². Pyrazole derivatives are the subject of many research studies due to their widespread potential biological activities such as antimicrobial³, antiviral⁴, antitumor^{5,6}, antihistaminic⁷, antidepressant⁸, insecticides⁹ and fungicides⁹.

Several pyrazole derivatives have been found to possess significant activities such as 5-α-reductase inhibitor¹⁰, antiproliferative¹¹, antiparasitic¹², herbicides¹³. A good number of pyrazoles have also been reported to have interesting biological activities like anti-inflammatory¹⁴ and antiprotozoal^{15,16} which render them valuable active ingredients of medicine and plant protecting agents. Further current literature indicates 1, 2-pyrazole derivatives to possess various biological activities¹⁷.

Human and animal diseases caused by helminth parasites have great impact on public health. Toxocariasis is an infection caused by the nematode *Toxocara* commonly found in the intestines of puppies and older dogs (*Toxocara canis*) and cats (*Toxocara cati*). Humans become infected either by ingesting embryonated eggs accidentally or eating contaminated food with soil containing the eggs (such as unwashed raw vegetables). Hymenolepiasis is caused by (*Hymenolepis nana* or *Hymenolepis diminuta*) the dwarf tapeworm which is the most common cause of all intestinal cestode infections. In an infected person the worms can remain encysted in tissue so infection can persist for years.

Treatment with Praziquantel or Albendazole is recommended alternative to these drugs are now being sought¹⁸. The continuous and longterm reliance on a small range of compounds has led to the development of drug resistance in many helminth strains. In addition, after treatment with Albendazole or Mebendazole several side effects have been reported in hosts such as gastrointestinal symptoms (epigastric pain, diarrhea, nausea, vomiting); nervous system symptoms (headache, dizziness) and allergic phenomena (edema, rashes, urticaria). Some anthelmintic drugs such as Praziquantel and Albendazole are contraindicated for certain groups of patients like pregnant and lactating women¹⁹.

The global burden of both, human and domestic animal parasitic diseases coupled with the emergence of drug resistance has made the development of new chemotherapy a critical need²⁰.

Present study was undertaken to synthesize some novel pyrazole clubbed with quinazolinone compounds and investigating their antifungal and anthelmintic activity.

MATERIALS AND METHODS:

Melting points were determined on an electro thermal apparatus using open capillaries and are uncorrected. Thin-layer chromatography was accomplished on 0.2-mm pre-coated plates of silica gel G6 F254 (Merck). Visualization was made with UV light (254 and 365nm) or with an iodine vapor. IR spectra were recorded on a Shimadzu-fourier transform infra red (FTIR)-8400 Spectrophotometer using KBr disc. ¹H NMR spectra were recorded on a Bruker DPX-400 MHz spectrometer. Chemical shifts are expressed in δ ppm downfield from TMS as an internal standard. The mass spectral data were obtained with a SHIMADZU-GCMS-QC-2010.

EXPERIMENTAL PROCEDURE

Synthesis of 3, 5 dibromo Anthranilic Acid (1):

20gm of anthranilic acid dissolved in 25 c.c. bromine in glacial acetic acid (9 cc bromine in 25 cc glacial acetic acid) was added drop by drop from separating funnel till the reddish colour of the liquid persisted. Then content was converted to a thick mass. So it will form dibromoanthranilic acid. The reaction was monitored by TLC. After completion of reaction, the solvent was removed under vacuum when the reaction was completed. The solid was crystallized from methanol to give pure product (2). Their melting points, yields and molecular formula are given in Table-1.

Yield: 79%; mp 202-204 °C; IR (cm-1): 3312 (N-H stretching of primary amine), 3066 (C-H stretching of aromatic ring), 1726, 1675 (C=O stretching of carboxylic acid), 1604 (N-H deformation of NH group), 1560 and 1432 (C=C stretching of aromatic ring), 1004 (C-H in plane bending for aromatic ring); 695(C-Br); ¹H NMR (CDCl₃) δ ppm: 7.03-7.58 (m, 2H, ArH), 5.38 (s, 1H, NH), 9.94 (s, 1H, COOH); MS: m/z 293,275,213, 189, 174, 134; Anal.Calcld. For C₇H₅ Br₂NO₂: C, 28.51; H, 1.71; N, 4.75. Found: C, 28.80; H, 1.64; N, 4.77%.

Synthesis of 6, 8-dibromo-2-methyl-4H-3, 1-benzoxazin-4-one (2)

A mixture of 3, 5 di Bromo Anthranilic Acid (1,0.01 mol) and acetic anhydride (10.2 ml(0.1 mol)) was refluxed on gentle flame for 1 hr. The excess of acetic anhydride was distilled off under reduced pressure and the residue was dissolved in petroleum ether and kept aside for 1 hr. The reaction was monitored by TLC. After completion of reaction, the solvent was removed under vacuum when the



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SYNTHESIS AND SCREENING OF ANALGESIC ACTIVITY OF SOME NOVEL PYRAZOLE

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SYNTHESIS AND SCREENING OF ANALGESIC ACTIVITY OF SOME NOVEL PYRAZOLE

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ABSTRACT: The present study was aimed to study the analgesic potency of some new pyrazole compounds. Various Quinazolinone clubbed Pyrazole derivative compounds (7a₁, 7a₂, 7b₁, 7b₂) were synthesized by using anthranilic acid as starting material as per standard chemical procedure. The synthesized compounds were characterized by physical and spectral analysis by using UV-visible spectrophotometer, Fourier transform infra red (FTIR) Spectrophotometer, ¹H Nuclear Magnetic Radiation spectrometer and Gas Chromatography Mass Spectrophotometer.-QC-2010. Moreover Pyrazole derivatives have found their clinical application as analgesic agent. In this study the synthesized novel Pyrazole derivatives were screened for in-vivo analgesic properties by tail-flick method. The result obtained is compare with standard diclofenac. It has been observed that the maximum analgesic activity was recorded by the compound **7a₁** having 359 % analgesic activity followed by compound **7b₁** (268 %), **7b₂**(204 %) & **7a₂** (159%) analgesic potential. The compounds **7a₁** showed nearly similar percentage analgesic activity compared to standard drug Diclofenac sodium, whereas **7b₁**, **7b₂** & **7a₂** registered percentage analgesic activity relatively less than standard drug. The compound **7a₁** possess maximum analgesic potency.

Keywords:

Pyrazole, Quinazolinone, Analgesic, Diclofenac, Tail-flick

INTRODUCTION: International Association for the Study of Pain (IASP) has defined pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It can be defined as characteristic neuro-physiological sensation which arises from noxious stimuli. Analgesics are the agents which relieve or decrease pain sensation by increasing threshold to painful stimuli without causing loss of consciousness.

The cause of the pain may be physiologic, inflammation and neuropathic. Pain can be classified into two types: Integumental pain which is superficial and related to skin muscle and joints and visceral pain which is deep seated and related to heart, kidney, stomach, gall bladder etc.

Analgesics are the drugs which decrease the pain sensation. There are 2 types of analgesic agents: Opioid analgesics and Non steroidal anti-inflammatory agents (NSAIDs). Opioid analgesics are mainly used to treat the visceral pain. They cause respiratory depression, CNS depression, drug dependence. But opioid analgesics lack anti-inflammatory, antipyretic or uricosuric action. NSAIDs on the other hand are mainly used to treat integumental pain.

The main physiological peripheral receptors are sensitized by pro-inflammatory autoids like prostaglandin, 5-HT, histamine, bradykinin, interleukin etc. These drugs are most effective against pain associated with inflammation.

When a tissue is injured, prostaglandin synthesis increases in that tissue. The prostaglandins have 2 major actions: They are the mediators of inflammation as well as they sensitize the pain receptors at the nerve endings by lowering the threshold of response to painful stimuli. Moreover allows the other mediators (histamine, bradykinin, 5-HT etc.) which cause inflammation to intensify activation of the sensory neurons. Thus, a drug that prevents synthesis of prostaglandins will be effective in treating pain due to inflammation. The mechanism of action involves the inhibition of cyclooxygenases enzymes in the arachidonic acid cascade for synthesis of prostaglandins.

Pyrazoles are five member ring heterocyclic compounds, have some structural features with two nitrogen atoms in adjacent position and are also called as Azoles¹. Recently Pyrazole derivatives have been found in nature¹, β-[1-pyrazolyl] alanine was isolated from the seeds of water melons [Citrullus lanatus]. The best described property of almost every group of pyrazoles is in the treatment of inflammation and inflammation associated disorders, such as arthritis². Pyrazole derivatives are the subject of many research studies³ due to their widespread potential biological activities such as antimicrobial³, antiviral⁴, antitumor^{5,6}, antihistaminic⁷, antidepressant⁸, insecticides⁹ and fungicides⁹.

Several pyrazole derivatives have been found to possess significant activities such as 5-α-reductase inhibitor¹⁰, antiproliferative¹¹, antiparasitic¹², herbicides¹³. A good number of pyrazoles have also been reported to have interesting biological activities like anti-inflammatory¹⁴ and antiprotozoal¹⁵ which render them valuable active ingredients of medicine and plant protecting agents. Further, current literature indicates 1,2-pyrazole derivatives to possess various biological activities¹⁷. Quinazolinone are classes of fused heterocycles that are of considerable interest because of the diverse range of their biological properties, for example, anticancer, diuretic, anti-inflammatory, anticonvulsant and antihypertensive activities¹⁸.

SYNTHESIS AND ANTIBACTERIAL ACTIVITY SCREENING OF SOME NOVEL PYRAZOLE DERIVATIVES

PRATAP KUMAR PATRA^{*1}, CH NIRANJAN PATRA², SUBASINI PATTA³^{*1}Sree Dattha Institute of Pharmacy, Ibrahimpatnam, Hyderabad 501510, ²Roland Institute of Pharmaceutical sciences, Khodashing,³Berhampur University, Bhanjavihar, Berhampur. Email: pratappatra83@gmail.com

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ABSTRACT

Objective: To synthesise a series of quinazolinone clubbed pyrazole derivatives and evaluate for their antibacterial activity.

Method: Various Quinazolinone clubbed Pyrazole derivative compounds were synthesized as per standard chemical procedure and characterized by physical and spectral analysis. The antimicrobial activities of all the synthesized compounds were evaluated separately for their possible antimicrobial activity against common pathogenic bacteria. Bacteria used in the present study were *Staphylococcus aureus* (*S. aureus*), *Bacillus subtilis* (*B. subtilis*), as gram positive and *Escherichia coli* (*E. Coli*), *Pseudomonas aeruginosa* (*P. aeruginosa*) as gram negative bacteria. The study was conducted by cup-plate method.

Result: The antibacterial data's of the newly synthesized compounds indicate that some of them show better antibacterial activity than compared to their reference drug Ampicillin.

Conclusion: Four (7a1, 7a2, 7b1, 7b2) new biologically active pyrazole were synthesized for the first time. Synthesized compounds exhibited good antibacterial activity against the tested microorganism.

Keywords: Pyrazole, Quinazolinone, Antibacterial, Zone of inhibition, Ampiciline.

INTRODUCTION

Pyrazoles are five member ring heterocyclic compounds, have some structural features with two nitrogen atoms in adjacent position and are also called as Azoles [1]. Recently Pyrazole derivatives have been found in nature [1], β -[1-pyrazolyl] alanine was isolated from the seeds of water melons [*Citrullus lanatus*]. The best described property of almost every group of pyrazoles is in the treatment of inflammation and inflammation associated disorders, such as arthritis [2]. Pyrazole derivatives are the subject of many research studies due to their widespread potential biological activities such as antimicrobial[3], antiviral[4], antitumor[5,6], antihistaminic[7], antidepressant[8], insecticides[9] and fungicides[9].

Several pyrazole derivatives have been found to possess significant activities such as 5- α -red-uctase inhibitor [10], anti-proliferative [11], anti-parasitic [12], herbicides [13]. A good number of pyrazoles have also been reported to have interesting biological activities like anti-inflammatory [14] and antiprotozoal [15-16] which render them valuable active ingredients of medicine and plant protecting agents. Further, current literature indicates 1, 2-pyrazole derivatives to possess various biological activities [17].

In this present study some novel pyrazole clubbed with quinazolinone compounds were synthesized and were evaluated for antimicrobial activity by cup-plate method.

MATERIALS AND METHODS

Melting points were determined on an electro thermal apparatus using open capillaries and are uncorrected. Thin-layer chromatography was accomplished on 0.2-mm precoated plates of silica gel G60 F254 (Merck). Visualization was made with UV light (254 and 365nm) or with an iodine vapor. IR spectra were recorded on a Shimadzu-fourier transform infra red (FTIR)-8400 Spectrophotometer using KBr disc. ¹H NMR spectra were recorded on a Bruker DPX-400 MHz spectrometer. Chemical shifts are expressed in δ ppm downfield from TMS as an internal standard. The mass spectral data were obtained with a SHIMADZU-GCMS-QC-2010.

Experimental procedure

Synthesis of 3, 5 dibromo Anthranilic Acid (1)

20gm of anthranilic acid dissolved in 25 c.c. bromine in glacial acetic acid(9 cc bromine in 25 cc glacial acetic acid) was added drop by

drop from separating funnel till the reddish colour of the liquid persist. Then content was converted to a thick mass. So it will form dibromo anthranilic acid. The reaction was monitored by TLC. After completion of reaction, the solvent was removed under vacuum when the reaction was completed. The solid was crystallized from methanol to give pure product (2). Their melting points, yields and molecular formula are given in Table-1.

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Synthesis of 6, 8-dibromo-2-methyl-4H-3, 1-benzoxazin-4-one (2)

A mixture of 3, 5 dibromo Anthranilic Acid (1,0.01 mol) and acetic anhydride (10.2 ml(0.1 mol) was refluxed on gentle flame for 1 hr .The excess of acetic anhydride was distilled off under reduce pressure and the residue was dissolve in petroleum ether and kept a side for 1 hr. The reaction was monitored by TLC. After completion of reaction, the solvent was removed under vacuum when the reaction was completed. The solid was crystallized from ethanol to give pure product (2). Their melting points, yields and molecular formula are given in Table-1.

Yield: 71%; mp 179-181 °C; IR (cm⁻¹): 3076,3000 (C-H stretching of aromatic ring), 1689 (C=O stretching of **benzoxazin-4-one** ring), 1639 (C=N stretching of pyridine ring), 1495 (C=C stretching of aromatic ring), 1127 (COC stretching of **benzoxazin-4-one** ring),933 (C-H in plane bending for aromatic ring); 684(C-Br stretching of aromatic ring); ¹H NMR (CDCl₃) δ ppm: 1.87 (s, 3H, CH₃), 7.39-7.89 (m, Ar-H); MS: *m/z* 317,289,276,237,213,158,105; Anal.Calcd. for C₉H₅Br₂NO₂: C, 33.89; H, 1.58; N, 4.39. Found: C, 33.91; H, 1.54; N, 4.42%.

Synthesis of 3-amino-6,8-dibromo-2-methylquinazolin-4(3H)-one (3)

A 100mL round-bottom flask equipped with condenser and septum was charged with a solution of 6,8-dibromo-2-methyl-4H-3,1-benzoxazin-4-one (2, 0.01 mmol) in ethyl alcohol (30 mL),followed by the hydrazine hydrate (0.03 mmol) was added and the mixture

EVALUATION OF ANTI-DIARRHOEAL ACTIVITY OF METHANOLIC RHIZOME EXTRACT OF *PICRORRHIZA KURROA* ROYLE EX. BENTH

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ABSTRACT

Picrorrhiza kurroa (Scrophulariaceae) is a small perennial herb growing in the hilly parts of the north-Western Himalayas region in India and Nepal. The objective of the present study was to evaluate and compare anti-diarrhoeal activity of *Picrorrhiza kurroa* royle ex. Benth on magnesium sulphate induced enteropooling and gastro intestinal motility test using charcoal meal methods. The results suggested that there was a significant reduction in the peristaltic movements in charcoal meal test and reduction in the intestinal fluid secretions in magnesium sulphate induced enteropooling method indicating its anti-diarrhoeal activity. Two doses of the test extract i.e. 250mg/kg, 500mg/kg were used to evaluate the anti-diarrhoeal activity. Atropine sulphate was used as the standard in the gastro intestinal motility test to compare the test results. Loperamide was used as the standard drug in magnesium sulfate induced enteropooling method to compare the test results. The study concluded that the methanolic rhizome extract of *Picrorrhiza kurroa* showed significant Anti-diarrhoeal action.

Keywords: *Picrorrhiza kurroa*, Anti-diarrhoeal action, Loperamide, magnesium sulfate induced enteropooling, gastro intestinal motility test, Atropine sulfate

INTRODUCTION

Picrorrhiza kurroa royle ex. Benth belonging to the family Scrophulariaceae is a small perennial herb that is widely distributed in the north – West India on the slopes of Himalayas between 3000 and 5000mts[1,2]. *Picrorrhiza kurroa* is an important herb in the traditional Ayurvedic system of medicine and has been used to treat liver and bronchial problems. Other traditional uses include treatments of dyspepsia, bilious fever, chronic dysentery and scorpion sting. The most important active constituents of *Picrorrhiza kurroa* are the cucurbitacin glycosides, apocyanin, drosin, iridoid glycosides, picrosides and kutkin[3,4]. Diarrhoeal diseases are one of the leading causes of morbidity and mortality in developing countries and are responsible for the death of millions of people each year[5]. There are a large number of epidemiological and experimental evidence pertaining to worldwide acute diarrhoeal disease, which is one of the principle causes of death in infants[6.] As there is no literature available on anti-diarrhoeal action of *Picrorrhiza kurroa*, the present study was taken up to evaluate for Anti-Diarrhoeal action using magnesium sulfate induced enteropooling and gastro intestinal motility test methods of methanolic rhizome extract of *Picrorrhiza kurroa* royle ex. Benth.

MATERIALS AND METHODS

Plant collection, identification and authentication

The plant specimen was collected from S.V University, Tirupati, India and identified as *Picrorrhiza kurroa* Royle ex. Benth. Belonging to the family Scrophulariaceae, Voucher No: SDIP, Ref No: 002 dated 26/10/2012 and authenticated by Dr.Madhavachetty, Botanist, Tirupati. The rhizomes of the plant were dried in vacuum oven at 40° C.

Preparation of plant extract

Rhizomes of *Picrorrhiza kurroa* plant are coarsely powdered and are successively extracted by continuous hot percolation method using Soxhlet apparatus employing methanol followed by distillation to recover the excess solvent. Methanolic extraction yielded sufficiently good quantity of the product. The extract was later subjected to drying and stored in a desiccator for further use[7]. The extract is soluble in water. Therefore, from the dried methanolic extract,

accurately 250mg/ml and 500mg/ml solutions were prepared using distilled water.

Standard used for the activity

Loperamide and Atropine sulfate were used as the standard drugs to compare the test results. Loperamide was prepared in the concentration of 3mg/kg in distilled water and Atropine sulfate was prepared in the concentration of 5mg/kg body weight.

Animals used for the activity

Male wistar rats (150-180 gms) were used for the study and kept at the laboratory animal house of Sree Dattha Institute of Pharmacy for acclimatization to laboratory environment. They were kept in well cross ventilated room at 27±2°C for 1 week before the commencement of experiment. Animals were provided with commercial rodent pellet diet and water ad libitum.

Method

Anti-diarrhoeal activity was evaluated using two methods i.e magnesium sulfate induced enteropooling and gastro intestinal motility test using charcoal meal methods.


Magnesium sulfate induced enteropooling method:

Male wistar rats were fasted for 18hrs and divided into four groups of five animals each. Solution of magnesium sulfate was made in the concentration of 10% w/v using distilled water. Group-I animals received normal saline (2ml, p.o.) served as control group. Group-II animals served as standard and received loperamide (3mg/kg, p.o.). Group-III animals received the test extract in the concentration of 250mg/kg and Group-IV animals received the test extract in the concentration of 500mg/kg p.o. immediately after the treatment magnesium sulfate (10% w/v) was administered. After 30minutes following the administration of magnesium sulfate, the rats were sacrificed and the small intestine was removed after tying the ends with threads and weighed. The intestinal content was collected into a graduated cylinder and their volume was measured. The intestine was reweighed and the difference between the full and empty intestine was calculated^{8,9}. The results are tabulated in Table: 1.


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EVALUATION OF ANTI DEPRESSANT AND NOOTROPIC ACTIVITY OF CALOPHYLLUM INOPHYLLUM

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Antidepressant.

ABSTRACT

Calophyllum inophyllum L. has been used as folk medicine in the treatment of ocular burn and it has demonstrated potential pharmacological activities. The aim of the study is to perform preliminary phytochemical screening, and to evaluate the nootropic and antidepressant activity effect of methanolic extracts of *Calophyllum inophyllum*. *Calophyllum inophyllum* leaves and stem bark were extracted using methanol as solvent by Soxhlet apparatus. The percentage yield of CILE was found to be 16.27% and percentage yield of CISBE was found to be 17.62%. Preliminary phytochemical screening revealed the presence of alkaloids, carbohydrates, glycosides, saponins, tannins, flavonoids, proteins, amino acids and steroids. Doses up to 2000mg/kg were found to be safe after acute toxicity tests. The results for tail suspension test and forced swim suggest antidepressant activity and the electro shock induced amnesia and diazepam induced amnesia suggest nootropic activity of the extract with p value < 0.005. .

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Formulation and evaluation of Gastroretentive Doxofylline tablets

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ABSTRACT

In the present work, an attempt has been made to develop gastro retentive floating tablets of Doxofylline .HPMC K4M and K15M were used as controlled release polymers. All the formulations were prepared by direct compression method on 12 station rotary tablet punching machine. The blend of all the formulations showed good flow properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. FH 5 was the best optimized floating formulation because it released drug completely in 12hrs.It was also observed that the increasing concentration of polymers had a retarding effect on the drug release from the polymer matrices.

Key words:, Doxofylline, gastric retention, controlled delivery

INTRODUCTION

Historically, oral drug administration has been the predominant route for drug delivery. During the past two decades, numerous oral delivery systems have been developed to act as drug reservoirs from which the active substance can be released over a defined period of time at a predetermined and controlled rate. From a pharmacokinetic point of view, the ideal sustained and controlled release dosage form should be comparable with an intravenous infusion, which supplies continuously the amount of drug needed to maintain constant plasma levels once the steady state is reached [1].

Although some important applications, including oral administration of peptide and protein drugs, can be used to prepare colonic drug delivery systems, targeting drugs to the colon by the oral route. More often, drug absorption is unsatisfactory and highly variable among and between individuals, despite excellent in vitro release patterns. The reasons for this are essentially physiological and usually affected by the GI transit of the form, especially its gastric residence time (GRT), which appears to be one of the major causes of the overall transit time variability [2].

Site and time specific oral drug delivery have recently been of great interest in pharmaceutical field to achieve improved therapeutic efficacy [3,4,5].Doxofylline is a member of methyl xanthines structurally related to theophylline, used in clinical management of patients with obstructive respiratory disorders, in particular Chronic Obstructive Pulmonary Disorder (COPD) and Asthma. The elimination half life of Doxofylline is 7 hrs which indicated its suitability in formulating into a sustained release dosage form. The oral bioavailability of Doxofylline has been reported to be 60%.Due to its high solubility in acidic medium (pH 1.2), prolonged gastric retention of doxofylline may offer numerous advantages, including, increase in the extent of absorption, improved bio-availability and therapeutic efficacy. Frequent administration of Doxofylline (400mg b.i.d/t.i.d) also prompted to make floating sustained release tablets of Doxofylline. Based on this, an attempt was made through this investigation to formulate floating matrix tablets of doxofylline using different polymers. The solubility and stability of doxofylline in hydrochloric acid helps for better absorption in acidic environment. By employing gastro-retentive

Antiulcer and antioxidant potential of *Zizyphus jujuba* Mill root extract in Aspirin and ethanol induced gastric ulcers.

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Abstract

The root of *Zizyphus jujuba* Mill. (*Rhamnaceae*) (ZJ) has been used to treat mouth ulcers as indigenous medicine. However there is no scientific report of its use for protection and treatment of gastric ulcers.

The aqueous root extract of ZJ (AREZJ) was evaluated for antiulcerogenic potential in aspirin and ethanol induced ulcer models in Wistar rats along with *in vitro* antioxidants potential. Single dose toxicity studies were carried out to determine LD₅₀.

Two doses i.e. 150 and 250 mg/kg b.wt were evaluated for antiulcer activity by measuring ulcer index and percentage of ulcer healing in two of the ulcer models. Antioxidants activity was estimated *in vitro* by DPPH, H₂O₂ free radical scavenging and reducing power assay. Phytocostituents were determined by standard method.

Based on ulcer index, percentage protection of 76.92% in aspirin model and 70% in ethanol model were noted with a dose of 250 mg/kg b.wt of AREZJ, whereas standard drug omeprazol (50 mg/kg b.wt) showed 80.77 % and 80 % protection in aspirin and ethanol models respectively. AREZJ showed 89.2% DPPH and 88.5% H₂O₂ free radical scavenging activity at concentration of 200 µg/ml and 80 µg/ml respectively. AREZJ also exhibited 87.5% reducing power at 50 µg/ml. Phytochemical screening of AREZJ showed presence of alkaloids, carbohydrates, flavanoids, glycosides, proteins and tannins. No mortality was noted till 2500 mg/kg b.wt of AREZJ, indicating higher LD₅₀ value.

AREZJ was found to have antiulcerogenic effect, which could be related to its antioxidant potential.

Keywords: Antiulcer, Antioxidant potential, Ethanol induced gastric ulcer.

Introduction

Zizyphus jujuba Mill. also known as jujube or Chinese date is a tree that belongs to the family *Rhamnaceae*. It grows worldwide specially in south Asia between Lebanon, Iran, Pakistan, India, Bangladesh, Nepal, the Korean peninsula, southern and central China. It is highly acceptable wild vegetable across south India. For many years fruit and its seeds are used in Chinese and Korean traditional medicine. Various part of *Zizyphus jujuba* has been found to posses activities like hypnotic-sedative and anxiolytic, anti-Cancer, antioxidant, anti-inflammator, immunostimulant, cardiovascular, antiulcer, anti-obese, antifertility /

contraceptive, antifungal, hypoglycemic and wound healing properties [1-12].

Ulcer is the asymptomatic gastrointestinal disorder defined as a breach in mucosa of alimentary tract, which extends through the muscularis mucosa into the submucosa or deeper and occurs due to imbalance between aggressive factors like acid, pepsin, *Helicobacter pylori* [13] and defensive factors like prostaglandins, gastric mucus, bicarbonate secretion, innate resistance of mucosal cells [14-15]. The wide incidence and prevalence of ulcer is also attributed due to several other factors such as stress, regular or frequent use of non-steroidal anti inflammatory drugs and reactive oxygen species and bacterial infections [16].

Medicinal plants have been an invaluable source of therapeutic agents to treat various disorders including peptic ulcer disease [17-





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Factors Affecting Microspheres Formation

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ABSTRACT

The current review provides an in-depth discussion of multiple factors influencing microspheres formation which ranging from degree of speed by homogenizers, duration of mixing, concentration of polymers, selection of aqueous and oily phase and their ratios, viscosity role, and reasons behind different sizes of spheres, texture of microspheres ie. rough or smooth, entrapment efficiency, role of emulsifier, importance of cross linking agents with their concentration, solubility ,temperature influence in formation of spheres, solvent selection criteria, drug delivery from surface of microspheres etc. forms ground work and essential to go through all above mentioned factors in order to develop of ideal and in turn to improve stability of microspheres as multi particulates and improve knowledge behind updates of production of microspheres.

Keywords: Aqueous and Oily Phase role, Emulsifier, Stirring speed, Conc. of Polymers in formation of Microspheres, PDE.

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FORMULATION AND EVALUATION FAST DISSOLVING TABLETS OF NARTRIPTAN USING SUPER DISINTEGRANTS

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ABSTRACT

Naratriptan hydrochloride is used for acute oral migraine therapy. In the present study an attempt was made to prepare oral fast dissolving tablets of Naratriptan hydrochloride with the dose of 2.5mg in order to improve the quick onset of action and patient compliance. Fast dissolving tablets of Naratriptan were prepared by using cross carmellose sodium, sodium starch glycolate, cross povidone by direct compression method. Study of the preformulation characteristics and FTIR studies indicate that there was no interaction between Naratriptan and excipients used in the formulation. Out of different formulae from (F1 – F12) F3 found to be optimized which showed a faster rate of drug release. Stability studies were conducted for the optimized

formulae found to be satisfactory. These findings suggest that the fast dissolving tablets of Naratriptan is considered to be potentially useful for treatment of migraine where quicker onset of action is desirable.

KEYWORDS: Naratriptan, Fast Dissolving Tablets, Superdisintegrants, Dissolution Profile.

INTRODUCTION

FAST-DISSOLVING TABLETS

Fast-disintegrating and fast-dissolving tablets are becoming popular as novel delivery systems for drug administration. They are more convenient for children, elderly patients, patients with swallowing difficulties, and in the absence of potable liquids. The most desirable formulation for use by the elderly is one that is easy to swallow, easy to handle. Taking these requirements into consideration, attempts have been made to develop a fast-disintegrating tablet. Since such a tablet can disintegrate in only a small amount of water in the oral cavity, it is easy to take for any age patient, regardless of time or place. For example,



FORMULATION AND EVALUATION OF BUCCAL MUCOADHESIVE TABLETS OF GLIPIZIDE

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ABSTRACT

The present research work is aimed to prepare a buccal tablet for a low bioavailable anti diabetic drug glipizide. Preparing a buccal tablet not only improve the bioavailability but also aver comes the first pass effect. Bioadhesive polymers such as carbopol, chitosan, guar gum and HPMC K15M have been employed in the present study. Suitability of the drug for the buccal delivery system has been studied and found that glipizide is suitable candidate and further studies have been carried out. Various formulations have been developed and evaluated for precompression and post compression parameters which revealed good flow properties of the blend and physical attributes of the prepared tablets were found to be practically within control limits. From the drug release studies it was found that formulation F3 containing carbopol has good drug release when compared to other formulations.

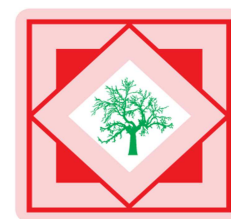
With respect to all the evaluation parameter formulation F3 was considered as the optimized one and is subjected to specific evaluation tests like swelling index, ex-vivo residence time, Moisture absorption, surface pH, Bioadhesion strength and found to be acceptable. The drug release was by zero order kinetics and drug release follows non-Fickian diffusion mechanism.

KEYWORDS: Buccal tablet, Anti diabetic drug, Bioadhesive, Zero order kinetics, Non-Fickian diffusion.



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Formulation characterization and *in-vitro/in-vivo* evaluation of orodispersible tablets of Nebivolol HCl

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ABSTRACT

Objective of the present research work was to prepare orodispersible tablets of Nebivolol hydrochloride (NEB) for dysphagic patients. Nebivolol, an anti-hypertensive drug, was chosen as a model drug in this study. Oral bioavailability of nebivolol is only 12% due to extensive first pass hepatic metabolism by Cytochrome P450 2D6 enzyme. Orodispersible tablets of NEB were prepared using different super-disintegrating agents such as croscopolidone, croscarmellose sodium and sodium starch glycolate at different concentrations. The best formulation was selected based on disintegration and dissolution profile that was further taken for sublimation studies using camphor, menthol and thymol. Drug-excipients interaction studies were carried out by FTIR spectrophotometer with each of the excipients and optimized formulation. The orodispersible tablet formulation containing 10% w/w of menthol showed disintegration time of 11 sec with more than 98% drug release within 14 min. Therefore, this formulation was optimized and considered for further *in vivo* studies. *In vivo* studies of orodispersible tablets in rabbits showed significantly better pharmacokinetic profile (AUC, T_{max} , C_{max}) compared to marketed conventional tablets. Therefore, from this study it was concluded that, orodispersible tablets of NEB may prove to be more efficacious in the treatment of hypertension in dysphagic patients.

Keywords: Orodispersible tablets, Super-disintegrants, Sublimation, Pharmacokinetics

INTRODUCTION

Dysphagia is a biomechanical disorder considered as a clinical syndrome. It is defined as "an inability to swallow, or a sensation that solids or liquids do not pass easily from the mouth to the stomach" [1, 3]. From many reported studies it has been estimated that over six million adults have dysphagia [1]. It can occur in all age groups, but the prevalence increases with increase in age [1, 3]. Other categories that experience problems using conventional dosage forms include are mentally ill, uncooperative and nauseated patients, those with condition of motion sickness, sudden episodes of allergic attack or coughing [2]. Oral conventional formulations such as tablets, capsules and liquids pose difficulty in swallowing, especially in dysphasic patients [3].

Formulation, characterization and *in vivo* evaluation of novel edible dosage form containing nebivolol HCl

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The objective of this investigation was to develop a novel oral edible gel dosage form for nebivolol hydrochloride, with suitable rheological characteristics that can provide a means of administering the drug to dysphagic and geriatric patients. Edible gels were prepared using low acetylated gellan gum and sodium citrate in different concentrations. The effect of concentration of the solution on gelation time, viscosity, and drug release was studied. Optimized formulation had “spoon thick” consistency that is considered suitable for dysphagic patients as suggested by National Dysphagia Diet Task Force. The optimized formulation containing gellan gum (0.4 % w/v) and sodium citrate (0.3 % w/v) showed more than 95% drug release in 20 minutes. This formulation also showed significantly better pharmacokinetic profile when compared to marketed conventional tablets in New Zealand white rabbits ($n = 3$). Optimized formulation was found stable for 6 months when stored at $25 \pm 0.2^\circ\text{C}/60 \pm 5\% \text{RH}$. From this study, it can be concluded that the novel edible gel dosage form containing nebivolol hydrochloride may prove to be more efficacious in the treatment of hypertension in dysphagic patients.

Uniterms: Edible gel/pharmaceutics. Nebivolol HCl/delivery. Dysphagia/drugs administration.

O objetivo deste trabalho foi desenvolver um gel comestível para veiculação de cloridrato de nebivolol, com características reológicas adequadas, que podem fornecer meio de administrar o fármaco em casos de disfagia orofaríngea e pacientes geriátricos. Géis comestíveis foram preparados utilizando goma gelana de baixa acetilação e citrato de sódio, em diferentes concentrações. Estudou-se o efeito da concentração da solução no tempo de gelificação, a viscosidade e a liberação do fármaco. A formulação otimizada apresentava consistência de pudim, o que é considerado adequado para pacientes disfágicos como sugerido pela National Dysphagia Diet Task Force. A formulação otimizada contendo 0,4% (m/v) de goma gelana e 0,3% (m/v) de citrato de sódio mostrou que mais de 95% de fármaco foi liberado em 20 minutos. Esta formulação também mostrou, significativamente, melhor perfil farmacocinético, quando comparado com os comprimidos convencionais comercializados administrados a coelhos brancos neozelandeses ($n = 3$). A formulação otimizada manteve-se estável durante 6 meses, armazenada a $25 \pm 0,2^\circ\text{C}/60 \pm 5\% \text{de UR}$. A partir deste estudo, conclui-se que a nova forma de gel comestível contendo cloridrato de nebivolol pode ser mais eficaz no tratamento de hipertensão em pacientes portadores de disfagia.

Unitermos: Gel comestível/farmacotécnica. Cloridrato de nebivolol/veiculação. Disfagia/administração de fármacos.

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Original Article

Formulation and Evaluation of Didanosine Enteric Coated Sustained Release Tablet

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A Sustained release formulations can be utilized to avoid repetitive dosing of drugs in a day and few drugs like Didanosine incompatible with gastric juice, to avoid overcome the incompatibility of drug, tablet is coated with the enteric coat. The objective of the present study is to develop competitive enteric sustained release tablets of Didanosine for a period of 12 hrs, by preparing wet granulation method using different polymers and study the effect of polymers on their release pattern. The drug – excipients compatibility was done at accelerated temperature 25°C/55% ± 5% and 30°C/60% ± 5% relative humidity. Based on preformulation studies different formulation batches of Didanosine were prepared using selected excipient. Granules were evaluated for tests loss on drying, bulk density, tapped density, compressibility index, Hausner ratio before ring punched as tablet. Tablets were tested for weight variation, thickness, hardness, friability and in vitro drug release as per official procedure. Change in dissolution parameter study made it suitable for minute physiological variables. From the above results and discussion it is concluded that formulation of sustained release tablet of Didanosine containing 20 % of Ethyl cellulose Std 100 P, diluents MCC and with binder Povidone i.e formulation batch F6 can be taken as an ideal or optimized formulation of Enteric coated sustained release tablets for 12 hour release as it fulfills all the requirements for sustained release tablet.

Keywords: Didanosine, compatibility, enteric, preformulation, Povidone

1. INTRODUCTION

Conventional dosage form as to be administered several times to produce therapeutic efficacy, which yields fluctuations in plasma level. Repetitive dosing of drug causes poor compliance among the patients. Sustained release formulations can be utilized to avoid repetitive dosing of drugs in a day and few drugs like

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Design and Characterization of Ofloxacin and Dexamethasone Ocular Inserts Using Combination of Hydrophobic and Hydrophilic Polymers

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Abstract

Aim: The objective of this work was to develop ocular inserts of ofloxacin and dexamethasone and to evaluate their potential for controlled ocular delivery. **Materials and Methods:** Ofloxacin and dexamethasone were obtained as a gift sample from Indu Drugs, Pvt. Ltd., hydroxy propyl methyl cellulose (HPMC) (P₅₅ and E₁₅) from Pellets Pharma Ltd., HPMC K₄M from NSF Pharma Pvt. Ltd., Eudragit (RL-100 and L-100) from Biogen Extracts Pvt. Ltd., polyethylene glycol and ethanol were purchased from S.D. Fine Chemicals, Mumbai, India. Ocular Inserts were prepared by solvent casting technique using polymer Eudragit (RL-100 and L-100) and HPMC (K₄M, P₅₅ and E₁₅) at different concentration and combination. **Results and Discussion:** 10 formulations (F1-F10) were developed and all the formulations were subjected to evaluation for thickness, weight variation, folding endurance, pH, % moisture absorption, drug content, and *in vitro* release study. Infrared spectral analysis showed that there is no interaction of drug with polymer which indicates the intactness of drug in the formulation. On the basis of *in vitro* drug release studies, formulation F6 was found to be better than the other formulations and selected as an optimized formulation, which was further subjected to stability study. No significant change was observed in the drug content and physical features during storage at 25°C/60% RH and 40°C/75% RH for 9 months. **Conclusion:** In this study, an attempt was made to develop ocuserts of ofloxacin and dexamethasone combination with improved bioavailability, avoidance of repeated administration and dose reduction. From the experimental finding, it can be concluded that HPMC is a hydrophilic polymer good film forming and is a promising agent for ocular delivery. Eudragit was a satisfactory polymeric ingredient to fabricate the rate controlling membrane of the ocusert system. Incorporation of polyethylene glycol enhances the flexibility of film, achieving therapeutic levels of the drug in the formulation and also permeability of the drug through cornea. The kinetic treatment of *in vitro* dissolution data indicated that the optimized ocusert followed Peppas kinetics with zero-order drug release. The drug remained intact and stable in the ocuserts on storage.

Key words: Dexamethasone, ocular inserts, ofloxacin, solvent casting technique

INTRODUCTION

Delivery of medication to the human eye is an integral part of medical treatment. Conventional ocular dosage forms, i.e., eye drops and eye ointments have certain disadvantages such as poor availability, repeated administration, massive and unpredictable doses and drainage of drug by tear fluid. Ocular inserts offer many advantages over conventional dosage forms such as increased possibility of releasing drugs at a slow and constant rate, ocular residence time, accurate dosing, exclusion of

preservatives, and increased shelf-life.^[1-3] Moreover, the use of ocular inserts reduces systemic absorption, which or else freely occurs with eye drops. It also will ensure better patient compliance due to lower frequency of administration

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A NEW VALIDATED RP-HPLC METHOD FOR THE DETERMINATION OF METFORMIN HCL AND EMPAGLIFLOZIN IN ITS BULK AND PHARMACEUTICAL DOSAGE FORMS

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Keywords:

Metformin, Empagliflozin,
HPLC, Methanol

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ABSTRACT: A New method was established for simultaneous estimation of Metformin and Empagliflozin by RP-HPLC method. The chromatographic conditions were successfully developed for the separation of Metformin and Empagliflozin by using Symmetry C18 column (4.6×150mm) 5μ, flow rate was 1ml/min, mobile phase ratio was (70:30 v/v) methanol: phosphate buffer (KH₂PO₄ and K₂HPO₄) phosphate pH 3 (pH was adjusted with orthophosphoric acid), detection wavelength used was Waters HPLC Auto Sampler, Separation module 2695, photo diode array detector 996, Empower-software version-2. The retention times were found to be 2.403 mins and 3.907 mins. The % purity of Metformin and Empagliflozin was found to be 99.87% and 100.27% respectively. The analytical method was validated according to ICH guidelines (ICH, Q2 (R1)). The linearity study of Metformin and Empagliflozin was found in concentration range of 50μg-250μg and 5μg-25μg and correlation coefficient (r²) was found to be 0.999 and 0.999, % recovery was found to be 99.56% and 99.48%, %RSD for repeatability was 0.3 and 0.3, % RSD for intermediate precision was 1.3 and 0.4 respectively. LOD value was 2.17 and 0.0372 and LOQ value was 6.60 and 0.1125 respectively.

INTRODUCTION: Empagliflozin is a drug of the gliflozin class, approved for the treatment of type 2 diabetes in adults in 2014. The chemical name of empagliflozin is (empagliflozin; 1-chloro-4-[b-D-glucopyranos-1-yl]-2-[4-([S]-tetrahydrofuran – 3 – yl -oxy) benzyl]-benzene (**Fig. 1**). Empagliflozin is an inhibitor of the sodium glucose co-transporter-2 (SGLT-2), which is found almost exclusively in the proximal tubules of nephronic components in the kidneys¹. SGLT-2 accounts for about 90 percent of glucose reabsorption into the blood. Blocking SGLT-2 reduces blood glucose by blocking glucose reabsorption in the kidney and thereby excreting glucose (i.e., blood sugar) via the urine.

The side effects of this drug is a higher frequency of urinary tract infections. There are concerns it may increase the risk of diabetic ketoacidosis. Metformin is a biguanide antihyperglycemic agent used for treating non-insulin-dependent diabetes mellitus (NIDDM)³. The chemical name of Metformine Dimethylimidodicarbonimidic diamide (**Fig. 2**).

It improves glycemic control by decreasing hepatic glucose production, decreasing glucose absorption and increasing insulin-mediated glucose uptake⁴. Metformin is the only oral antihyperglycemic agent that is not associated with weight gain. Metformin may induce weight loss and is the drug of choice for obese NIDDM patients.

When used alone, metformin does not cause hypoglycemia; however, it may potentiate the hypoglycemic effects of sulfonylureas and insulin. Its main side effects are dyspepsia, nausea and diarrhea⁵.

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HERBAL EFFECT OF GREEN TEA IN TREATMENT OF CHRONIC PERIODONTITIS : A CLINICAL & MICROBIOLOGICAL STUDY

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Research Article

ABSTRACT : Background and objectives – Increased knowledge of anaerobic bacteria in the development of periodontal diseases has led to new treatment strategies aiming at suppression or elimination of periodontal pathogens. Over the last decades, green tea has been subjected to many scientific and medical studies. The aim of the present study is to evaluate the therapeutic efficacy of green tea catechin strips as an antimicrobial agent locally delivered drug in the management of chronic periodontitis in pocket of depth of 4-6 treatment mm, when used as an adjunct to scaling and root planing (Test group), as compared to sites that underwent scaling and root planing along with placebo (control group).

MATERIALS & METHODS - The present study was a randomized clinical trial with split mouth design in which a total no. of 30 sites in patients who were diagnosed with generalized chronic moderate periodontitis, consisting of both genders, aged between 25 to 50 years were selected. These selected sites were randomly divided into test group and control group. Test group - included 15 sites that were selected for the placement of Green tea strips; (local drug delivery) after scaling and root planing. Control group - included 15 sites that were treated with scaling and root planing along with placebo strips. Clinical parameters taken are the PI, GI, SBI, probing depth (PD), and clinical attachment level (CAL). Anaerobic culture was done to compare the total colony forming unit before and after the treatment. Clinical parameters and the total colony count were assessed at base line, 21 days and 90 days.

Result – Results showed a significant improvement in all the clinical parameters. There was significant decrease in mean probing depth from base line to 90 days, and also there was significant gain in CAL in the test group as compared to control group. There was a significant reduction in the total colony count from base line to 21 days in both the group, but more reduction was observed in the test group.

Conclusion - Within the limits of this study and on the basis of the clinical and microbiological parameters, green tea catechin local drug delivery along with scaling and root planing was more effective than scaling and root planing alone.

Key words –

Chronic Periodontitis
Green tea catechin
Local drug delivery,
Root planing, Scaling.

Source of support : Nil

Conflict of interest: None

INTRODUCTION : Periodontal diseases are the chronic inflammatory diseases of the periodontium, characterized by inflammatory destruction of gingiva and periodontal ligament. Most of the periodontal diseases are of microbial

etiology with environmental, systemic, and other factors playing a secondary role. The destruction seen in periodontal disease is due to microorganisms as well as host inflammatory response.¹



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PHYTOCHEMICAL INVESTIGATION AND HEPATOPROTECTIVE EFFECT OF *SCOPARIA DULCIS* AGAINST CARBON TETRACHLORIDE INDUCED LIVER DAMAGE IN RATS

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Keywords:

Scoparia dulcis,
Silymarin, Total bilirubin
Serum glutamine transaminase,

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ABSTRACT: The objective of the present study is to carry out the photochemical investigation and hepatoprotective activity study of different extracts of *Scoparia dulcis*. *Scoparia dulcis* Linn. belongs to the family Scrophulariaceae and have ruminant medicinal properties. The different extracts of this plant were prepared by successive extraction with petroleum ether, chloroform and ethanol. These extracts (PEESD, CESD and EESD) were then taken for preliminary phytochemical screening using standard methods. The hepatoprotective activity of the different extracts of *Scoparia dulcis* was evaluated by using carbon tetrachloride induced liver damage in experimental rats. In hepatotoxicity induced animals, an oral dose of 300 mg/kg, of the petroleum ether, ethanol and chloroform extracts of *Scoparia dulcis* exhibited a compelling decrease in marker enzyme levels and increased levels of antioxidant enzymes. In the above dose the plant extracts produced a significant decrease in the Lipid peroxidase levels in the tested animals against Carbon tetrachloride induced liver toxicity. The chloroform extract was found rich in phytochemical constituents and had the highest hepatoprotective activity. From the results of our present study we concluded that, PEESD, CESD and EESD of *Scoparia dulcis* Linn. showed significant antioxidant defence mechanism and hepatoprotective activity. Result shows PEESD, CESD and EESD have significant antioxidant activity on comparison with standard silymarin. The hepatoprotective potential may be attributed to the presence of polyphenolic compound for their antioxidant properties.

INTRODUCTION: The liver is the main metabolic organ of the body and it also plays an important role for secretion and excretion which is repetitively exposed to various xenobiotics, surrounding toxicants and chemo remedial agents because of its vital position in the body. Liver disease is a global complication.¹⁻⁴

Typical drugs used in the treatment of liver diseases are sometimes insufficient and can cause serious adverse effects. So, it is necessary to find alternative drugs for the treatment of liver disease to replace currently used drugs of better efficacy and safety. Medicines derived from plant extract are to a greater extent utilized to treat a wide variety of disease, through relatively little idea about their mode of action is available. There is an increasing interest in the pharmacological screening of various plants for their therapeutic use in Indian traditional system of medicine.

The carbon tetrachloride (CCl₄) induced intoxication is widely used model for liver injury in rats.

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Case Report

ANALYSIS OF PATIENT ADMISSIONS IN HOSPITAL DUE TO ADVERSE DRUG REACTION

Mr. Shivkumar Kashinath Shete*¹, Dr. K. Sattanathan²¹ Research scholar Mewar University Rajasthan, India² Research Supervisor Mewar University Rajasthan, India

ABSTRACT

The present study is prospective and observational non-interventional study was conducted in tertiary care center. All suspected ADRs which are observed in hospital stay will be assessed for causality, severity, preventability and predictability. The results were presented as number and percentage. Among the 7697 cases (both males and females), a total of 240 ADRs were detected, an overall incidence of 03.11 % adverse drug reactions in inpatients. The high prevalence of ADR mostly observed in the age group between 1-10 years 48 (20.00%) From this 240 ADR's where 7.96% on continuing t, 38.36% are recovering, 47.08% are recovered.

Keywords: Adverse drug reaction, Causality, Severity, Preventability, Probability.**Article Info:** Received 18 July, 2018; Review Completed 16 Aug 2018; Accepted 19 Aug 2018; Available online 15 Sep 2018

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INTRODUCTION

The WHO defines an "Adverse drug reactions "any response to a drug which is noxious and unintended and which occurs or doses normally used in man of prophylaxis diagnosis or therapy of disease or for the modification of physiologic function".¹

Pharmacovigilance has been defined by the WHO as 'the science and activities relating to the "detection, assessment, understanding and prevention of adverse effects or any other drug-related problems".²

Adverse drug reactions (ADRs) are types of adverse drug events (ADEs). ADEs include ADRs, medication errors and other drug-related problems. ADEs are the negative consequences of drug misadventures. Henri Manasse defined drug misadventure as the iatrogenic hazard that is an inherent risk when drug therapy is indicated.

The American Society of Health- System Pharmacists (ASHP) defines significant ADRs as any unexpected, unintended, undesired, or excessive response to a drug that includes the following.^{3,4,5}

- Requires discontinuing the drug
- Requires changing the drug therapy
- Requires modifying the dose
- Necessitates admission to the hospital
- Prolongs stay in a health care facility
- Necessitates supportive treatment
- Significantly complicates diagnosis
- Negatively affects prognosis or results in temporary or permanent harm, disability or death.

METHODOLOGY

Study Location

The study is carried out at Aware Global Hospital in General Medicine & all Clinical Departments.



Formulation and Evaluation of Herbal Eye Gel from *Heliotropium indicum* linn leaf extract for Conjunctivitis

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ABSTRACT

Plants have played a significant role in maintaining human health and improving the quality of human life for thousands of years. The present work was designed with the aim to formulate and evaluate the ocular herbal gel containing *Heliotropium indicum* linn leaf extract. Cold infusion of the leaves used to remove cataract in the eye. The ocular herbal gel formulation was prepared from aqueous extract in varied concentration and was evaluated. The gel was formulated by using carbopol 934, EDTA, Benzalkonium chloride, and required amount of distilled water. Then the ocular pH 7.4 was

maintained by drop wise addition of triethanolamine. The herbal ocular gels were sterilized and assessed for various parameters like clarity, pH, physical appearance, physical stability, viscosity, uniformity of drug content, spreadability and anti- microbial studies. Stability studies were carried out as per ICH guidelines for 6 months at different temperatures and humidity. The formulations in gel were found to be more stable at ambient, refrigerator and incubated temperature. The results showed that formulation g1GL7 consisting aqueous leaf extract of *Heliotropium indicum* linn have better stability than other formulations.

KEYWORDS:

Heliotropium indicum linn, Ocular herbal gel, Bacterial conjunctivitis and Anti- microbial.

1. INTRODUCTION

In improving the quality of human life plants have played a significant role. Herbal medicine is based on the principle that plants contain constituents that can promote health and alleviate illness. All over the world the plants research has increased and the collected evidences showed the immense potential of medicinal plants used in various traditional system. There are many medicinal plants generally used in ocular diseases which are easily available and possess biological activity. The efficacy of many traditional medicines in curing ocular disorders is recognized by modern science also. In pink eyes there is an inflammation of conjunctiva which is also known as Conjunctivitis which is the most common disorder encountered in ophthalmology. It causes redness, burning sensation.

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sensitivity to light, dryness, grittiness sensation, itchy and scratchy feeling, watering of eyes, and swelling of eyelid. The conjunctivitis caused due to bacteria known as bacterial conjunctivitis.

Heliotropium indicum (HI) linn (Family Boraginaceae) is a medicinal plant. It has various medicinal uses in the treatment of disease conditions such as abdominal pains, amenorrhoea, dysmenorrhoea, skin rashes, wounds, hypertension, ocular infections, convulsion and dizziness. Cold infusion of the leaves used as an enema stops abdominal pains; this preparation also removes cataract in the eye; the juice from the leaves is squeezed into the eye to stop dizziness; decoction of the whole plant is used to treat convulsion in children. Other medicinal uses of *Heliotropium indicum* linn comprises the use of juice of the leaves as an antiseptic and anti-inflammatory agent when applied to wounds, sores, boils, gum boils and pimples on the face. Boiled with castor oil, it is applied to sores from scorpion bites and also locally used in treating ophthalmic disorders like erysipelas and pharyngodynia^{1,2}. Our aim of the



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Evaluation of the clinical use of nebulization therapy and antibiotics in in-patients with chronic obstructive pulmonary disease: A randomized prospective study at a tertiary care teaching hospital

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ORIGINAL RESEARCH ARTICLE

ABSTRACT

Background: An observational, prospective study was conducted at a tertiary care teaching hospital in Hyderabad, T.S., India. The aim of this study was to evaluate the clinical use of nebulization therapy and antibiotics in in-patients with chronic obstructive pulmonary disease.

Subject and Methods: A total of 115 patients from the In-patient Department of General Medicine in Osmania General Hospital, who were prescribed nebulizers and antibiotics and those who fulfilled the exclusion and inclusion criteria were selected for the study which was conducted for 6 months. Information significant to the study was collected from the case records and discussions conducted with the in-patients and bystanders during ward rounds. Daily follow-ups were conducted to assemble data in therapy, add-on therapy and clinical improvement.

Results: The mean age was 59 years and the standard deviation was 11 years. Of the population, 77% were smokers and 51% were alcoholics. The most commonly used Bronchodilator is Deriphylline with a percentage of 78.10% and Antibiotic Monocef with a percentage of 72%. The most commonly used formulation is Orals with a percentage of 44.80%. A population of 43.50% of patients resulted with A grade severity index which represents low risk and low symptoms. 85% of individuals responded positively after the nebulization therapy with Oxygen therapy provided to them, as their SpO₂ levels with O₂ therapy changed into the normal range. There was a significant difference between the SpO₂ with O₂ percentages and SpO₂ without O₂ percentages ($\alpha = 0.05$).

Conclusion: Nebulization therapy had more clinical improvement when compared to Inhalation therapy as the Nebulizers require less intensive training for COPD patients. Antibiotics added to the treatment decreased the frequency of exacerbations.

Keywords: Chronic Obstructive Pulmonary Disease, Nebulization, Antibiotics.

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INTRODUCTION

COPD is a known leading cause of morbidity and mortality worldwide which results in social and economic burden which is increasing progressively. COPD is a disease characterized as 'airflow limitation that is not fully reversible' by, World Health Organization, Global Obstructive Lung Disease (Pauwels et al., 2001) and American Thoracic Society (Celli and Mac Nee, 2004). This airflow limitation is associated with a progressive abnormal inflammatory response to noxious particles. World Health Organization (WHO) states COPD

as the fourth leading cause of death in the world, with approximately 2.75 million deaths per annum, or 4.8% of total deaths. COPD has been considered as one of the main leading cause of death in many countries as follow: 1. United States of America: COPD is the fourth leading cause of death in USA (Celli and MacNee, 2004). A cohort study was conducted in the USA, which showed 1,301 out of 5,542 adults died due to COPD (National Health and Nutrition Examination Survey, NHANES); 2. Europe: Mortality rates vary from country to country, 20 per



INDO AMERICAN JOURNAL OF PHARMACEUTICAL RESEARCH



IN VITRO ANTIOXIDANT POTENCY STUDIES OF HYDRO ALCOHOLIC LEAF EXTRACT OF CASSIA UNIFLORA

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Keywords

Antioxidant,
DPPH, ABST,
Superoxide Ion,
Ascorbic Acid,
Gallic Acid.

ABSTRACT

To study the antioxidant potency of hydro alcoholic extract of Cassia uniflora. Hydro alcoholic leaf extracts of the plants was studied for its Free radical scavenging activity against DPPH, ABST and Superoxide ion. Hydro alcoholic crude extracts of leaves of Cassia uniflora at concentrations of 10, 25, and 50 µg/ml were studied against DPPH, ABST and Superoxide ion to know their antioxidant potential. Cassia uniflora leaf hydro alcoholic extract possessed an IC₅₀ value 26.32 µg/ml in DPPH radical scavenging assay on compare to standard Vitamin C (3.59 µg/ml), in ABST radical scavenging assay 8.76 µg/ml and standard vitamin C (2.32 µg/ml) and in Super oxide ion scavenging recorded as 45.84 µg/ml and for standard gallic acid was found to 0.61 µg/ml. The crude extracts showing better activity against DPPH ABST and Superoxide ion. Hence, can be recommended for potential usage as an antioxidant agent in pharmaceutical and nutraceutical industries.

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RESEARCH ARTICLE

RP-HPLC Method Development and Validation of Regorafenib in pure Form and Pharmaceutical Dosage Form

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ABSTRACT:

A new, simple, accurate, precise, robust and isocratic RP-HPLC method has been developed and subsequently validated for the determination of Regorafenib in pure form and pharmaceutical dosage forms as per ICH guidelines. The separation achieved on a Symmetry C₁₈ Column, 250 mmx4.6 mm i.d. and 5µm particle size column as a stationary phase and Methanol: Phosphate buffer (pH adjusted to 4.80 with phosphoric acid) in the ratio of 70:30v/v used as mobile phase at a flow rate of 1.0 ml/min. The UV detection was performed at 268nm. The retention time for Regorafenib was found to be 3.544minutes. The detector response was linear in the concentration range of 0-16µg/ml. The respective linear regression equation being $Y=58945.x+9634$ with $R^2=0.999$. The percentage of Regorafenib in pharmaceutical dosage form was found to be within the limits. The limit of detection and the limit of quantification were found to be 0.90µg/ml and 2.90µg/ml respectively. The results of the study showed that, the proposed RP-HPLC method was simple, rapid, precise, accurate and stability indicating, which can be used for the routine determination of Regorafenib in pure form and pharmaceutical dosage forms.

KEYWORDS: Regorafenib, RP-HPLC, Method Development, Validation, Precision, Accuracy, ICH Guidelines.

INTRODUCTION:

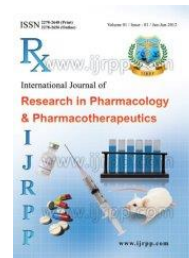
Regorafenib (BAY 73-4506, Commercial name Stivarga) is an oral multi-kinase inhibitor developed by Bayer which targets angiogenic, stromal and oncogenic receptor tyrosine kinase (RTK). Regorafenib is an orally-administered inhibitor of multiple kinases. It is used for the treatment of metastatic colorectal cancer and advanced gastrointestinal stromal tumors. FDA approved on September 27, 2012. Approved use of Regorafenib¹ was expanded to treat Hepatocellular Carcinoma in April, 2017.

Regorafenib is indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy. Regorafenib is also indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who has been previously treated with imatinib mesylate and sunitinib malate.

Regorafenib is a small molecule inhibitor of multiple membrane-bound and intracellular kinases involved in normal cellular functions and in pathologic processes such as oncogenesis, tumor angiogenesis, and maintenance of the tumor microenvironment. In in vivo models, regorafenib demonstrated anti-angiogenic



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Research article

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The study of prescription pattern in respiratory tract infection diseases in a tertiary care hospital

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ABSTRACT

Introduction

A respiratory tract infection is an infection anywhere in the respiratory tract (i.e nose, throat, lungs). The infection can be caused by bacteria, viruses or fungi. Respiratory infections are very common. They are believed to be one of the main reasons why people visit their General Physician (GP) or Pharmacist. Respiratory tract infection is of two types Upper Respiratory Tract infection and Lower Respiratory Tract infection.

Aim

To study the prescription monitoring in respiratory tract infections in a tertiary care hospital.

Methodology

The data were collected in a prescribed performa from the medical case sheets, Drug charts, Laboratory investigations of 119 Inpatients. This was a prospective observational study carried out for Inpatients in Pulmonology department.

Results

119 patients in Pulmonology department are administered with different types of antibiotics. Majorly Macrolide antibiotics are administered. Corticosteroids are administered in patients of age group 79-88 years. 60(50.4%) patients were administered with Macrolides, 52(43.6%) were administered with Cephalosporins, 37(31.09%) patients were administered with Pencillins, 11(9.24%) were administered with Flouroquinolones, 7(5.88%) patients were administered with Tetracyclins and the rest of patients were administered with other types of antibiotics like Carbapenems, Glycopeptides, Sulphonamides, Oxazolidines, Antimicrobials.

Conclusion

It was observed that the patients were prescribed rationally with antibiotics, Corticosteroids(particularly in elderly patients). A prescription based survey is considered to be one of the scientific methods to access and evaluate the rationality of the prescription for observation of drug utilization study. This observational, prospective study on drug use reflects the actual clinical practice in the communication.

Keywords: Respiratory tract infection, Antibiotics, Prescription, Rational, Inpatients, Pulmonology

Research Article

Volume 7 Issue 3

**IN VITRO ANTIOXIDANT ACTIVITY ON ETHANOLIC EXTRACT OF BLACK GRAPES
(*VITIS VINIFERA*) AND PRELIMINARY PHYTOCHEMICAL SCREENING**

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These author(s) have no
conflict of interest to declare.

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Abstract:

The aim of study is to assess the preliminary phytochemical screening and in vitro antioxidant activity of ethanolic extract obtained from fruits of black grapes of *Vitis vinifera*. The assessment of antioxidant activity performed by in vitro method using DPPH (2,2'-diphenyl-1-picrylhydrazyl), reducing power and hydrogen peroxide. Black grapes have good source of reducing sugars, Flavanoids, Saponins and Monosaccharides. The ethanolic extract of black grapes has been reported to show high scavenging activity against the DPPH free radical generating system. The antiradical activity of test compound and ascorbic acid against DPPH ic_{50} values were found to be as 17.3 ± 0.71 , to 57.7 ± 0.5 increased with respectively concentrations with that of reference standard, ascorbic acid (47.6 ± 0.48 to 89.1 ± 0.51). Antioxidant activity of black grapes was found to be good and about near to the standards.

Keywords *Vitis Vinifera*, Antioxidant activity



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Research article

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Comparison of analytical parameter of genetically transformed hairy roots of *withania somnifera* with normal roots

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ABSTRACT

Withania somnifera, known as Ashwagandha, widely considered as Indian Ginseng, is a plant of repute in Indian system of traditional medicine. The present study was aimed to compare high performance thin layer chromatography(HPTLC) profile of methanol extract of hairy roots of *Withania somnifera* with normal roots extracts purchased from different places. The normal roots extracts were obtained from different places like Tulsi Amrit, Indore; Natural Remedies, Bangalore; Ansar Industries, Surat; Amsar Private Limited, Indore; Prashant Pharmaceuticals, Rajpipla. Transgenic hairy roots were induced in *W. somnifera* by infecting leaf explants with two wild type strain of *Agrobacterium rhizogenes* ATCC 15834 and MTCC 4364 using MS media. Chromatographic method was used for separation of withanolide-D from extracts of roots. The *W. somnifera* hairy roots extract and normal root extracts purchased from different places and standard Withanolide-D sample were used in HPTLC using Solvent system: Toluene: Ethyl acetate: Formic acid (5:5:1) [V]. HPTLC profiling of extracts confirm about presence of Withanolide-D. HPTLC fingerprint profile scanned at 530nm for methanolic extract revealed with Rf value in range of 0.51 to 0.55. The hairy root extract of *Withania somnifera* showed almost similar rf (0.53) value and similar peak area (5934.27) when compared with the standard Withanolide-D. The HPTLC method for routine quality control and comparison of present species can be carried out by using method for extracts of plant which serve in qualitative, quantitative and was appropriate for standardization of extracts.

Keywords: *Withania somnifera*, Withanolide-D Authetification, Fingerprint, HPTLC profile, Standardization.

INTRODUCTION

India has one of the oldest, richest and most diverse cultural traditions associated with the use of

medicinal plants. This knowledge is accessible from thousands of medical texts and manuscripts. The substances having medical value have been

Synthetic Novel Flavanoid derivatives act as potential Antidiabetic agent against Streptozocin induced in diabetic Rats

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ABSTRACT:

Diabetes mellitus is a heterogeneous group of diseases characterized by chronic elevation of glucose in the blood. It arises because the body is unable to produce enough insulin for its own needs, either because of impaired insulin secretion, impaired insulin action, or both. Chronic exposure to high blood glucose is a leading cause of renal failure, visual loss and a range of other types of tissue damage. Diabetes also predisposes to arterial disease, not least because it is often accompanied by hypertension, lipid disorders and obesity. Many cases of diabetes and almost all of its unwanted long-term consequences are potentially avoidable, but this will require intervention at a societal as well as at a medical level. The three classic symptoms of diabetes are thirst, polyuria and weight loss. As glucose is lost in the urine it draws fluid and other small molecules with it, causing excessive urination, which in turn causes dehydration and thirst. Weight is lost because of rapid breakdown of fat and protein reserves to compensate for the loss of glucose and metabolic inefficiency due to lack of insulin action. These symptoms may be less prominent in older people with type 2-diabetes, who may present with symptoms less directly related to diabetes, or with complications of diabetes ranging from infections to heart disease, or simply as the result of a screening blood test. The objective of the present research work was the synthesis of 2- (2, 3, 4, & 5 substituted phenyl) 3-hydroxy-4H-Chromen-4-one and evaluation of *in vivo* anti diabetic activity against streptozocin induced diabetic Rats. Based on this a new series of compound had been planned to synthesize by reacting 2-hydroxy acetophenone and various aromatic aldehydes in the presence of potassium hydroxide, methanol and 30% hydrogen peroxide. The synthesized compounds were characterized by IR, NMR, and Mass spectroscopy. The present experimental data of blood sugar, serum lipid profile and urinary data displayed that all the synthesized compounds had the potential ability to reduce the diabetes mellitus which was induced by streptozocin in rats.

KEYWORDS: Diabetes mellitus, renal failure, polyuria, streptozocin and NMR etc.

INTRODUCTION:

Flavonoids (or bioflavonoids) (from the Latin word flavus meaning yellow, their color in nature) are a class of plant and fungus secondary metabolites. Chemically, they have the general structure of a 15-carbon skeleton, which consists of two phenyl rings (A and B) and heterocyclic ring (C). This carbon structure can be abbreviated C6-C3-C6. According to the IUPAC nomenclature [1, 2] they can be classified into: flavonoids or bioflavonoids, isoflavonoids, derived from 3-phenylchromen-4-one (3-phenyl-1,4-benzopyrone), neoflavonoids, derived from 4-phenylcoumarine (4-phenyl-1,2-benzopyrone) structure.

Table-1: Molecular structure of the flavone backbone

2-phenyl – 4H-chromen-4-one	3-phenyl-3,4-dihydro-2H-1-benzopyran	4-phenyl-2H-chromen-2-one
2-phenyl – 4H-chromen-4-one	2-phenyl-3,4-dihydro-2H-1-benzopyran-3,4-diol	3-hydroxy-2-phenyl-3,4-dihydro-2H-1-benzopyran-4-one
2-phenyl-3,4-dihydro-2H-1-benzopyran		2-phenyl-3,4-dihydro-2H-1-benzopyran-3-ol
3-hydroxy-2-phenyl-3,4-dihydro-2H-1-benzopyran-4-one		2-phenyl-3,4-dihydro-2H-1-benzopyran-4-ol

The three flavonoid classes above are all ketone-containing compounds, and as such, are anthoxanthins (flavones and flavonols). This class was the first to be termed bioflavonoids. The terms flavonoid and bioflavonoid have also been more loosely used to describe non-ketone polyhydroxy polyphenol compounds which are more specifically termed flavanoids. The three cycle or

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Pharmacokinetic and pharmacodynamic studies of etodolac loaded vesicular gels on rats by transdermal delivery.

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Abstract

BACKGROUND: The present study includes the development of liposomal and ethosomal gels for transdermal delivery to overcome the side effects associated with oral route.

METHODS: The liposomes and ethosomes were prepared by 3² factorial design using film hydration and cold methods, respectively. Different concentrations of liposomal (ETO-LG) and ethosomal (ETO-EG) gels were prepared at 1%, 2 and 3% (w/v) using carbopol 940 NF. 1%w/v ETO-LG & ETO-EG were optimized upon rheological studies of prepared gels. The optimized gels were further characterized for various physicochemical properties and biophysical studies using FTIR, pharmacokinetic (PK) and pharmacodynamic (PD) studies. The pharmacodynamic activity was performed using carrageenan paw oedema model. The prepared vesicular gels were compared with 45% v/v ethanolic ETO-solution and marketed gel PROXYM® in all the characteristic parameters.

RESULTS: The pharmacokinetic study reveals that the half life of etodolac in ETO-EG was 1.56 folds whereas ETO-LG showed 1.31 folds higher than PROXYM®. The mean residence time (MRT) of etodolac in ETO-EG and ETO-LG is increased in 1.57 and 1.25 folds, respectively, when compared to PROXYM®. The ETO-EG showed higher percentage reduction in oedema (81.67%) compared to other test products.

CONCLUSION: The pharmacokinetic and pharmacodynamic studies indicated that the vesicular gels show better results compared to PROXYM®. The correlation coefficient value between PK and PD was found to be 0.9635. Graphical abstract

KEYWORDS: Correlation coefficient; Etodolac; Pharmacodynamic; Pharmacokinetic; Transdermal delivery

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