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Bapatla, Bapatla (Dist), Andhra Pradesh-522101

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

Calendar Year – 2022

S.No	Title of paper	Name of the author/s	Department of the teacher	Name of journal	Year of publication	ISSN number	Link to website of the Journal	Link to article / paper / abstract of the article	Is it listed in UGC Care list
1.	A Comparative Study on Interactions and Influence of Alkalizers on Dissolution Rate of Telmisartan	Talasila Eswara Gopala Krishna Murthy	Pharmaceutics	International journal of pharmaceutical and phytopharmacological research	2023	2249-6084	home - International Journal of Pharmaceutical and Phytopharmacological Research (eijppr.com)	A Comparative Study on Interactions and Influence of Alkalizers on Dissolution Rate of Telmisartan - International Journal of Pharmaceutical and Phytopharmacological Research (eijppr.com)	Yes
2.	A Comparative Study on Interactions and Influence of Alkalizers on Dissolution Rate of Telmisartan	K. Ranjith	Pharmaceutical Analysis & Chemistry	International journal of pharmaceutical and phytopharmacological research	2023	2249-6084	home - International Journal of Pharmaceutical and Phytopharmacological Research (eijppr.com)	A Comparative Study on Interactions and Influence of Alkalizers on Dissolution Rate of Telmisartan - International Journal of Pharmaceutical and Phytopharmacological Research (eijppr.com)	Yes
3.	Evaluation of antidepressant and nootropic activities of leaf extract of Rhizophora apiculata	Annie Mande	Pharmacology	Egyptian Pharmaceutical Journal	2023	2090-9853	Egyptian Pharmaceutical Journal (lww.com)	Evaluation of antidepressant and nootropic activities of lea... : Egyptian Pharmaceutical Journal (lww.com)	Yes
4	Drug utilization pattern In Pediatrics With Gastro-Intestinal Tract Infections- A prospective study.	Neelam Begum	Pharmacology	YMER	2023	0044-0477	YMER – An International Peer-Reviewed Journal (ymerdigital.com)	Past issues – YMER (ymerdigital.com)	Yes

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	Glycyrrhizic acid based cosmeceutical face sheet mask	Bodepudi Sudheer Chowdary	Pharmacology	Journal of Pharmacy & Allied Sciences	2023	3005-2726	Current Science Publishing	1694837922.pdf (currentsci.com)	Yes
6	Glycyrrhizic acid based cosmeceutical face sheet mask	K.Poorna Chandra Rao	Pharmaceutical Analysis & Chemistry	Journal of Pharmacy & Allied Sciences	2023	3005-2727	Current Science Publishing	1694837922.pdf (currentsci.com)	Yes
7	Glycyrrhizic acid based cosmeceutical face sheet mask	Dr. T.E Gopala Krishna Murthy	Pharmaceutics	Journal of Pharmacy & Allied Sciences	2023	3005-2728	Current Science Publishing	1694837922.pdf (currentsci.com)	Yes
8	Applications Of Internet Of Things (Iot) In Pharmaceutical Sector: A Brief Review	Dr. K. Rajya lakshmi	Pharmaceutics	European Journal Of Pharmaceutical And Medical Research	2023	2394-3211	Current Issues | Home (ejpmr.com)	EJPMR - A Journal Following UGC Guidelines - Refereed Journal - Peer Reviewed Journal - European Journal Pharmaceutical And Medical Research	Yes
9	Evaluation of wound healing activity of statin impregnated collagen scaffold in wistar albino rats	Talasila Gopala Krishna Murthy	Pharmaceutics	Current Indian Science	2023	2210-3007	Home ::: Current Indian Science	Evaluation of Wound Healing Activity of Statin Impregnated Collagen Scaffold in Wistar Albino Rats | Bentham Science (eurekaselect.com)	Yes
10	Evaluation of wound healing activity of statin impregnated collagen scaffold in wistar albino rats	Bodepudi Sudheer Chowdary	Pharmacology	Current Indian Science	2023	2210-3007	Home ::: Current Indian Science	Evaluation of Wound Healing Activity of Statin Impregnated Collagen Scaffold in Wistar Albino Rats | Bentham Science (eurekaselect.com)	Yes
11	Acute Oral Toxicity Studies and Evaluation of Central Analgesic Activity of Various extracts	Mande Annie	Pharmacology	Toxicology International	2022	0976-5131	Informatics Journals (informaticsglobal.com)	Acute Oral Toxicity Studies and Evaluation of Central Analgesic Activity of Various extracts of Leaves of Rhizophora apiculata (informaticsglobal.co	Yes

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	of Leaves of Rhizophora apiculata							iii)	
12	Acute Oral Toxicity Studies and Evaluation of Central Analgesic Activity of Various extracts of Leaves of Rhizophora apiculata	T.E.G.K Murthy	Pharmaceutics	Toxicology International	2022	0976-5132	Informatics Journals (informaticsglobal.com)	Acute Oral Toxicity Studies and Evaluation of Central Analgesic Activity of Various extracts of Leaves of Rhizophora apiculata (informaticsglobal.com)	Yes
13	Design, Development and In vivo Evaluation of Core in Cup Tablets of Budesonide	V Sai kishore	Pharmaceutics	Research Journal of Pharmacy and Technology	2022	0974-360X	RJPT - Research Journal of Pharmacy and Technology (rjptonline.org)	RJPT - Design, Development and In vivo Evaluation of Core in Cup Tablets of Budesonide (rjptonline.org)	Yes
14	Anti-Microbial activity of Ficus benghalensis Triterpinoids	B.Sudheer Chowdary	Pharmacology	International Journal of All Research Education and Scientific Methods(IJARESM)	2022	2455-6211	Ijaresm : : UGC Approved journal at Lowest Price within 1 day	Anti-microbial activity of Ficus benghalensis Triterpenoids (ijaresm.com)	Yes
15	Anti-Microbial activity of Ficus benghalensis Triterpinoids	Y.Sushma	Pharmaceutical Analysis & Chemistry	International Journal of All Research Education and Scientific Methods(IJARESM)	2022	2455-6212	Ijaresm : : UGC Approved journal at Lowest Price within 1 day	Anti-microbial activity of Ficus benghalensis Triterpenoids (ijaresm.com)	Yes
16	Anti-Microbial activity of Ficus benghalensis Triterpinoids	K.Poorna Chandra Rao	Pharmaceutical Analysis & Chemistry	International Journal of All Research Education and Scientific Methods(IJARESM)	2022	2455-6213	Ijaresm : : UGC Approved journal at Lowest Price within 1 day	Anti-microbial activity of Ficus benghalensis Triterpenoids (ijaresm.com)	Yes

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17	Anti-Microbial activity of Ficus benghalensis Triterpinoids	S.Shobha	Pharmaceutical Analysis & Chemistry	International Journal of All Research Education and Scientific Methods(IJARESM)	2022	2455-6214	Ijaresm : : UGC Approved journal at Lowest Price within 1 day	Anti-microbial activity of Ficus benghalensis Triterpenoids (ijaresm.com)	Yes
18	Review on Anti inflammatory activity of herbal constituents against cycloxygenase and tumor necrosis factor alpha- A computational approach	Bodepudi Sudheer Chowdary	Pharmacology	YMER	2022	0044-0477	YMER – An International Peer-Reviewed Journal (ymerdigital.com)	Past issues – YMER (ymerdigital.com)	Yes
19	Review on Anti inflammatory activity of herbal constituents against cycloxygenase and tumor necrosis factor alpha- A computational approach	K Poorna Chandra Rao	Pharmaceutical Analysis & Chemistry	YMER	2022	0044-0478	YMER – An International Peer-Reviewed Journal (ymerdigital.com)	Past issues – YMER (ymerdigital.com)	Yes
20	Review on Anti inflammatory activity of herbal constituents against cycloxygenase and tumor necrosis factor alpha- A computational approach	Ch Venu Babu	Pharmaceutics	YMER	2022	0044-0479	YMER – An International Peer-Reviewed Journal (ymerdigital.com)	Past issues – YMER (ymerdigital.com)	Yes
21	Prediction of linearity and non-linearity in pharmaceutical optimization studies with python	T.E.G.K Murthy	Pharmaceutics	International Journal of Research in AYUSH and pharmaceutical sciences	2022	2456-9909	International Journal of Research in AYUSH and Pharmaceutical Sciences (ijraps.in)	Prediction of Linearity and Non-Linearity in Pharmaceutical Optimization Studies with Python | International Journal	Yes

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								of Research in AYUSH and Pharmaceutical Sciences (ijraps.in)	
22	Artificial Intelligence: Applications in healthcare Industry	T.E.G.K Murthy	Pharmaceutics	International Journal of Research in AYUSH and pharmaceutical sciences	2022	2456-9909	International Journal of Research in AYUSH and Pharmaceutical Sciences (ijraps.in)	Artificial Intelligence: Applications in Healthcare Industry | International Journal of Research in AYUSH and Pharmaceutical Sciences (ijraps.in)	Yes
23	Role of Artificial Neural Network in Pharmaceutical Sciences	T E Gopala krishna Murthy	Pharmaceutics	J Young Pharm	2022	0975-1505	Author Guidelines | Journal of Young Pharmacists (jyoungpharm.org)	Role of Artificial Neural Networks in Pharmaceutical Sciences | Journal of Young Pharmacists (jyoungpharm.org)	Yes

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

Calendar Year 2021

S.No	Title of paper	Name of the author/s	Department of the teacher	Name of journal	Year of publication	ISSN number	Link to website of the Journal	Link to article / paper / abstract of the article	Is it listed in UGC Care list
1.	The RP-UPLC method for simultaneous quantification of ivabradine and metoprolol	GV Subrahmanyam	Pharmacognosy	Int. J. of Pharmacy and Analytical Research	2021	2320-2831	IJPAR JOURNAL	The RP-UPLC method for simultaneous quantification of ivabradine and metoprolol | IJPAR JOURNAL	Yes
2.	The RP-UPLC method for simultaneous quantification of sitagliptin and ertuglifozin	GV Subrahmanyam	Pharmacognosy	Journal of Pharma creations	2021	2348 - 6295	Journal of Pharmacreations	The RP-UPLC method for simultaneous quantification of Sitagliptin and Ertugliflozin | Journal of Pharmacreations	Yes
3.	The RP-UPLC method for simultaneous Quantification of lesinurad and allopurinol	GV Subrahmanyam	Pharmacognosy	Indo American Journal of Pharmaceutical Sciences	2021	2349-7750	Home - INDO AMERICAN JOURNAL OF PHARMACEUTICAL SCIENCES (iajps.com)	Volume08 Mar 2021 - INDO AMERICAN JOURNAL OF PHARMACEUTICAL SCIENCES (iajps.com)	Yes
4.	Design, Development and In Vivo Evaluation of Core in Cup Tablets of Azathioprine	V Sai kishore	Pharmaceutics	Current Trends in Biotechnology and Pharmacy	2021	2230-7303	Current Trends in Biotechnology and Pharmacy (abap.co.in)	Design, Development and In Vivo Evaluation of Core in Cup Tablets of Azathioprine | Current Trends in Biotechnology and Pharmacy (abap.co.in)	Yes

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5.	Molecular docking and dynamic simulations of benzimidazoles with beta-tubulins	K Poorna Chandra Rao	Pharmaceutical Analysis & Chemistry	Bioinformation	2021	PMC8131577	Bioinformation Volume 20 @ 2024 since 2005	Molecular docking and dynamic simulations of benzimidazoles with beta-tubulins - PMC (nih.gov)	Yes
6.	Molecular docking and dynamic simulations of benzimidazoles with beta-tubulins	Kapu Ranjith	Pharmaceutical Analysis & Chemistry	Bioinformation	2021	PMC8131578	Bioinformation Volume 20 @ 2024 since 2006	Molecular docking and dynamic simulations of benzimidazoles with beta-tubulins - PMC (nih.gov)	Yes
7.	Molecular docking and dynamic simulations of benzimidazoles with beta-tubulins	Singarapalle Shobha	Pharmaceutical Analysis & Chemistry	Bioinformation	2021	PMC8131579	Bioinformation Volume 20 @ 2024 since 2007	Molecular docking and dynamic simulations of benzimidazoles with beta-tubulins - PMC (nih.gov)	Yes
8.	Molecular docking and dynamic simulations of benzimidazoles with beta-tubulins	Bodepudi Sudheer Chowdary	Pharmacology	Bioinformation	2021	PMC8131580	Bioinformation Volume 20 @ 2024 since 2008	Molecular docking and dynamic simulations of benzimidazoles with beta-tubulins - PMC (nih.gov)	Yes
9.	Role of pharmaceutical sciences in future drug discovery	Gopala KMT Eswara	Pharmaceutics	Future Drug Discovery	2021	2631-3316	Future Drug Discovery (future-science.com)	Role of pharmaceutical sciences in future drug discovery | Future Drug Discovery (future-science.com)	Yes
10.	Pharmacognostical evaluation of aerial parts of Decalepis hamiltonii	T.E.Gopala Krishna Murthy	Pharmaceutics	Asian Journal of Phytomedicine and Clinical Research	2021	2321-0915	Asian Journal of Phytomedicine and Clinical Research (ajpcrjournal.com)	Pharmacognostical evaluation of aerial parts of decalepis hamiltonii.pdf (ajpcrjournal.com)	Yes
11.	Pharmacognostical evaluation of aerial parts of Decalepis hamiltonii	J Venkata Suresh	Pharmacognosy	Asian Journal of Phytomedicine and Clinical Research	2021	2321-0916	Asian Journal of Phytomedicine and Clinical Research (ajpcrjournal.com)	Pharmacognostical evaluation of aerial parts of decalepis hamiltonii.pdf (ajpcrjournal.com)	Yes

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12.	Pharmacognostical evaluation of aerial parts of Holostemmaada-kodien	J Venkata Suresh	Pharmacognosy	Asian Journal of Research in Chemistry and Pharmaceutical Sciences	2021	2349-7106	Asian Journal of Research in Chemistry and Pharmaceutical Sciences (AJRCPS) - Home	Asian Journal of Research in Chemistry and Pharmaceutical Sciences (AJRCPS) - Archives - Year - Volume 9 - Issue 4 - download pdf	Yes
13.	Pharmacognostical evaluation of aerial parts of Holostemmaada-kodien	T.E.Gopala Krishna Murthy	Pharmaceutics	Asian Journal of Research in Chemistry and Pharmaceutical Sciences	2021	2349-7107	Asian Journal of Research in Chemistry and Pharmaceutical Sciences (AJRCPS) - Home	Asian Journal of Research in Chemistry and Pharmaceutical Sciences (AJRCPS) - Archives - Year - Volume 9 - Issue 4 - download pdf	Yes
14.	Design, Development and characterization of simvastatin liposomal loaded gels for transdermal drug delivery	V.Sai Kishore	Pharmaceutics	International Journal of Pharmaceutical Research and Applications	2021	2249-778	International Journal of Pharmaceutical Research and Applications (IJPRA) (ijprajournal.com)	International Journal of Pharmaceutical Research and Applications (IJPRA) (ijprajournal.com)	Yes
15.	Development and validation of RP-HPLC method for the estimation of Sofosbuvir and related impurity in bulk and pharmaceutical dosage form	Shiny Ganji	Pharmacognosy	Future Journal of Pharmaceutical Sciences	2021	2314-7253	Home | Future Journal of Pharmaceutical Sciences (springeropen.com)	Articles | Future Journal of Pharmaceutical Sciences (springeropen.com)	Yes
16.	Multi response Optimization of HPLC Method : Simultaneous Estimation of protease inhibitors and NNRTI in human plasma	Ganna Anitha	Pharmaceutical Analysis & Chemistry	Journal of Chromatographic sciences	2021	1945-239X	Journal of Chromatographic Science | Oxford Academic (oup.com)	Multiresponse Optimization of HPLC Method: Simultaneous Estimation of Protease Inhibitors and NNRTI in Human Plasma | Journal of Chromatographic Science | Oxford Academic (oup.com)	Yes

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17.	Multi response Optimization of HPLC Method : Simultaneous Estimation of protease inhibitors and NNRTI in human plasma	Sree Janardhanan Vaithiyanathan	Pharmaceutical Analysis & Chemistry	Journal of Chromatographic sciences	2021	1945-239X	Journal of Chromatographic Science | Oxford Academic (oup.com)	Multiresponse Optimization of HPLC Method: Simultaneous Estimation of Protease Inhibitors and NNRTI in Human Plasma | Journal of Chromatographic Science | Oxford Academic (oup.com)	Yes
18.	Effects of Aegle marmelos (L.) Methanolic Leaf Extracts on Biochemical Parameters in Diabetic Rats	Sathish Kumar Manoharan	Pharmacology	Journal of Reports in Pharmaceutical Sciences	2021	2322-5106	Journal of Reports in Pharmaceutical Sciences (lww.com)	Effects of Aegle marmelos (L.) Methanolic Leaf Extracts on B... : Journal of Reports in Pharmaceutical Sciences (lww.com)	Yes

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

Calendar - 2020

S.No	Title of paper	Name of the author/s	Department of the teacher	Name of journal	Year of publication	ISSN number	Link to website of the Journal	Link to article / paper / abstract of the article	Is it listed in UGC Care list
1.	Design and development of ondansetron hydrochloride pH independent control released matrix tablets	T.E.G.K Murthy	Pharmaceutics	Pakistan Journal of Pharmaceutical Sciences	2020	1011-601X	» Home | Pakistan Journal of Pharmaceutical Sciences (pjps.pk)	Design and development of ondansetron hydrochloride pH independent control released matrix tablets - PubMed (nih.gov)	Yes
2.	Comparative in vivo evaluation of marketed sustained release and optimized pulsatile formulation of propranolol hydrochloride	V Sai kishore	Pharmaceutics	International Journal of Research in Pharmaceutical Sciences	2020	0975-7538	International Journal of Research in Pharmaceutical Sciences (ijrps.com)	View of Comparative in vivo evaluation of marketed sustained release and optimized pulsatile formulation of propranolol hydrochloride | International Journal of Research in Pharmaceutical Sciences (ijrps.com)	Yes
3.	Design and Development of pulsatile drug delivery of Diltiazem Hydrochloride	V.Sai Kishore	Pharmaceutics	Research Journal of Pharm. And Tech	2020	0974-360X	RJPT - Research Journal of Pharmacy and Technology (rjptonline.org)	RJPT - Design and Development of Pulsatile drug delivery of Diltiazem Hydrochloride (rjptonline.org)	Yes
4.	Comparative in vivo evaluation of marketed sustained release and optimized pulsatile formulation of	V.Sai Kishore	Pharmaceutics	Studies in Indian place Names	2020	2394-3114	Studies in Indian Place Names (tpnsindia.org)	Comparative in Vivo Evaluation of Marketed Sustained Release and Optimized Pulsatile Formulation of Diltiazem Hydrochloride |	Yes

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	Diltiazem hydrochloride							Studies in Indian Place Names (tpnsindia.org)	
5.	New Liquid Chromatographic Method Development and Validation of Ledipasvir and Related Impurity by RP-HPLC in bulk and pharmaceutical dosage forms	Shiny Ganji	Pharmacognosy	Inventi Rapid: Pharma Analysis & Quality Assurance	2020	0976-3813	Molecules | An Open Access Journal from MDPI	https://fjps.springeropen.com/articles/10.1186/s43094-021-00285-5	Yes
6.	Development Of Bilayer Tablets Of Losartan Potassium And Metformin Hydrochloride Layer Using Natural Gums As Polymers	Dr. K. Rajyalakshmi	Pharmaceutics	Asian Journal of Pharmaceutical and Clinical research	2020	2455-3891	Vol 13 Issue 7 July 2020 | Asian Journal of Pharmaceutical and Clinical Research (innovareacademics.in)	AJPCR Content (innovareacademics.in)	Yes
7.	Synthesis, characterization, analgesic and anti-inflammatory activity of new pyrazole derivatives	B.Sudheer Chowdary	Pharmacology	(Arkivoc) The Free Internet Journal for Organic Chemistry	2020	1551-7012	ARKAT USA, Inc. - Publisher of ARKIVOC (Free Journal of Organic Chemistry) (arkat-usa.org)	ARKAT USA, Inc. - Browse ARKIVOC - Volume ark.5550190.p011.070 (arkat-usa.org)	Yes
8.	Design and characterization of chronopharmaceutical drug delivery of propranolol hydrochloride	V.Sai kishore	Pharmaceutis	International Journal of Pharmaceutical Sciences and Research	2020	0975-8232	INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH (ijpsr.com)	DESIGN AND CHARACTERIZATION OF CHRONOPHARMACEUTICAL DRUG DELIVERY OF PROPRANOLOL HYDROCHLORIDE | INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH (ijpsr.com)	Yes

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9.	Effects of Aegle marmelos (L.) Methanolic Leaf Extracts on Cardiovascular Parameters in Diabetic Rats	Manoharan Sathish Kumar	Pharmacology	Journal of Diseases and Medicinal Plants	2020	2469-8210	Journal Home:: Journal of Diseases and Medicinal Plants:: Science Publishing Group	Archive:: Journal of Diseases and Medicinal Plants:: Science Publishing Group	Yes
10.	Evaluation of Biochemical Changes in Diabetic Rats Treated with Aegle marmelos (L.) Methanolic Leaf Extract	Sathish Kumar Manoharan	Pharmacology	Pharmacogn. Res	2020	0974-8490	Pharmacognosy Research | An Open Access Journal in Pharmacognosy and Natural Products (phcogres.com)	PharmacognRes-12-2-127.pdf (phcogres.com)	Yes

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

Calendar Year - 2019

S.No	Title of paper	Name of the author/s	Department of the teacher	Name of journal	Year of publication	ISSN number	Link to website of the Journal	Link to article / paper / abstract of the article	Is it listed in UGC Care list
1.	Relationship between dopamine and serotonin on the effect of Ginkgo biloba extract in the treatment of obsessive-compulsive disorder in Rodents	T.E.G.K Murthy	Pharmaceutics	Indian Journal of Pharmaceutical Sciences	2019	0250-474X	About us | Indian Journal of Pharmaceutical Sciences (ijpsonline.com)	Relationship between Dopamine and Serotonin on the Effect of | 3637 (ijpsonline.com)	Yes
2.	Design and Development of Rizatriptan Benzoate Oral Dispersible Films	T.E.G.K Murthy	Pharmaceutics	International Research Journal of Pharmacy	2019	2230-8407	International Research Journal of Pharmacy (irjponline.com)	100248 85-91 (irjponline.com)	Yes
3.	Influence of Kollidon SR on Ondansetron HCL pH Independent Drug Release form Hydropropyl Methyl Cellulose	T.E.Gopala Krishna Murthy	Pharmaceutics	Research Trends in Pharmaceutical sciences and research	2019	2583-5718	Recent Trends in Pharmaceutical Sciences and Research (matjournals.in)	211977749.pdf (core.ac.uk)	Yes

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	Matrix Tablets								
4.	Prescribing Patterns of Drugs in Pregnant Women Among Outpatients and Inpatients in Obstetrics & Gynecology Department	Neelam Begum	Pharmacology	International Journal of Pharmaceutical and Clinical Research	2019	0975 1556	IJPCR	Volume11,Issue2 - International Journal of (ijpcr.com)	Yes
5.	Comparative Invivo study of pure drug and fast dissolving tablets of Simvastatin	T.E.Gopala Krishna Murthy	Pharmaceutics	Journal of drug delivery and therapeutics	2019	2250-1177	Journal of Drug Delivery and Therapeutics (jddtonline.info)	Comparative in vivo study of pure drug and fast dissolving tablets of Simvastatin | Journal of Drug Delivery and Therapeutics (jddtonline.info)	Yes
6.	Topical Combination delivery of Benzoyl Proxide and Adapalene Niosomal Gel for Acne Treatment	V.Sai Kishore	Pharmaceutics	Asian Journal of Pharmaceutics	2019	1998-409X	Asian Journal of Pharmaceutics (AJP) (asiapharmaceutics.info)	Topical Combination Delivery of Benzoyl Peroxide and Adapalene Niosomal Gel for Acne Treatment | Asian Journal of Pharmaceutics (AJP) (asiapharmaceutics.info)	Yes
7.	Sensitive Hplc-Ms/Ms Method For Estimation Of Elagolix In Human Plasma	K.Poorna Chandra Rao	Pharmaceutical Analysis & Chemistry	International Journal of Research and Analytical Reviews (IJRAR)	2019	2348 – 1269	Ijrar.org	http://www.ijrar.org/papers/IJRAR19J2908	Yes

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	Samples								
8.	Benzoyl Peroxide and Adapalene Niosomal Gel for Treatment of Acne by Topical Combination Delivery System in vitro & in vivo studies	V.Sai Kishore	Pharmaceutics	Journal of the Gujarat research society	2019	0374-8588	Journal of the Gujarat Research Society	Benzoyl Peroxide and Adapalene Niosomal Gel for Treatment of Acne by Topical Combination Delivery System in vitro & in vivo studies | Journal of the Gujarat Research Society	Yes
9.	Wound healing activity of Euphorbia antiquorum stem extract on rats	B. Sudheer Chowdary	Pharmacology	Asian Journal of Pharmacy and Pharmacology	2019	2455-2674	Asian Journal of Pharmacy and Pharmacology (ajpp.in)	Current Issues of Asian Journal of Pharmacy and Pharmacology (ajpp.in)	Yes
10.	Hypoglycemic and antidiabetic activity of tuberous roots of Cyanotis cristata in normal and Alloxan induced diabetic rats.	J. Venkata Suresh	Pharmacognosy	Journal of Global Trends in Pharmaceutical Sciences	2019	2230-7346	Search Result | CABI Digital Library	cabidigitallibrary.org/doi/full/10.5555/20203164 3	Yes
11.	Phytochemical , in vitro Antioxidant and in vivo Safety Evaluation of Leaf Extracts of Tragia plukenetii	Sathish Kumar Manoharan	Pharmacology	Pharmacognosy Journal	2019	0975-3575	Pharmacognosy Journal | An Open Access, Peer Reviewed Journal in the field of </br>Pharmacognosy (phcogj.com)	Phytochemical, in vitro Antioxidant and in vivo Safety Evaluation of Leaf Extracts of Tragia plukenetii | Pharmacognosy Journal	Yes

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

Calendar Year - 2018

S.No	Title of paper	Name of the author/s	Department of the teacher	Name of journal	Year of publication	ISSN number	Link to website of the Journal	Link to article / paper / abstract of the article	Is it listed in UGC Care list
1.	Development of metoprolol tartrate sustained release formulations by using modified starches	T.E.Gopala Krishna Murthy	Pharmaceutics	Asian Journal of research in pharmaceutical sciences	2018	2231-5659	Asian Journal of Research in Pharmaceutical Sciences (ajpsonline.com)	Asian Journal of Research in Pharmaceutical Sciences (ajpson	Yes
2.	Comparative in vivo Evaluation of Delayed release pellets and oral solution containing fenofibric acid	T.E.G.K Murthy	Pharmaceutics	International research journal of pharmacy and medical sciences	2018	2581-3277	IRJPMS	IRJPMS	Yes
3.	Formulation Development Evaluation and Optimization of Orodispersible tablets of Frovatriptan for the treatment of Migraine	Gopala Krishna Murthy Talasila	Pharmaceutics	American Journal of Pharmatech research	2018	2249-3387	American Journal of PharmTech Research (ajptr.com)	American Journal of PharmTech Research (ajptr.com	Yes
4.	Formulation and evaluation of esomeprazole fast dissolving buccal films	T.E.G.K Murthy	Pharmaceutics	Asian Journal of Pharmaceutical and Clinical Research	2018	2455-3891	AJPCR Content (innovareacademics.in)	FORMULATION AND EVALUATION OF ESOMEPRAZOLE FAST DISSOLVING BUCCAL FILMS | Asian Journal of	Yes

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								Pharmaceutical and Clinical Research (innovareacademics.in)	
5.	Design and Development of spherical agglomerated crystals loaded fast dissolving tablets for enhancing the solubility of Ibuprofen	V. Saikishore	Pharmaceutics	IndoAmerican Journal of Pharmaceutical Sciences	2018	2349-7750	Home - INDO AMERICAN JOURNAL OF PHARMACEUTICAL SCIENCES (iajps.com)	::INDO AMERICAN JOURNAL OF PHARMACEUTICAL SCIENCES:: (iajps.com)	Yes
6.	Development of pH independent drug release system for dipyridamole	T.E.G.K Murthy	Pharmaceutics	Indian Journal of Pharmaceutical Education and Research	2018	0019-5464	Indian Journal of Pharmaceutical Education and Research | Indian Journal of Pharmaceutical Education and Research (ijper.org)	IndJPhaEdRes_52_3_374.pdf (ijper.org)	Yes
7.	Effect of formulation factors on orodispersible triptan formulations – novel approach in treatment of migraine	T.E.G.K Murthy	Pharmaceutics	Asian Journal of Pharmaceutical and Clinical Research	2018	2455-3891	Innovare Academic Sciences	EFFECT OF FORMULATION FACTORS ON ORODISPERSIBLE TRIPTAN FORMULATIONS â€“ NOVEL APPROACH IN TREATMENT OF MIGRAINE | Asian Journal of Pharmaceutical and Clinical Research (innovareacademics.in)	Yes
8.	Formulation and evaluation of lansoprazole fast dissolving buccal films	T.E.G.K Murthy	Pharmaceutics	Asian Journal of Pharmaceutics	2018	1998-409X	Asian Journal of Pharmaceutics (AJP) (asiapharmaceutics.info)	Formulation and Evaluation of Lansoprazole Fast Dissolving Buccal Films | Asian Journal of Pharmaceutics (AJP) (asiapharmaceutics.info)	Yes

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9.	Development of fenofibric acid drug loaded pellets by extrusion spheronization: A statistical design for optimization of process variables	Gopala Krishna Murthy Talasila	Pharmaceutics	World Journal of Pharmaceutical Research	2018	2277-7105	Welcome to WJPR	WJPR - Research Article	Yes
10.	Multi-particulate Drug delivery systems of fenofibric acid: Optimization of formulation using statistical experimental design	T.E.G.K Murthy	Pharmaceutics	UK Journal of Pharmaceutical and Biosciences	2018	2347-9442	Pharmaceutical and Biosciences Journal (UK Journal of Pharmaceutical Biosciences) (i-scholar.in)	Multi-Particulate Drug Delivery Systems of Fenofibric Acid: Optimization of Formulation Using Statistical Experimental Design | Mukkala | Pharmaceutical and Biosciences Journal (UK Journal of Pharmaceutical Biosciences) (i-scholar.in)	Yes
11.	Development of Fenofibric acid delayed release pellets: Optimization of process variables in fluid bed process	Gopala Krishna Murthy Talasila	Pharmaceutics	Indo American Journal of Pharmaceutical sciences	2018	2349-7750	Home - INDO AMERICAN JOURNAL OF PHARMACEUTICAL SCIENCES (iajps.com)	::INDO AMERICAN JOURNAL OF PHARMACEUTICAL SCIENCES:: (iajps.com)	Yes
12.	Comparative invivo evaluation of extended release pellets and oral solution containing methylphenidate hydrochloride	Murthy TEGK	Pharmaceutics	International Journal of Pharmaceutical Sciences and health	2018	2249 – 5738	International Journal of Pharmaceutical Science and Health Care (rspublication.com)	Untitled 1 (rspublication.com)	Yes
13.	Formulation and evaluation of immediate release tablets of pioglitazone hydrochloride	T.E.G.K Murthy	Pharmaceutics	International Journal of Pharmaceutical Science and Research	2018	0975-8232	INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH (ijpsr.com)	Volume 9 (2018) | INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH	Yes

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	by employing modified super disintegrants							rjpsr.com)	
14.	Design and Development of oral modified release formulations for losartan potassium with natural and modified gums	T.E.Gopalakrishna Murthy	Pharmaceutics	Research journal of pharmaceutical dosage forms and technology	2018	0975-4377	Research Journal of Pharmaceutical Dosage Forms and Technology (rjpdft.com)	Research Journal of Pharmaceutical Dosage Forms and Technology (rjpdft.com)	Yes
15.	Study on Antirheumatoid Arthritis Activity	Neelam begum	Pharmacology	IOSR Journal Of Pharmacy	2018	2250-3013	https://www.iosrjournals.org/IOSR-PHR.html	http://iosrphr.org/pages/volume8-issue4-ver-1.html	Yes
16.	Design and Development of Tramadol Hydrochloride Lozenges for Pediatrics	T. V. Rao	Pharmaceutics	Research Journal of Pharmaceutical Dosage Forms and Technology	2018	0975-4377	Research Journal of Pharmaceutical Dosage Forms and Technology (rjpdft.com)	Research Journal of Pharmaceutical Dosage Forms and Technology (rjpdft.com)	Yes

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A Comparative Study on Interactions and Influence of Alkalizers on Dissolution Rate of Telmisartan

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ABSTRACT

For preformulation studies in formulation development, compatibility studies are crucial. Telmisartan is an angiotensin II receptor blocker [ABRs]. It is also used in the treatment of heart attack and stroke. It is a BCS class II drug. Since telmisartan's solubility is pH-dependent, a few alkalizing agents are utilized to speed up the solubility and dissolution process. The objective of this study was to enhance the solubility of telmisartan. Alkalizing agents such as magnesium hydroxide, sodium bicarbonate, aluminium hydroxide, and barium carbonate are used. Telmisartan solid dispersions with the selected alkalinising agents were formulated by employing a kneading technique and subjected to IR spectral, HPLC and in-vitro dissolution studies. Magnesium hydroxide was found to be preferable compared to other alkalizers based on docking, IR spectral and HPLC techniques and *in-vitro* dissolution studies. The results demonstrated the enhanced solubility of telmisartan with magnesium hydroxide and sodium lauryl sulphate at ratios. This study concluded that addition of alkalising agent like magnesium hydroxide improves solubility of class – II drugs.

Key Words: *Telmisartan, Docking studies, HPLC, FTIR, Solid dispersions*

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INTRODUCTION

Telmisartan is a class of angiotensin II receptor blockers. It functions by preventing the action of specific natural substances that narrow blood arteries, letting blood flow more freely and the heart pump more effectively. It is also used in the treatment of heart attack and stroke [1-6]. According to the BCS classification, telmisartan is classified as a class II drug, i.e., highly permeable but poorly soluble [7]. Excipient compatibility screening is widely accepted as a crucial step in the development process. Telmisartan is a pH-dependent solubility drug [7]. So, it has more solubility in alkaline pH. To improve the solubility, alkalizers such as magnesium hydroxide, sodium bicarbonate, aluminium hydroxide, and barium carbonate are used. The alkalizing agents are incorporated into the drug by using the solid dispersion method by kneading technique. Drug-excipient mixtures are packed in blister packs and stored at 40^0c for 15 days. The blends were analysed with HPLC and FTIR [8-15]. Drug solubility, stability, dissolution rate and bioavailability may alter as a result of interactions between active ingredient and inactive excipients in a solid form. Excipients are typically used to improve process parameters and effectiveness. Due to telmisartan's poor flow characteristics and inability to dissolve in water, required excipients are added and compatibility studies were perfomed.

This article explains how alkalizers are employed to improve the solubility of telmisartan. This study's objective was to assess telmisartan's physical and chemical stabilities and rate of dissolution when combined with excipients.

MATERIALS AND METHODS

Telmisartan, Magnesium hydroxide, sodium bicarbonate, aluminium hydroxide, barium carbonate, Sodium lauryl

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MATERIALS AND METHODS

Telmisartan, Magnesium hydroxide, sodium bicarbonate, aluminium hydroxide, barium carbonate, Sodium lauryl

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Evaluation of antidepressant and nootropic activities of leaf extracts of *Rhizophora apiculata*

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Background
Rhizophora (R.) apiculata is a traditional mangrove plant having antioxidant, anti-inflammatory, and central analgesic activities.
Objective
The current study was performed to assess the beneficial neurological activities of the plant using rodent models and also to explore the phytochemical distribution of plant extracts using the hyphenated analytical technique.
Materials and methods
Ethyl alcohol and aqueous extracts were subjected to phytochemical screening, followed by GC-MS analyses. In experimental studies, the animals were divided into normal, positive control (standard), negative control, and extract-treated groups at three doses of each extract. The tail suspension method and forced swim tests were used as requisite animal models for the evaluation of antidepressant activity. Imipramine was used as the standard drug for the evaluation of antidepressant studies. Nootropic activity was evaluated by using the radial arm maze and Y-maze models. For these studies, scopolamine was used to impair the cognition of the animals and donepezil was used as the standard drug. The results were displayed as mean±standard error mean, and two-way ANOVA was used to analyze statistical significance between the test groups.
Results and conclusion
Preliminary phytochemical analyses showed that the leaves contain a wide range of secondary metabolites in abundance. As per GC-MS characterization, a few bioactive compounds like 3-O-methyl-D-glucose, desulphosinigrin, 1,25-dihdroxy vitamin D3, and ethyl iso-allocholate were identified. Ethyl alcohol extract (at 300 mg/kg; and 600 mg/kg) and aqueous extract (at 200 mg/kg; and 400 mg/kg) of *R. apiculata* exhibited antidepressant activity in both models. The plant extracts were proved to have cognition-enhancing activities at tested doses. The results stated that the plant *R. apiculata* is proved to have antidepressant and cognition-enhancing activities. Thus, it may provide a chance in the therapeutic management of neurological ailments. The effects of leaf constituents on brain neurotransmitter levels and the histology of the brain need to be established by future investigations.

Keywords:
antidepressant activity, flavonoid content, GC-MS study, nootropic activity, *Rhizophora apiculata*

Egypt Pharmaceut J 22:557–566

1687-4315

Introduction

Depression is a serious psychological disorder related to the brain, which is characterized by severe sadness, dysphoria, insomnia, anorexia and deprivation of interest in all pleasures. Symptoms of depression may include intense sadness, mood swings, irritability, insomnia, and social distancing. Depression may be caused by the deprivation of monoamine neurotransmitters at the synapse [1]. Tricyclic antidepressants and monoamine oxidases are the major drugs that are used in the current treatment. The majority of these medications have severe adverse effects as they are synthetic in nature. Hence, this is a small approach to derive active molecules from natural sources for the treatment of depression and to improve the cognitive skills of those who are suffering from neurodegenerative disorders.

Cognition enhancers are the drugs that are used in the management of cognition deficiency in the elderly with Alzheimer's disease, stroke, schizophrenia, Parkinson's disease, and cerebral palsy [2]. The reduced levels of neurotransmitters like Acetylcholine (Ach) are mainly associated with reduced cognition in chronic diseases. Few plants with antidepressant activity like

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Drug utilization pattern In Pediatrics With Gastro-Intestinal Tract Infections- A prospective study.

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2. B. Pharmacy final year student, Bapatla College of Pharmacy, BAPATLA.

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ABSTRACT

Aim: To conduct a prospective study on prescribing pattern of drugs in paediatrics suffering with gastrointestinal infections. **Background:** Prescription analysis can identify places where encounters with drugs written by prescribing doctors need to improve. **Methodology**: A prospective study was carried out in Likith Sai Amar Eye and Children Hospital in patients up to 12 years of age from march 2022 to May 2022. A total of 75 patients were recruited for the study based on inclusion and exclusion criteria. Prescriptions were collected and relevant data was entered into the proforma designed as per the study requirements and prescriptions were analysed for the calculation of the prescription indicators. **Results:** This investigation revealed that the data obtained out of 75 paediatrics, 66.66% were males and 33.33% were females. Further prescriptions with maximum drugs are 46.6% and least is 10.6 %.The highly prescribed drugs were belonging to the class of antibiotics especially cephalosporins .

Conclusion: A prescription-based survey is seen to be one of the most effective ways to monitor medication utilization. It is also beneficial to improve the prescriber's prescribing practices and, as a result, clinical standards.

KEYWORDS: Pediatrics, Prescription pattern, gender, Gastro intestinal infections, antibiotics.

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Research Article

Glycyrrhizic acid based cosmeceutical face sheet mask

Bodepudi Sudheer Chowdary* , **Talasila Eswara Gopala Krishna Murthy, Keerthi Poorna Chandra Rao** , **Cheboyina Pallavi** and **Tejaswini Pola**

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Keywords
Anti-microbial activity, face mask, glycyrrhizic acid, minimum inhibitory concentration, honey, UV protection

Abstract

The application of cosmetics for the skin started in the Egyptian ages. The protection of the skin and face is essential for everyone in the modern era because of various pollutants released into the environment by the technology. Even the skin can be affected by the UV light directly due to the destruction of Ozone layer. The various microbial infections caused by the *Staphylococcus, Micrococcus,* and *Corynebacterium species* can affect the skin by eczema like conditions. Formulate and evaluation of Glycyrrhizic acid from the liquorice root along with honey and other ingredients on the *E.Coli, Staphylococcus aureus, Bacillus subtilis microorganisms.* The face mask was prepared by mixing the Glycyrrhizic acid and honey in the base contains the Sodium benzoate, Propylene glycol, HPMC, Tween 80 and perfume. The application of the formulation as the face mask by using the paper sheet on the skin can be able to moisturise, protect from UV and also provide anti-microbial activity. The formulation was evaluated for the organoleptic parameters, pH and antimicrobial activity. The results show that the formulation exerted significant antimicrobial activity and non-irritant effects on the skin with the pH 6.8. The zone of inhibition was observed for the respective microorganism groups. The work concluded that isolated herbal compounds can improve efficacy and safety when compared with synthetic molecules which can easily be compatible with the skin.

1. Introduction

Herbal plants have been used in cosmetics since the time of the ancient travellers. The word "cosmetics" comes from the Latin word "cosmetae," which was used to refer to the servants who performed the bathing for the men and ladies of the Roman monarchs [1]. Cosmetics are defined as "any article meant to be rubbed, poured, sprinkled, sprayed or applied to any area of the human body for washing, beautifying, encouraging attractiveness or altering the appearance, and includes any material intended for use as a component of cosmetic [2]. About 67% of consumers globally used various creams and lotions for the sun protection and protecting the skin from pollutants globally. Mechanism of skin damage by Environmental irritants, UV rays and pollutants from outdoors and indoors (smoke, gas, particles, heavy metals, ozone and free radicals) are involving the breakdown of skin's collagen and elastin, which is accompanied by hyperpigmentation, inflammation, and dehydration phenomena [3]. The major issues for the skin damage may be due to the inhibition of enzymes like P53 the formation of the free radicals are increased which are majorly involved in the damage of the skin [4]. Even sunlight and radiation also involved in pigmentation due to the production of melanin which is very natural phenomena to protect the skin from the sunlight [5]. Along with the external factor's microorganisms like *Staphylococcus species, Bacillus* and *Escherichia coli* are causing various skin diseases [6]. According to WHO and many other

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Review Article

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EJPMR

APPLICATIONS OF INTERNET OF THINGS (IOT) IN PHARMACEUTICAL SECTOR: A BRIEF REVIEW

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ABSTRACT

Highly advanced technologies are required to compete in market shares on global scale, for the pharmaceutical and life sciences sectors. Companies in the pharmaceutical and life sciences industries devote greater time, effort, and resources for digitalizing their operations. In five years, 80% of businesses are anticipated to use IOT in their digitally transformed businesses, with the number of linked devices predicted to reach 50 billion by 2025. The Internet of Things (IOT) is revolutionizing the pharmaceutical industry by enabling and automating pharmaceutical manufacturing, drug discovery, remote patient monitoring and other processes. The potential for digitization to assist pharmaceutical companies in overcoming numerous obstacles is enormous. This article aims to provide readers a glimpse of various applications of the Internet of Things in the pharmaceutical industry.

KEY WORDS: IOT, drug manufacturing, pharmaceutical industry.

INTRODUCTION

IOT is a network of internet-connected devices that can gather, analyse, and transmit crucial information using built-in sensors. By the end of 2025, there may be 50 billion integrated devices, according to estimates. 80% of businesses are anticipated to use IOT within their organizations over the next five years to automate every department. IOT has the ability to completely modernize the pharmaceutical industry by enabling and automating drug research, clinical trials, patient monitoring from a distance, access, and other processes.

Healthcare services must be more quickly and easily accessible in light of the Industry 4.0 transformation. Pharmaceutical businesses must also speed up the manufacturing process and transport medications in a secure manner in better regulated transit and delivery.

These procedures produce enormous amounts of data, which will be efficiently harvested, analyzed, and used for analytics for subsequent processes and upgrades. The analysis of obtained data provides useful insights into plant operations, forecasts the need for repair before equipment becomes inoperable, and tracks the supply chain throughout the production.

IOT in pharm fabrication

Industry 4.0, which refers to the digitalization of industry, was first used in a public context at Hannover Messe in 2011. The German Academy of Engineering and the Science and Industry Research Union define the term "Industry 4.0" as the technological integration of cyber-physical systems into production and logistics[1] as well as the use of IOT and services in industrial processes, such as the resulting consequences for value creation, business models and downstream services and work organizations.

Companies that manufacture pharmaceuticals make use of cutting-edge technology and information systems. A number of specialized IT systems, some of which are centralized, are used to monitor the processes. While some local systems fall short of meeting all the requirements for high-quality manufacturing in a highly regulated sector. It is necessary to have 360[2]-degree real-time views of the plant functioning across several systems in addition to monitoring individual systems. Additionally integrated will be automated data collection and real-time IOT data analysis from equipment on the plant floors. Direct communication between departments, plant floor operations, and management continues to be a barrier because there is no real-time data integration to improve process flow and on-time product manufacturing.

IOT-PM, or Internet of Things in Pharmaceutical Manufacturing: has the potential to fundamentally alter how pharmaceutical manufacturing plants run. It allows access to the production activities to be tracked at any time from a distance. Thus, real-time monitoring helps to reduce waste, improve equipment usage, and save expenses associated with manufacturing. Industrial IOT

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RESEARCH ARTICLE

Evaluation of Wound Healing Activity of Statin Impregnated Collagen Scaffold in Wistar Albino Rats

Talasila Gopala Krishna Murthy[1,*] and Bodepudi Sudheer Chowdary[1]

[1]*Department of Pharmaceutics, Bapatla College of Pharmacy, Bapatla, India*

Abstract:

Background:

Wound healing is a dynamic process that is affected by various processes. Medications involved in wound healing can interfere with clot formation, inflammation reduction, and cell proliferation. Collagen is the natural existing compound that has the ability to enhance tissue regeneration. Various drugs used for healing have cons like inhibiting DNA, RNA, or protein synthesis, resulting in decreased fibroplasias and neovascularisation of wounds.

Objective:

The objective of this work is the formulation of the collagen scaffold impregnated with the Atorvastain using cow urine as solvent.

Methods:

The methodology involves the isolation of the collagen from the bones of the animals by using acetic acid. The obtained collagen was subjected to homogenization and sonification to get a fine powder. To this solvent, Atorvastatin and glycerine were added then it was dried at 60°C for 24 hrs to get the impregnated scaffold. The formulated scaffold was evaluated for wound healing activity by using the excision wound model.

Results:

The result shows that the scaffolds are good in nature and meet all the standards of the standard scaffold. The wound healing activity is assessed by using the excision wound healing model in rats. The results show the significant value of 99% wound healing activity from the statin-impregnated scaffold. The biological parameters like total collagen, hexosamine, and uronic acid were evaluated and these observations indicated higher values of 4.024 ± 0.069, 304 ± 4.11, and 75.83 ± 1.93 compared with the plain scaffold.

Conclusion:

The optimised formulation exhibited good mechanical strength with better wound healing activity. The percent wound healing activity and antimicrobial activity observed from the collagen scaffold was found to be more significant compared with the scaffolds not containing statins.

Keywords: Atorvastatin, Antimicrobial activity, Collagen scaffold, Cow urine, Statins, Wound healing.

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1. INTRODUCTION

Wound healing is a complex and dynamic process of replacing devitalized and missing cellular structures and tissue layers. The wound-healing process consists of four highly integrated and overlapping haemostasis, inflammation, proliferation, and tissue remodelling or resolution phases [1]. Many factors can affect wound healing by interfering with one or more phases in this process, thus causing improper or impaired tissue repair. Many medications, such as those which interfere with clot formation, platelet function, inflammatory responses and cell proliferation have the capacity to affect wound healing. Systemic glucocorticoids are frequently used as anti-inflammatory agents, are able to inhibit wound repair *via* global anti-inflammatory effects and suppression of cellular wound responses, including fibroblast proliferation and collagen synthesis [2]. Topical application of NSAIDs like ibuprofen on the surfaces of chronic wounds provides moist wound healing, reduces persistent and temporary wound pain, and benefits chronic venous leg ulcer healing [3]. Most

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Acute Oral Toxicity Studies and Evaluation of Central Analgesic Activity of Various extracts of Leaves of *Rhizophora apiculata*

Annie Mande[1], Narender Malothu[1]*, Nagaraju Banadaru[1] and T. E. G. K. Murthy[2]

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ARTICLE INFO

KEYWORDS: Acute Oral Toxicity, Analgesic Activity, Histopathology, Tail Immersion Method, *R. apiculata*

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The present study aimed to determine the acute toxicity and screening of central analgesic activity of various extracts of *Rhizophora apiculata* leaves. The animals (Mice) were divided into control (no drug) and extract-treated groups (n=5), which were treated with diethyl ether extract, ethyl alcohol extract, and aqueous extract of *R. apiculata* leaves in various doses for specific regulatory needs. The groups which were given the highest safe doses were observed for 14 days. Then blood samples were collected from high dose treated live mice through the retro-orbital route and were analysed for haematological, biochemical, and histopathological study. Evaluation of central analgesic activity was carried out by using tail immersion and hot plate methods. No considerable alterations were observed in body weight and organ-to-body weight index with the administration of extracts. An increase in albumin, globulin, total protein content and high-density lipoproteins, white blood cells, mean corpuscular volume, and eosinophils were observed. And a decrease in low-density lipoproteins, very low-density lipoproteins, triglycerides, and red blood cells were observed. Lymphocyte and monocyte levels were also reduced. The results also showed that the ethyl alcohol and aqueous extracts have elevated the time taken to flick response in the tail immersion test, and reduced the number of jumps, paw lick responses in the hot plate method. It was concluded that the diethyl ether and ethanolic extracts were found to be safe, which falls under non-toxic chemicals (LD50>2000 smg/kg) whereas the aqueous extract was found safe up to 550 mg/kg beyond which, it has shown mortality. Ethyl alcohol and aqueous extracts were also proved to have analgesic activity.

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RESEARCH ARTICLE

Design, Development and In vivo Evaluation of Core in Cup Tablets of Budesonide

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ABSTRACT:
Budesonide is widely used drug for treatment of active inflammatory bowel disease (IBD). Core in-cup tablets were prepared to achieve a prolonged release of Budesonide and for alleviating the symptoms of inflammatory bowel disease. The objective of this study was to investigate differences in the pharmacokinetic patterns between an optimized core in cup tablet formulation and pure Budesonide suspension. In-vivo evaluation studies were performed based on the uniform and reliable results of in-vitro drug release studies. Various pharmacokinetic parameters were compared to obtain mean plasma drug concentration curve versus time. The pure drug suspension and Core-in-cup tablets formulation of Budesonide were administered to two groups of white New Zealand rabbits (n=6) through the oral route following cross over design pattern. The drug concentration in plasma samples were measured using LC-MS/MS method. Pharmacokinetic parameters were determined for each formulation. The comparison of the plasma time curves of the dosage forms showed that each dosage form caused significant differences in the drug plasma levels. The optimized core in cup tablet formulation shown some lag phase initially before releasing the drug. The mean residence time of core in cup tablet formulation was found to be more than the pure drug suspension formulation. The oral administration of Budesonide resulted in a low and quite variable AUC of 154.1±1.44 ng/ml/hr., whereas the optimized core-in-cup tablets resulted in AUC of 918.2±3.11 ng/ml/hr. The bioavailability of optimized formulation was enhanced six times compared with pure drug suspension. From the above results, it can be concluded that the prepared core in cup tablet can be considered as one of the promising formulation techniques for chronotherapeutic management of inflammatory bowel disease.

KEYWORDS: LC-MS/MS, Budesonide, Core in cup tablet, *In-vivo* studies.

INTRODUCTION:

Budesonide is a novel synthetic corticosteroid and drug of the first choice in the treatment of inflammatory bowel disease, especially in the treatment of ulcerative colitis and Crohn's disease.[1] Budesonide have half-life of 2-4 h with an oral bio availability of 10%. Inflammatory bowel diseases can be treated more effectively by local delivery of drug targeted to the colon.

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Colonic drug delivery is also useful for enhanced systemic absorption of drugs because of less hostile environment existing in the colon compared to stomach and small intestine. Budesonide undergoes approximately 85% first pass metabolism.[2] To overcome this drawback, the present study was undertaken to investigate the colon targeted drug delivery system of budesonide through core in cup tablet.[3] Due to the distal location of the colon in the gastrointestinal tract, pulsatile drug delivery should prevent drug release in the stomach and small intestine and produce a gradual onset of drug release upon entry into the colon.[4] Hence in the present study, core in cup tablet of Budesonide was designed with the intention of delivering the drug in the colon region for effective treatment of inflammatory

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Anti-microbial activity of *Ficus benghalensis* Triterpenoids

B. Bhavani Padmaleela[1], A. Baby Sushma[2], G. Renuka[3], G. Yamini[4], D. Bharath Chandu[5], K. Poorna Chandra Rao[6], S.Shobha[7], Y. Sushma[8], B. Sudheer Chowdary[9]*

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INTRODUCTION

From the ancient times the humans are based their lives on the plants. Without the plants there is no life for the humans. Plants are not only for the food source they are also used for the medication purpose to treat various ailments. Even though how much technology is developed by the human still depend up on the plants for their regular needs.[1] The development of the new discovery of drugs is about 80 % percent based on the plant origin.[2] Therefore, the identification and isolation of the various chemical constituents are very much needed even though it is a folk fore medicine.[3] The first antimicrobial agent in the world was salvarsan, a remedy for syphilis that was synthesized by Ehrlich in 1910.[4] As per the WHO recent evidences said that the why we need the anti-microbial agents is due to increased frequency of the microbial infections, increased severity of infections and increased failures of therapies.[5] In the present era of technology advancement, various operations are performed with the help of computer to increase the reliability, productivity and most importantly the ease of the work.[6] The process of virtual screening technique for docking small molecules into a known protein structure is a powerful tool for drug design and has become an integral part of the drug discovery process.[7] *Ficus bengalensis*, commonly known as the banyan tree, is a sacred plant that has been worshipped since the Vedic era. *Ficus benghalensis* had been known as India's national tree. Because of its size and solidity, the banyan tree is known as the "royal" tree in nature.[8] It is also known as the enlightenment tree, which is described in both Hinduism and Buddhism. In the famous ayurvedic scripts like charaka samhitha, sushrutha samhitha, Dhanvantari Nighantu written by charaka, sushruta.[9] this plant is used to treat stabilisation of pregnancy, diabetes, perpetual, Gynecology, wound healing, astringent to the bowls, healing of fractures & dislocation, hemorrhagic disorders, burning sensation, obesity, aphrodasiac, immunomodulator, vaginal disorders, anti-inflammatory, antistress, antiallergic, antimicrobial , antiplasmodial , mosquito larvicidal, anti-ulcer , antifungal , antilipidemic anti-atherogenic properties.[10] The ficus benghalensis is of topical, indigenous, and topical origin and is found throughout Asia, including India, the sub-Himalayan region, the deciduous forests of the Deccan and South India, Myanmar (Burma), Thailand, Southeast Asia, southern China, and Malaysia.This plant is considered invasive in the Bahamas, Australia, Singapore, Western Samoa, and the Chagos Islands.[11] Matured leaves are glossy, green, with a glossy appearance, lethergy, and glabourous.[12] Fruits are dark red in colour, globose, sessile in axillary pairs, fleshy pericarp and with achenesen trenched in them of 1.5–2.0 cm in diameter, red to dark purple when ripe, seeds are tiny.[13] Various phytochemical constituents present in the *Ficus benghalensis* are rutin, Quercetin-3-galactoside, Carpachromene , Genistein, Friedelin, 3-Friedelanol, Benghalensisteroic acid and Benghalensin etc.[14]

MATERIALS AND METHODS

Extraction Process : The *Ficus benghalensis* bark was cleaned and removed any impurities present on it. The bark was cut into small pieces then subjected to shade dried and oven at 45^0 C. The dried bark was coarsely powdered and sealed in the air tight container. The coarse powder was subjected to soxhlation procedure by using the methanol as a solvent. The methanolic extract was concentrated under reduced pressure to yield a dark brown viscous mass.[15] The preliminary phytochemical screening of the extract showed the presence of triterpenes, carbohydrates, cardiac glycosides, saponins and amino acids.[16] The extract was dissolved in a minimum amount of methanol and adsorbed on silica gel (60– 120 mm, 245 g) for the preparation of slurry. The air dried slurry was poured over the silica gel column packed in petroleum ether (60–80^0C). Elution of the same column with chloroform–methanol (97:3) triterpinoids recrystallized from acetone.[17]The presence of triterpinoids were identified by the salkowski test.

Anti Bacterial Activity : For the antibacterial activity the samples of Staphylococcus aureus and Escherichia coli was selected. Mannitol salt agar media is used to culture the Staphylococcus aureus and Bacto-tryptone agar media *Escherichia coli*. [18,19] Disc diffusion method was used for antibacterial activity. A stock solution of extract was prepared by dissolving

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Anti-microbial activity of *Ficus benghalensis* Triterpenoids

B. Bhavani Padmaleela[1], A. Baby Sushma[2], G. Renuka[3], G. Yamini[4], D. Bharath Chandu[5], K. Poorna Chandra Rao[6], S.Shobha[7], Y. Sushma[8], B. Sudheer Chowdary[9]*

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INTRODUCTION

From the ancient times the humans are based their lives on the plants. Without the plants there is no life for the humans. Plants are not only for the food source they are also used for the medication purpose to treat various ailments. Even though how much technology is developed by the human still depend up on the plants for their regular needs.[1] The development of the new discovery of drugs is about 80 % percent based on the plant origin.[2] Therefore, the identification and isolation of the various chemical constituents are very much needed even though it is a folk fore medicine.[3] The first antimicrobial agent in the world was salvarsan, a remedy for syphilis that was synthesized by Ehrlich in 1910.[4] As per the WHO recent evidences said that the why we need the anti-microbial agents is due to increased frequency of the microbial infections, increased severity of infections and increased failures of therapies.[5] In the present era of technology advancement, various operations are performed with the help of computer to increase the reliability, productivity and most importantly the ease of the work.[6] The process of virtual screening technique for docking small molecules into a known protein structure is a powerful tool for drug design and has become an integral part of the drug discovery process.[7] *Ficus bengalensis*, commonly known as the banyan tree, is a sacred plant that has been worshipped since the Vedic era. *Ficus benghalensis* had been known as India's national tree. Because of its size and solidity, the banyan tree is known as the "royal" tree in nature.[8] It is also known as the enlightenment tree, which is described in both Hinduism and Buddhism. In the famous ayurvedic scripts like charaka samhitha, sushrutha samhitha, Dhanvantari Nighantu written by charaka, sushruta.[9] this plant is used to treat stabilisation of pregnancy, diabetes, perpetual, Gynecology, wound healing, astringent to the bowls, healing of fractures & dislocation, hemorrhagic disorders, burning sensation, obesity, aphrodasiac, immunomodulator, vaginal disorders, anti-inflammatory, antistress, antiallergic, antimicrobial , antiplasmodial , mosquito larvicidal, anti-ulcer , antifungal , antilipidemic anti-atherogenic properties.[10] The ficus benghalensis is of topical, indigenous, and topical origin and is found throughout Asia, including India, the sub-Himalayan region, the deciduous forests of the Deccan and South India, Myanmar (Burma), Thailand, Southeast Asia, southern China, and Malaysia.This plant is considered invasive in the Bahamas, Australia, Singapore, Western Samoa, and the Chagos Islands.[11] Matured leaves are glossy, green, with a glossy appearance, lethergy, and glabourous.[12] Fruits are dark red in colour, globose, sessile in axillary pairs, fleshy pericarp and with achenesen trenched in them of 1.5–2.0 cm in diameter, red to dark purple when ripe, seeds are tiny.[13] Various phytochemical constituents present in the *Ficus benghalensis* are rutin, Quercetin-3-galactoside, Carpachromene , Genistein, Friedelin, 3-Friedelanol, Benghalensisteroic acid and Benghalensin etc.[14]

MATERIALS AND METHODS

Extraction Process : The *Ficus benghalensis* bark was cleaned and removed any impurities present on it. The bark was cut into small pieces then subjected to shade dried and oven at 45^0 C. The dried bark was coarsely powdered and sealed in the air tight container. The coarse powder was subjected to soxhlation procedure by using the methanol as a solvent. The methanolic extract was concentrated under reduced pressure to yield a dark brown viscous mass.[15] The preliminary phytochemical screening of the extract showed the presence of triterpenes, carbohydrates, cardiac glycosides, saponins and amino acids.[16] The extract was dissolved in a minimum amount of methanol and adsorbed on silica gel (60– 120 mm, 245 g) for the preparation of slurry. The air dried slurry was poured over the silica gel column packed in petroleum ether (60–80^0C). Elution of the same column with chloroform–methanol (97:3) triterpinoids recrystallized from acetone.[17]The presence of triterpinoids were identified by the salkowski test.

Anti Bacterial Activity : For the antibacterial activity the samples of Staphylococcus aureus and Escherichia coli was selected. Mannitol salt agar media is used to culture the Staphylococcus aureus and Bacto-tryptone agar media *Escherichia coli*. [18,19] Disc diffusion method was used for antibacterial activity. A stock solution of extract was prepared by dissolving

REVIEW ON ANTI INFLAMMATORY ACTIVITY OF HERBAL CONSTITUENTS AGAINST CYLCOOXYGENASE AND TUMOUR NECROSIS FACTOR ALPHA- A COMPUTATIONAL APPROACH

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Abstract:

This work done a review on the anti-inflammatory herbal compounds based on the insilico screening against COX1 & COX2 and TNF alpha. These are the prominent factors responsible for inflammation produced by any kind of risk factor. By inhibiting this factor is very essential for the regulation of inflammation in the chronic disorders particularly. Most of the marketed available drugs are act through the inhibition of these compounds. This attains the attention of researchers as targets in the anti-inflammatory activity. This article provides the research done on the herbal chemical constituents at the insilico level of determining the anti-inflammatory activity which some of the compounds evaluated invivo also. This will help for the researchers to identify and isolate the newer compounds for the anti-inflammatory activity.

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Research Article

PREDICTION OF LINEARITY AND NON-LINEARITY IN PHARMACEUTICAL OPTIMIZATION STUDIES WITH PYTHON

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ABSTRACT

Novel simple user-friendly python programme was developed to predict linearity and non-linearity in pharmaceutical optimization. Optimization is the process of obtaining optimum formulation. There are independent and dependent variables in optimization techniques regarding pharmaceutical formulations. The number of levels of independent factor is usually selected based on the linear/ non-linear relationship existing between the dependent and independent variable. The programme is run after entering the independent and dependent variables. The program is used to detect the best fitted model based on the observed correlation between dependent and independent factors, to predict the outcome against the input (independent variables). The program output is the regression coefficients, regression equations, predicted dependent variable and standard error of point estimate. The model offering the low error of point estimate is assumed to be the best fitted model for the given data. The model is applied successfully for both linear and non-linear data.

INTRODUCTION

Optimization refers to obtaining resulting actions of our own interest by changing the independent variables one by one [1]. Orthogonal functions satisfying a second order differential equation, rotatable design and simplex lattice designs are commonly employed to optimise the composition of pharmaceutical formulations [2]. Evolutionary operations, Lagrangian, search and canonical analysis are commonly used for optimisation studies. The preferred optimization techniques are sequential optimization techniques, simultaneous optimization techniques and combination of both. A sequential model- based optimization (SMBO) study involves the performance of experiments repeatedly and the observations are fitted in to different models to identify the better choices about the configurations to be investigated. It allows interpolation of performance observed between parameter settings and facilitate for extrapolation to other regions of design space. Simultaneous methods involve (a) framing the experimental design (b) performing the experiments as per experimental design (c) insertion of the results in appropriate mathematical model (d) observing the maximum or minimum response through the best fitted model identified from a set of equations. To ascertain the system behaviour, a predictive model is required. Optimization algorithms are used in (a) experimental design, model development, parameter estimation, and statistical analysis; (b) process design, development, analysis, and retrofit; (c) model predictive control of risk factors and real-time optimization; and (d) identification, implementation and the coordination of a series of process operations related to the manufacturing and distribution of drug product. In the operation of pharmaceutical processes, there is huge interest in improving the scheduling and

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International Journal of Research in AYUSH and Pharmaceutical Sciences

Review Article

ARTIFICIAL INTELLIGENCE: APPLICATIONS IN HEALTHCARE INDUSTRY

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Artificial Intelligence, Technologies, Healthcare, Treatment.

ABSTRACT

Artificial intelligence (AI) is becoming a core part of the digital health systems to shape and support modern medicine. The situations such as pandemic COVID-19 pressing health systems to consider technology, such as artificial intelligence powered clinical decision support for faster and more informed decisions. AI utilises machine learning models to search medical data and uncover insights to improve health outcomes and patient experiences. AI is mainly used for clinical decision support and imaging analysis. Clinical decision support tools help the physician to take decisions about treatments, medications, physical and psychological health and other patient needs by providing quick access to information or research that's relevant to their patient. In medical imaging, AI tools are used to analyze CT scans, X-rays, MRIs and other images/ findings that a human radiologist might miss. Many healthcare organizations around the world started field-testing new AI-supported technologies to overcome the challenges like COVID-19 pandemic created. Various healthcare applications with AI are presented in this article.

INTRODUCTION

The pandemic crisis such as COVID-19 stressed the need to develop effective drugs and drug delivery systems within short period of time. The traditional healthcare system approach involves lot of time, huge investment with limited success rate. Artificial intelligence is defined as a branch of computer science that enables computer systems to perform various tasks with intelligence similar to humans[1]. AI is mainly dealing with the design and application of algorithms for analyzing, learning and interpreting data [2]. The process of AI involves obtaining information, developing rules for using information, approximate or accurate conclusions, and self-correction [3].

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With the implementation of AI, the computers or machines exhibit the characteristics of humans such as reasoning, generalizing and learning from past experience, etc. The use of AI in diverse sectors of the pharmaceutical industry includes drug discovery and development, drug repurposing, improving pharmaceutical productivity and clinical trials [4]. AI allows the rapid discovery and development of drugs. Different AI tools are being applied to support the drug development process [5]. The response towards the administered drug is different from individual to individual and hence therapeutic drug monitoring is required. The monitoring of patient response and the dispensing of personalised medicine is possible with the help of AI. AI has inspired computer-aided drug discovery [6]. The pros of AI are improved diagnosis, better clinical decisions, streamlining of process and opportunity to serve rural community. The cons include complications of learning, difficulties to adapt, need of human assistance and problems involved in selection of correct AI platform. Several programmes of AI are reported along with their applications. AI appears to be transforming the future of healthcare field but still it has to make an impactful

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Review Article

Role of Artificial Neural Networks in Pharmaceutical Sciences

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ABSTRACT

Artificial Neural Networks (ANN) are becoming the tool of choice for the pharmaceutical industry due to their ability to mimic the brain's way of functioning. Computational and statistical methods have recently sparked the pharmaceutical industries interest in identifying possible pharmaceutical products that fulfil all technical requirements. Researchers are developing ANN from various scientific areas to overcome prediction, optimization, recognition, and control problems. Conventional techniques can only be used in specific, well-constrained situations. ANN analyses incomplete or unstructured information and converts it into more sensible analysable data by detecting the underlying patterns and similarities. This technology also creates new ideas by rearranging existing knowledge. For example, ANN can construct a promising modelling technique when data sets exhibit nonlinear correlations, which is prominent in pharmaceutical operational processes. In the pharmaceutical industry, this thinking network can be used in disease diagnosis, genomics and proteomics, drug design, to determine physicochemical properties of a drug, drug testing, optimization, pharmacokinetics, *in vitro* and *in vivo* correlations, and also to study drug interactions. In this short review article, various applications of ANN in pharmaceutical research are presented.

Key words: Artificial Neural Networks, Pharmaceutical Sciences, Drug Design, Drug Discovery, Drug Delivery, Formulation Development.

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INTRODUCTION

The brain is an essential organ in the human body that can control the whole body. It can quickly analyze disordered and unclear information within a short time. It is interconnected with the number of cells, particularly neurons. There are about 1011 neurons in the human brain and about 10000 connections with one another via 1014 synapses—the human brain functions with many yet undiscovered mathematical models involving biological networks. Human brain functionality is the same as one mathematical model: Artificial Neural Networks (ANN) are the type of artificial intelligence system. ANN is the same as the structure of biological neural networks in the human brain. Like, Neurons in the brain are equivalent to a processing element (PE) or artificial node in ANN.[1]

Before knowing more about ANN, it is essential to recognise the worth of artificial intelligence (AI). In the recent decade, researchers have been using AI to drive the emergence of computational precision medicine. AI allows the identification of complex biomarker signatures, i.e. disease-specific altered networks of genes and proteins shared throughout tumour types and across multi-omics layers, which overcomes the outdated 'one gene, one medication, one illness' paradigm.[2] Nevertheless, AI is also being used extensively in precision medicine to construct and optimize diagnosis routes, treatment techniques, and prognoses. This has resulted in a respectable achievement for identifying risk factors for complicated disorders such as cancer by examining gene diversity in an environment. It is also being used to create biomarkers that may be used to stratify patients depending on their sickness risk, prognosis, and/or responsiveness to therapy. The advanced computing capability of using AI for biological data processing is also being used to accelerate the drug development process of precision medicine,[3] AI relies on a convergence of technologies with additional. Synergies with life science technology to harness the value of extensive multi-modal data in the form of predictive models supporting decision-making.

Additionally, AI facilitates the design, selection and repurposing of drugs interacting with targets. AI and machine learning (ML) improve medication design and development by understanding disease heterogeneity, discovering dysregulated molecular pathways and therapeutic targets, creating and optimizing drug candidates, and assessing clinical effectiveness *in silico*. By offering a previously unrivalled degree of understanding of both patient specificities and medication candidate features.[4]

Among the different networks in AI, ANN has a prime role in pharmaceutical drug development applications. ANN is made up of a bunch of interconnected nodes. All of these nodes are useful in

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Research article

Open Access

The RP-UPLC method for simultaneous quantification of ivabradine and metoprolol

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ABSTRACT

In order to develop a newer or improved analytical method, the analyst has to set some goals. The method should be precise to the drug under study. It is necessary to determine the analyte at trace levels accurately. The UPLC techniques have now become extremely reliable and indispensable. Ivabradine, lowers the pacemaker firing rate, consequently lowering heart rate and reducing myocardial oxygen demand. Metoprolol is a beta-1-adrenergic receptor inhibitor specific to cardiac cells with negligible effect on beta-2 receptors. Run time was selected to be 3 min because the analysis gave peaks around 1.197 and 1.628 ±0.02 min of ivabradine and metoprolol. The analytical method was found to be linear over the range 1.25-7.5 µg/mL for ivabradine and 6.25-37.5 µg/mL for metoprolol of the target concentration.

Keywords:RP-UPLC, Ivabradine, Metoprolol, Precision, Accuracy

INTRODUCTION

Ultra Performance Liquid Chromatography spectroscopic detection is a powerful hyphenated technique for the analysis of drugs. Its sensitivity, accuracy and short analysis time make it ideal for determination of many drugs in dosage forms. Further, with the development of more sophisticated instrumentation, efficient column materials, sensitive detectors and moderate pricing, the UPLC techniques have now become extremely reliable and indispensable. In view of these advantages, the author has chosen to develop UPLC methods in this investigation for determination of some of selected drugs [1].

Ivabradine is a novel heart-rate lowering medicine for the symptomatic management of stable angina pectoris and chronic heart failure. Ivabradine (Corlanor®) was approved by the FDA in April 2015 for the treatment of chronic heart failure in patients who either is not on beta-blockers due to contraindications or is already receiving maximum beta-blocker dose. Recently, a new indication was added to treat symptomatic heart failure from dilated cardiomyopathy in patients of six months or more in age [2].

Ivabradine binds by entering and attaching to a site on the channel pore from the intracellular side and disrupts IF ion current flow, which prolongs diastolic depolarization and lowering the heart rate. The "IF" currents are located in the sino-atrial

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Research article

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The RP-UPLC method for simultaneous quantification of Sitagliptin and Ertugliflozin

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ABSTRACT

In order to develop a newer or improved analytical method, the analyst has to set some goals. The method should be precise to the drug under study. It is necessary to determine the analyte at trace levels accurately.The UPLC techniques have now become extremely reliable and indispensable.Sitagliptin works to competitively inhibit the enzymedipeptidyl peptidase 4 (DPP-4).Ertugliflozin is a small inhibitor of the SGLT2 and its activity increases glucose excretion, reducing hyperglycemia without the requirement of excessive insulin secretion.The percent recovery of Sitagliptin and Ertugliflozinwas found to be in between 98.0 to 102.0%. The analytical method was found to be linear over the range 25-150 µg/mL of Sitagliptin and 3.75-22.5 µg/mL Ertugliflozinof the target concentration.

Keywords: RP-UPLC, Sitagliptin.Ertugliflozin, Precision, Accuracy

INTRODUCTION

Ultra Performance Liquid Chromatography spectroscopic detection is a powerful hyphenated technique for the analysis of drugs. Its sensitivity, accuracy and short analysis time make it ideal for determination of many drugs in dosage forms. Further, with the development of more sophisticated instrumentation, efficient column materials, sensitive detectors and moderate pricing, the UPLC techniques have now become extremely reliable and indispensable. In view of these advantages, the author has chosen to develop UPLC methods in this investigation for determination of some of selected drugs [1].

Sitagliptin is an oral dipeptidyl peptidase-4 (DPP-4) inhibitor used in conjunction with diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. The effect of this medication leads to glucose dependent increases in insulin and decreases in glucagon to improve control of blood sugar. Sitagliptin was granted FDA approval on October 16, 2006.Sitagliptin works to competitively inhibit the enzyme dipeptidyl peptidase 4 (DPP-4). This enzyme breaks down the incretins GLP-1 and GIP, gastrointestinal hormones released in response to a meal. By preventing breakdown of GLP-1 and GIP, they are able to increase the secretion of insulin and suppress the release of glucagon by the alpha cells of the pancreas. This drives blood glucose levels towards normal [2].

Ertugliflozin is a new oral hypoglycemic (anti-diabetic drug) of the new dipeptidyl peptidase-4 (DPP-4) inhibitor class of drugs. This enzyme-inhibiting drug is to be used either alone or in combination with metformin or a thiazolidinedione for control of type 2 diabetes mellitus. The drug works to competitively inhibit a protein/enzyme,

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THE RP-UPLC METHOD FOR SIMULTANEOUS QUANTIFICATION OF LESINURAD AND ALLOPURINOL

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Abstract:
In order to develop a newer or improved analytical method, the analyst has to set some goals. The method should be precise to the drug under study. It is necessary to determine the analyte at trace levels accurately. The UPLC techniques have now become extremely reliable and indispensable. Lesinurad is an oral uric acid transporter 1 (URAT1) inhibitor indicated for the treatment of hyperuricemia associated with gout. Allopurinol is a xanthine oxidase enzyme inhibitor that is considered to be one of the most effective drugs used to decrease urate levels and is frequently used in the treatment of chronic gout. Run time was selected to be 2 min because the analysis gave peaks around 0.401 and 0.718 ±0.02 min of Lesinurad and Allopurionol. The percent recovery was found to be in between 98.0 to 102.0%. The analytical method was found to be linear over the range 50-300 µg/mL of Lesinurad and Allopurionol of the target concentration.

Keywords: *RP-UPLC, Lesinurad, Allopurionol, Precision, Accuracy*

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Design, Development and *In Vivo* Evaluation of Core in Cup Tablets of Azathioprine

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Abstract

Azathioprine is the drug of choice for treatment of active inflammatory bowel disease (IBD). Core-in-cup tablets have been developed based on combination of hydrophobic polymers and a gelling hydrophilic polymer, microcrystalline cellulose, to achieve a prolonged release formulation of Azathioprine tablets using Cellulose acetate phthalate as coating polymer to produce a delivery system in which the release of drug is modulated. The objective of this study was to investigate differences in the pharmacokinetic patterns between an optimized core in cup Tablet formulation and pure drug of Azathioprine. The formulations were administered to 2 groups of white New Zealand rabbits (n=6) following cross over design pattern and the plasma levels were measured using LC-MS/MS method. Pharmacokinetic parameters were determined for each formulation. The comparison of the plasma time curves of the dosage forms showed that each dosage form caused significant differences in the drug plasma levels. The optimized core in cup Tablet formulation showed some lag phase initially before releasing the drug. The mean residence time of core in cup Tablet formulation (21.59 ±0.036hrs) was found to be more than pure drug of Azathioprine (2.66 ±0.02hrs). Core in cup Tablet formulation alleviating the conditions of experimental model of colitis, if the time of administration and pulse time are adjusted to the circadian pattern. From the above results, it can be concluded that the prepared core in cup tablet can be considered as one of the promising formulation techniques for chronotherapeutic management of inflammatory bowel disease.

Keywords: LC-MS/MS, Azathioprine, core in cup tablet, In-vivo studies

Introduction

Azathioprine is widely used as an immunosuppressant and drug of choice in the treatment of inflammatory bowel disease, especially in the treatment of ulcerative colitis and Crohn's disease.[1]The bioavailability of Azathioprine upon oral administration is limited to an extent of 41-50%. Inflammatory bowel diseases can be treated more effectively by local delivery of drug targeted to the colon. Colonic drug delivery is also useful for enhanced systemic absorption of drugs because of less hostile environment existing in the colon compared to stomach and small intestine. Azathioprine undergoes approximately 50% first pass metabolism(2) To overcome this drawback, the present study was undertaken to investigate the colon targeted drug delivery system of Azathioprine through core in cup tablet(3) Due to the distal location of the colon in the gastrointestinal tract, pulsatile drug delivery should prevent drug release in the stomach and small intestine and produce a gradual onset of drug release upon entry into the colon(4) Hence in the present study, core in cup tablet of Azathioprine was designed with the intention of delivering the drug in the colon region for effective treatment of inflammatory bowel disease. Optimized tablet formulations demonstrated good potential to deliver the drug to the colon by successfully exhibiting a lag time of 5 h during in vitro drug release study(5) An in vivo evaluation study conducted to ascertain pharmacokinetic parameters in rabbits revealed that the onset of drug absorption from the Core-in-cup tablets was significantly delayed compared to that from the Marketed Azathioprine SR formulation.

Materials and Methods

The *in vivo* study of the optimized formulations were performed as per the guidelines approved by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Ministry of social Justice and Empowerment, Government of India. Prior approval by Institutional animals ethics committee was obtained for conduction of experiments (Ref: IPT / IAEC/1053/PO/Re/S/07/CPCSEA, Dated 27-12-2020). Marketed Azathioprine pure drug and optimized core in cup tablet prepared in the laboratory conditions and chosen on the basis of lag time achieved, in-vitro release studies and stability conditions were chosen as dosage forms for administration.

Preparation of Azathioprine core tablets: After preliminary experiments, the optimum formulation of core tablets was obtained. The core tablets were prepared by wet granulation method. The required quantities of Azathioprine, PVPK-30 (as a binder), Moringa oliferagum (as a polymers) and lactose (as a diluent) were weighed and mixed uniformly and prepared

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Research Article

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Special Report

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Future Drug Discovery

Role of pharmaceutical sciences in future drug discovery

Srinivasa Reddy Bonam*[1], Mahendran Sekar[2], Girija S Guntuku[3], Sridhar G Nerella[4], Krishna M Pawar A[5], Siva R Challa[6,7], Gopala KMT Eswara[8] & Sivamma Mettu[9]

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The recent emergence of COVID-19 influenced the layman's knowledge of drugs. Although several drugs have been discovered serendipitously, research has moved to the next-generation era of drug discovery. The use of drugs is inevitable and they have become lifesavers in the present era. Although research from different scientific backgrounds has supported the translational research of drug discovery, the prime role of pharmacy has to be remembered. Here we have summarized the role of some important subjects in pharmacy education, which have paved different ways in drug discovery and development.

Lay abstract: Despite existing therapies for various ailments, emerging diseases or disorders need more selective treatments. Traditionally 'pharmacy' is thought of as a medical store, but time has changed pharmacy into a multidisciplinary subject with core research domains, including pharmacognosy, pharmaceutical biotechnology, pharmaceutical analysis, pharmaceutical chemistry, pharmacology and pharmaceutics. The main objective of these subjects is to provide strong support for both basic and translational research. Here we summarize the role of each of these domains of pharmaceutical science in the design and development of pharmaceuticals.

Tweetable abstract: How pharmacy's core research domains provide strong support for both basic and translational drug discovery research.

First draft submitted: 28 June 2021; Accepted for publication: 20 September 2021; Published online: 18 October 2021

Keywords: bioinformatics • drug discovery and development • pharmaceutical analysis • pharmaceutical biotechnology • pharmaceutical chemistry • pharmaceutical engineering • pharmaceutical research • pharmaceutics • pharmacognosy • pharmacology • pharmacy • statistics

The use of drugs in daily life has increased in recent years due to the emergence of new diseases and chronic disorders [1]. In addition, due to our present lifestyle (i.e., exposure to harmful pollutants and micro-organisms), novel and safer pharmacological treatments are heavily needed. Therefore the runaway progress of drug discovery and development is inevitable, and it is reasonable to expect the emergence in a short time of outcrops of large

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PHARMACOGNOSTICAL EVALUATION OF AERIAL PARTS OF *DECALEPIS HAMILTONII*

J. Venkata Suresh[*1] and T. E. Gopala Krishna Murthy[2]

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[2]Department of Pharmaceutics, Bapatla College of Pharmacy, Bapatla, Andhra Pradesh, India.

ABSTRACT

In this study, the pharmacognostical parameters for the aerial portions (leaves and stem) of the plant *Decalepis hamiltonii* were evaluated (Asclepiadaceae). The plant has historically been used to treat diabetes, blood problems, gout, jaundice, thirst, haemorrhage and urticaria. To fully harness this folk herb's therapeutic potential, an effort has been made to correctly identify it. According to this perspective, the morphoanatomy of the leaves and stem, along with quantitative microscopy, microscopic linear measurements, WHO-recommended physico-chemical determinations and genuine phytochemical procedures, are the key diagnostic characters that have been carried out to help the full pharmacognostical evaluation of the plant. The parameters discussed in this research could be suggested as the benchmarks for determining the legitimacy of *Decalepis hamiltonii*. This research aids in separating this medication from its other species.

KEYWORDS

Decalepis hamiltonii (Asclepiadaceae), Pharmacognostical, Leaf and Stem.

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INTRODUCTION

Early man investigated his local natural environment, experimented with a wide range of plants, animals, and minerals and created a wide range of medicinal substances. Man has created a variety of methods and tools for health care as a result of his quest for eternal health and longevity and his need to find relief from suffering[1]. A increasing corpus of medical literature supports the clinical usefulness of herbal remedies, and plants are valued in pharmaceutical research as a

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PHARMACOGNOSTICAL EVALUATION OF AERIAL PARTS OF *HOLOSTEMMAADA-KODIEN*

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ABSTRACT

With this study, the various pharmacognostic and phytochemical standards for the aerial portions (leaves and stem) of the plant *Holostemmaada-kodien* were to be established (Asclepiadaceae). The plant *Holostemmaada-kodien* is traditionally used as an alterative and astringent to the bowels; it also has medicinal properties f r ulcers, biliousness, "kapha," blood disorders, worms, itching, leucoderma, and vesicular calculi (Ayurveda). Diabetes, stomachic, gonorrhoea, cough, tonic. To fully harness this folk herb's therapeutic potential, an effort has been made to correctly identify it. According to this perspective, the morphoanatomy of the leaves and stem, along with quantitative microscopy, microscopic linear measurements, WHO-recommended physico-chemical determinations, and genuine phytochemical procedures, are the key diagnostic characters that have been carried out to help the full pharmacognostical evaluation of the plant. The parameters discussed in this research could be suggested as the benchmarks for determining the veracity of *Holostemmaada-kodien*. This research aids in separating this medication from its other species.

KEYWORDS

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INTRODUCTON

The medicinal plants play a significant part and form the foundation of both the herbal medicines industry as well as local populations' traditional medicine. The majority of the basic medications used in practically all traditional treatments come from wild plants. When obtained from markets, the raw materials are frequently contaminated[1]. The issues of adulteration and substitution at the raw material level are generally a problem for local

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Design, Development and Characterization of Simvastatin Liposomal Loaded Gels for Transdermal Drug Delivery

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Date of Submission: 10-06-2021 Date of Acceptance: 25-06-2021

ABSTRACT: The objective of the present study was to develop the controlled release transdermal drug delivery systems of Simvastatin using Liposomes incorporated in a gels, which will control the release of drug, increasing the bioavailability of the drug and thus decreasing the dosing frequency of the drug. It was investigated by encapsulating the drug in various Liposomal formulations composed of various ratios of Soya Lecithin: Span 80 or Tween 80 or sodium deoxycholate prepared by rotary evaporation sonication method.Lipid:surfactant ratio of 90:10 is more effective when compared to other ratios .

The Liposomes were incorporated into reservoir gels and evaluated for the Drug content, P^H , viscosityextrudability, and spreadability. The evaluation parameter values of gels shown good characteristic features of gel. Prepared Liposomes gels were subjected to In-vitro diffusion studies Experimental results of the present study showed that deformable lipid vesicles improve the transdermal delivery, prolong the release, and improve the site specificity of the lipophilic model drug, simvastatin. The drug diffusion studies showed that a Liposomal vesicles followed zero order kinetics and mechanism of release followed peppas model.

KEY-WORDS: Thin film hydration method, Anti-hyperlipidemic, Controlled release, Lipid, Surfactant.

I. INTRODUCTION:

Liposomes have recently been introduced, which are capable of transdermal delivery of low as well as high molecular weight drugs[1]. Liposomes are enclosed vesicles containing a lipid bi layer composed of unimers that usually have a hydrophilic head and a hydrophobic tail and are oriented so that the hydrophobic head groups are inside the bi layer. Liposomes are highly biocompatible with low toxicity that helps in conniving drug delivery system with improvedbioavailabilty[2].

Hydrogels are 3-dimensional networks consisting of hydrophilic polymers that swell in aqueous solution retaining large amount of water without dissolving. Hydrogels have biodegradable properties, high permeation of active materials with high degree of swelling and no associated toxicity or irritation makes them as ideal polymers for delivery of drugs through transdermal route as delivery vehicles[3] .

Simvastatinis a cholesterol-lowering agent and is structurally similar to the HMG, a substituent of the endogenous substrate of HMG-CoA reductase. Simvastatinlowers hepatic cholesterol synthesis by competitively inhibiting HMG-CoA reductase, the enzyme that catalyzes the rate-limiting step in the cholesterol biosynthesis pathway via the mevalonic acid pathway[4].Due to its short biological halflife (5.3 hours) and low bioavailability(5%), it requires frequent administration[5]. The maintenance of a constant plasma drug concentration of a anti lipidemic drug is important in ensuring the desired therapeutic response and to improve patient compliance, hence the objective of the study was made to develop controlled release transdermal drug delivery system of Simvastatin using Liposomes incorporated in a carbopol gel, which will control the release of drug, increasing the bioavailability of the drug and thus decreasing the dosing frequency of the drug.

II. MATERIALS AND METHODS:

Simvastatin was received as gift sample from Dr.Reddy's Laboratories, Hyderabad. Soya lecithin, sodium deoxycholate, triton X-100 was

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Development and validation of RP HPLC method for the estimation of Sofosbuvir and related impurity in bulk and pharmaceutical dosage form

Shiny Ganji[1*], Satyavati Dhulipala[2] and Appala Raju Nemala[3]

Abstract

Background: The present work is aimed at development and validation of RP HPLC method which is simple, specific, precise, and accurate for estimation of Sofosbuvir and its process-related impurity in bulk and pharmaceutical dosage forms. Extensive literature survey revealed no method for estimation of the above said. The chromatographic separation was achieved on Agilent Eclipse XDB-C18, 4.6 × 250 mm, 5 µm with mobile phase composed of 0.1% trifluoroacetic acid in 1000 ml of water:acetonitrile (50:50) using an isocratic mode of elution. Detection was made using UV detector at 260.0 nm and LC solution software for analysis of data. The developed method was validated according to ICH guidelines.

Results: The linearity of calibration curve for Sofosbuvir in concentration range of 160-480 µg/ml was good. The curve was linear for its process related impurity (Phosphoryl) in concentration range of 10-30 µg/ml. There exists a good correlation between peak area and analyte concentration. Retention time for Sofosbuvir was found to be 3.674 min and its impurity was 5.704 min. Relative standard deviation values for Sofosbuvir is 1.741 and its process related impurity is 0.043. LOD for Sofosbuvir and its impurity was found to be 0.01% (0.04 µg) and 0.03% (0.12 µg) respectively. LOQ for Sofosbuvir and its impurity was found to be 0.50% (0.125 µg) and 1.50% (0.375 µg) respectively.

Conclusion: All the results reveal that the proposed method was found to be highly sensitive, simple, precise, accurate, robust, and fast. Large number of samples can be analyzed in shorter time due to shorter retention times, so it can be successfully applied for routine analysis of Sofosbuvir and related phosphoryl impurity in bulk and pharmaceutical dosage forms.

Keywords: Sofosbuvir, Phosphoryl impurity, Method validation, RP HPLC, Sovaldi

Background

Many drugs are available as the marketed formulations for the treatment of different diseases. So, there is need for control of concentrations of these entities in dosage forms and also in body fluids. Quality assurance and quality control of these marketed formulations are essential for ensuring safety in population. During the course of assay and development of drugs in formulations, there may be interferences caused by a number of sources such as degradation products of the drugs when they are stored for a long time, the presence of other drugs in combination products and the various additives incorporated in formulations have to be kept in view.

HPLC is the most widely used analytical technique. The method is non-destructive and may be applied to thermally labile compounds (unlike GC), so it was most widely used for the analysis of most of the chemicals.

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Article

Article

Multiresponse Optimization of HPLC Method: Simultaneous Estimation of Protease Inhibitors and NNRTI in Human Plasma

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Abstract

Multiresponse optimization approach to develop a simple isocratic, highly sensitive and accurate HPLC method for the simultaneous determination of Efavirenz, Atazanavir, Lopinavir and Ritonavir in human blood plasma along with carvedilol as an internal standard. Optimized the factors (ACN, buffer concentration and flow rate) effecting and interacting with the responses (k_1, $Rs_{2,1}$, $Rs_{3,2}$ and tR_5) applying Central Composite Design a chemometric tool. All the mathematical models as well as response surfaces were defined and derived for the separation using this strategy. Chromatography was performed on Thermo Hypersil C_{18} column using mobile phase comprising of ACN: 10 mM KH_2PO_4 (51.2:48.8) with 1 mL min^{-1} flow rate and detection wavelength was fixed at 210 nm. The analysis time was within 9 min. The method developed was validated by following "Bioanalytical method validation" [USFDA-CDER, 2001]. The developed method can be applied for bioavailability and pharmacokinetic studies.

Introduction

The HIV build ups and archives resistance easily which commands the standard therapy for HIV/AIDS, HAART (Highly active antiretroviral therapy), which comprises of three or more drugs from more than one class. Atazanavir (ATV), Ritonavir (RTV) and Lopinavir (LPV) are protease inhibitors; Efavirenz (EFV) is a human immunodeficiency virus type-I (HIV-I) specific non-nucleoside reverse transcriptase inhibitor (NNRTI). PIs and NNRTIs combinations are presently recommended therapy for HIV Infection (1). Therapy including a protease inhibitor along with nucleoside reverse transcriptase inhibitors proved slow progression of HIV disease (2) and enhanced patients endurance compared with therapy including NRTIs alone. Since the protease inhibitors as HIV protease inhibitors also inhibit CYP3A4, in humans (3–6) and thereby suppress the oxidative metabolism of drugs administered thereby increases the $t_{1/2}$. The current study is to develop a simple and highly sensitive HPLC method to determine ATV, RTV, LPV and EFV simultaneously in human plasma, which assists in understanding the drug–drug interactions potential.

ATV is chemically described as, 3,12-bis (1,1-dimethylethyl)-8-hydroxy-4,11-dioxo-9-(phenylmethyl)-6-((4-(2-pyridinyl)phenyl)-methyl)-, dimethyl ester (7), RTV is chemically described as, 1,3-thiazol-5-ylmethylN-[(2S,3S,5S)-3-hydroxy-5-[(2S)-3-methyl-2-[methyl({[2-(propan-2-yl)-1,3-thiazol-4-yl]methyl})carbamoyl]amino-}butanamido]-1,6-diphenylhexan-2-yl] carbamate (8). LPV is chemically described as (2S) -N-[(2S, 4S, 5S) -5-[2- (2, 6-dimethylphenoxy) acetamido]-4-hydroxy-1,6-diphenylhexan-2-yl]-3-methyl-2-(2-oxo-1,3-diazinan-1-yl) butanamide1 (9). EFV is chemically described as (S)-6-chloro-4-(cyclopropylethynyl)-1,4-dihydro-4-(trifluoromethyl-)-2H-3,1-benzoxazin-2-one (10), and their chemical structures are given in Figure 1.

Though methods were reported for the simultaneous determination of selected drugs along with the other antiretroviral drugs both in human plasma (11–12) and pharmaceutical formulations (13–16), these methods experience either longer run time (17–18) or

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Though methods were reported for the simultaneous determination of selected drugs along with the other antiretroviral drugs both in human plasma (11–12) and pharmaceutical formulations (13–16), these methods experience either longer run time (17–18) or

Original Article

Effects of *Aegle marmelos* (L.) Methanolic Leaf Extracts on Biochemical Parameters in Diabetic Rats

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Abstract

Background: *Aegle marmelos* (L.) Correa is a widely found plant in India as well as in South Asia. For more than several centuries, it is being widely used for its medicinal properties. **Objective:** The objective of this study was to evaluate the biochemical changes in alloxan-induced diabetic rats treated with methanolic leaf extracts of *A. marmelos*. **Materials and Methods:** Six treatment groups (namely control, diseased, standard (glimepiride), low dose (100 mg/kg), medium dose (250 mg/kg), and high dose (500 mg/kg) of methanolic leaf extracts were used in the study. The biochemical effects were evaluated by the determination of albumin-to-globulin ratio (A/G ratio), albumin, amylase, bilirubin, blood urea, blood urea nitrogen, calcium, direct bilirubin, globulin, glucose-6-phosphate, glycated hemoglobin (HbA1c), homocysteine, indirect bilirubin, inorganic phosphate, lipase, mean blood glucose, serum uric acid, and vitamin D3. **Results:** No significant changes were observed in A/G ratio among the treatment groups when compared with the diseased and control treatment groups. Low- and medium-dose-treated animals showed a significant change in albumin, bilirubin, calcium, direct bilirubin, indirect bilirubin, globulin, glucose-6-phosphate, homocysteine, inorganic phosphate, lipase, and vitamin D3 levels when compared with standard treatment group as well as diseased group. Low-dose treatment group animals showed a significant increase in amylase and mean blood glucose levels than the diseased treatment groups, whereas low-dose treatment group animals showed a significant decrease in HbA1c levels than the diseased treatment groups. **Conclusion:** Through the biochemical changes, it is evident that the low and medium dose of methanolic leaf extract of *A. marmelos* can be used in the treatment of diabetes and its complications.

Keywords: *Aegle marmelos, alloxan, bael, diabetes, Rutaceae*

Introduction

Natural products have a very special place in drug research and development. Plants as a source of therapeutically useful drugs have been proved to the evidence of high economic importance. Search for new drugs from various plant sources occurs throughout the globe. In India though there are certain limitations or challenges in the resources, standardization of medicinal plants has gained significance in recent times.[1]

Aegle marmelos (L.) Correa is a widely found medicinal plant in India and South Asia. It is being commonly used for its therapeutic properties.[2] Analgesic, antioxidant, antibacterial, antifungal, anticancer, antidiarrheal, immunomodulant, antihyperlipidemic, antiulcer, diuretic, antifilarial, and hepatoprotective activities have been reported in various plant extracts of the plant.[3-28] Most of the phytocompounds are found to be accumulated in the leaves of the plants. Therefore, the present research work aimed at the evaluation of biochemical changes in diabetic rats treated with methanolic leaf extracts from *A. marmelos.*

Materials and Methods

Collection of plant material

The leaves of *A. marmelos* (L.) were collected from Dolas Nagar, Tadepalli Mandal, Guntur District, Andhra Pradesh, India. Authentication was performed by Dr. P. Satya Narayana Raju, Plant Taxonomist, Department of Botany and Microbiology, Acharya Nagarjuna University, Guntur, Andhra Pradesh, India. The reference specimen is preserved in the Department of Botany, Acharya Nagarjuna University, Nagarjuna Nagar, Guntur.

Preparation of plant extracts

The collected leaves were washed thoroughly with water and shade dried. Methanolic leaf

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Design and development of ondansetron hydrochloride pH independent control released matrix tablets

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Abstract: The oral control drug delivery is the most acceptable delivery system for patient acceptance, industrial application and economical but still it has several challenges to design a dosage form. The gastro intestinal pHis one of the major limitations for constant drug release due to different pH variations different regions (stomach *vs* small intestine) throughout the GIT. The aim of the present research work was to develop a pH independent oral control release drug delivery of pH dependent Ondansetron HCl for the treatment of CINV or PONV. The major limitation of the drug was found burst release in SGF pH 1.2 and highly precipitation in intestinal pH (pH 6.8 phosphate buffer). The formulator is challenging to develop constant controlled drug release in entire gastro intestinal tract. The techniques involve the use of pH modulating agents and acidifying agents to achieve pH independent controlled drug release. It was found that incorporation of anionic polymer (Eudragit L100-55) with control release nonionic HPMC matrix shows pH independent drug release in both SGF pH 1.2 and pH 6.8 phosphate buffer. In conclusion it was understood that the release profile of HPMC sellable matrices of Ondansetron HCl with manipulating the micro environmental pH, at variable pH conditions provided a efficient and predictable results.

Keywords: Ondansetron hydrochloric acid; pH independent; pH modulating agent; acidifying agent; HPMC swellable matrices.

INTRODUCTION

During the last decades many oral controlled release drug delivery systems were developed by using different techniques like matrix, diffusion, dissolution and diffusion, gastro-retentive drug delivery systems etc (Manthena *et al*, 2005). The main object of control drug delivery system is to achieve constant drug release from dosage form and to maintain constant plasma concentration for the treatment of chronic diseases. But the constant drug release from dosage form is not that much easy because of the control release system is influencing by the physicochemical properties of the drug, pH, GI transmit time and food. Out of all these pH and transmit time are majorly influencing the drug release. Many drugs are weakly basic and weakly acidic in nature out of some of the drugs are shows pH dependent solubility. Weakly basic drug is highly soluble in acidic environment of the stomach in low pH (pH.1.2) when the pH was increased in intestinal pH the solubility decreased or sometimes precipitated. This type of drugs to design constant release in GIT is a challenging to the formulators.

Ondansetron hydrochloride is a serotonin sub type-3(5-hydroxytryptamine-3) receptor antagonist (Venkatesh *et al*, 2006). It is a widely used drug for the treatment of several therapeutic purposes like antiemetic especially it is used in the prevention of post operative nausea and vomiting and chemotherapy or radiation induced nausea and vomiting. It is a weakly basic drug belongs to BCS class-II. The solubility exhibits high in stomach at 37^{0}C (23.3 g/L) at low pH (pH 1.2) and at higher pH (6.8 pH phosphate buffer) it exhibits poor solubility (0.036 g/L). For this reason, the design of control drug delivery system is very difficult because the solubility is completely pH-dependent. So this indicates incomplete results, irregular drug absorption and fluctuations in plasma concentrations. The recommended oral dose regimen of Ondansetron hydrochloride is 8 mg, three times a day .the elimination half life ($t_{1/2}$) is relatively short; around 3-5 h . Therefore, there is a need to develop controlled release drug delivery systems to extend pharmacological action.

The availability of existing literature indicates that some of the techniques were developed previously for pH-independent drug release (Smith *et al.*, 2009). Out of that, one is gastro retentive drug delivery system in which the drug will float constantly for long period of time which is a question mark and also in-vitro/in-vivo correlation is very poor (Daisychella *et al*, 2012). And another technique was developed pH modulating agents; this technique was somewhat better but the formulator was observed some manufacturing defects, to prolonged drug release is very difficult (Pygall *et al*, 2009). The present investigation is aimed to develop a pH-independent

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ORIGINAL ARTICLE

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Comparative in vivo evaluation of marketed sustained release and optimized pulsatile formulation of propranolol hydrochloride

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LC-MS/MS, Pharmacokinetic & Pharmacodynamic parameters, Propranolol hydrochloride, Pulsatile

ABSTRACT

Chrono pharmaceutical drug delivery system is devoted to the availability of active on a pace that idyllically matches biological requisite of disease therapy. It embodies time controlled and site-specific drug delivery systems, subsequently optimizing therapeutic action and lessening side-effects. In the present study, the optimized pulsatile formulation of Propranolol Hydrochloride ought to deliver a drug at the pre-set pattern at the right time and site is evaluated for pharmacodynamic and pharmacokinetic performance after oral administration and compared with an existing marketed sustained formulation of Propranolol HCl. The study was carried out in male New Zealand albino rabbits through the cross over design pattern and levels of plasma measured by means of LC-MS/MS method. Pharmacokinetic parameters of designed pulsatile formulation were measured and observed to have statistical significance with the existing marketed sustained formulation. The In-house pulsatile dosage form able to show the lag phase and the mean residence time of pulsatile dosage form (23.20.14h.) was found to be beyond the marketed sustained dosage form (14.8 0.01h.). Pharmacodynamic data revealed a maximum guard against adrenaline levels at 6 h post-oral intake and dropped to 50% after 12 h with Marketed formulation. Whereas in the case of pulsatile formulation administration, maximum protection was obtained at 12 h. and continued over a period of 18 h. It is concluded that the designed pulsatile formulation offers a promising way of drug release for a programmed time period at the desired site, once the administration time and pulse time are aligned with a circadian pattern.

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INTRODUCTION

Propranolol Hydrochloride is a synthetic β-adrenergic receptor blocker indicated in the management of hypertension, decrease angina frequency and other cardiovascular disorders. It is subjected to an extensive first-pass metabolism by the liver after taken orally and approximately 15 to 23% (Rao and Saikishore, 2015) of propranolol reach the systemic circulation. Its plasma half-life is from 3 to 6 hrs and rapidly eliminated, thus repeated administration desired for maintenance of plasma levels (Malhotra, 2017). A number of functions of the heart undergo circadian patterns.

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RESEARCH ARTICLE

Design and Development of Pulsatile drug delivery of Diltiazem Hydrochloride

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ABSTRACT:

In the present study, an effort was made to develop a novel dosage form by using a chrono-pharmaceutical approach for the treatment of hypertension using Diltiazem hydrochloride as a model drug. A time delayed capsule was prepared by sealing the pellets inside the insoluble hard gelatin capsule body with erodible hydrogel plug. The pellets were prepared by emulsion Fluidized Bed wurster (bottom spray) technology technique. Optimized pellets formulations were selected based on dissolution studies. The entire device was enteric coated, so that the variability in gastric emptying time can be overcome and a colon-specific release can be achieved. Hydrogel plug (HPMCK4 and lactose in 1:1 ratio) having 4.5kg/cm^2 hardness and 100 mg weight was placed in the capsule opening and found that it was suitable to avoid the drug release in small intestinal fluid and to eject out the plug in colonic fluid and releasing the pellets into colonic fluid after a lag time criterion of 5 hours. In order to simulate the pH changes along the GI tract, three dissolution media with pH 1.2, 7.4 and 6.8 were successively used. FTIR study confirmed that there was no interaction between drug and polymer. Among all the formulations Diltiazem hydrochloride pellets coated with Eudragit FS 30D in 35% w/w concentrations shown prolonged release for a period of 12 hours. The obtained results revealed the capability of the system in delaying drug release for a programmable period of time and can prevent a sharp increase in the incidence of blood pressure, during the early morning hours, a time when the risk of hypertension attacks is the maximum.

KEYWORDS: Diltiazem hydrochloride, Hypertension, Pulsatile, Pellets, Hydrogel Plug; Fluidized Bed wurster.

INTRODUCTION:

With the advancement of technology in the pharmaceutical field, drug delivery systems have drawn an increasing interest over the last few decades. Presently, the emphasis of pharmaceutical galenic research is turned towards the development of more efficacious drug delivery systems with already existing molecules rather than going for new drug discovery because of inherent hurdles posed in drug discovery and development process[1].

Several functions (e.g. BP, heart rate, stroke volume, cardiac output, blood flow) of the cardio vascular system are subject to circadian rhythms. Cardiac events also occur with a circadian pattern[2]. The cardiovascular events are more commonly occur in the morning and the incidence of sudden cardiac death is up to the 70% between 7 a.m. and 9 a.m. than during the rest of the day. Similarly the stroke and ventricular arrhythmias occur with greater frequency in the morning hours due to the plasma catecholamine's and cortisol, as well as vascular tone and effective circulating volume, are also highest in the morning hours[3]

Diltiazem hydrochloride is a calcium channel blocker used in the treatment of arrhythmia, angina pectoris and hypertension[4]. Because of its short biological half life (3.7 ± 1.2 hrs) frequent administration of dosing is necessary to satisfy the requirement of persistent medication. Prolonged release dosage forms are designed to complement the

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Comparative *in Vivo* Evaluation of Marketed Sustained Release and Optimized Pulsatile Formulation of Diltiazem Hydrochloride

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ABSTRACT

In the present study optimized pulsatile formulation of Diltiazem Hydrochloride is evaluated for pharmacodynamic and pharmacokinetic performance after oral administration and compared with an existing marketed extended release formulation of Diltiazem Hydrochloride. The study was carried out in male New Zealand albino rabbits following crossover design pattern and the plasma levels were measured using LC-MS/MS method. The In-house pulsatile dosage form shown lag phase and the mean residence time is(20.00.12h), found to be beyond the marketed dosage form (14.60.04h.).The pharmacodynamic data reveals maximum protection against adrenaline challenge was obtained at 6h. And is declined to 80% after 12h. with Marketed formulation. Whereas in case of pulsatile formulation administration, a maximum protection was obtained at 12h. and was prolonged over a period of 18 h. It is concluded that the designed pulsatile formulation offers a promising way of drug release for a programmable period of time at desired site.

KEY WORDS:LC-MS/MS; Pharmacokinetic & Pharmacodynamic parameters; Crossover design;Diltiazem hydrochloride; Pulsatile.

RESEARCH ARTICLE

inventi | Spreading Knowledge

New Liquid Chromatographic Method Development and Validation of Ledipasvir and Related Impurity by RP-HPLC in Bulk and Pharmaceutical Dosage Forms

Shiny Ganji[1]*, D Satyavati[2]

Abstract: The present work aims at development and validation of reverse phase liquid chromatographic method for determination of ledipasvir and related impurity in bulk and pharmaceutical dosage form. The chromatographic separation was achieved with Zorbax eclipse XDB C18 column (250 mm x 4.6 mm, 5µ) using buffer (0.03 M potassium dihydrogen phosphate in 1000 ml water) and acetonitrile (40:60). The flow rate of 1.0 ml/min with detection of 264 nm was used in the analysis. The calibration curve of ledipasvir was linear in the range of 120 µg – 360 µg. The method was validated with respect to linearity, precision, accuracy, specificity, robustness in accordance with ICH guidelines. The method was found to be accurate, specific, precise, simple and robust to analyze ledipasvir and related impurity in bulk and pharmaceutical dosage form.

INTRODUCTION

Ledipasvir is a drug for treatment of Hepatitis C that was developed by Gilead sciences. [1] It is directly acting antiviral agent that interferes with HCV replication and can be used to treat patients with genotypes 1a or 1b. [2-3] It is commonly used in combination with sofosbuvir for treatment of chronic hepatitis. [4] On Oct 10, 2014, FDA approved combination product of Ledipasvir 90 mg/ sofosbuvir 400 mg called Harvoni. [5] IUPAC name for Ledipasvir is Methyl N-[(2S)-1-[(6S)-6-[5-[9,9-Difluoro-7-[2- [(1S,2S,4R) -3- [(2S)-2- (methoxycarbonylamino)-3-methylbutanoyl] -3-azabicyclo [2.2.1] heptan -2-yl] -3H-benzimidazol -5-yl] fluoren-2-yl] -1H-imidazol-2-yl] -5-azaspiro [2.4]heptan-5-yl]-3-methyl-1-oxobutan-2-yl] carbamate. [6] The plasma half life of ledipasvir is 49.7 hrs. [7] Protein binding >99%. [8] It belongs to the class NS5A replication complex inhibitor. Molecular weight is 889. [9]

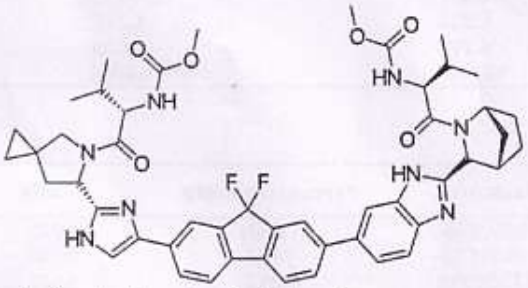

Figure 1: Chemical structure for ledipasvir

MATERIALS AND METHODS

HPLC water, Acetonitrile were purchased from Qualigens, Mumbai. All the chemicals were procured from S.D Fine Chemicals, Mumbai. Ledipasvir and its related impurity were a kind of gift sample from Mylan Laboratories, Hyderabad. Pharmaceutical dosage form used is Harvoni, whose composition is ledipasvir, sofosbuvir 90mg/400mg. Manufacturer is Gilead Sciences, Inc. with Batch No. 100784. It was procured from local pharmacy.

The chromatography performed for the separation of Ledipasvir and its related impurity was performed using Zorbax Eclipse XDB C18 column, 250 mm x 4.6 mm, 5µ. The mobile phase comprising of 0.03 M potassium dihydrogen phosphate in 1000 ml of water and acetonitrile (40:60) and pH was adjusted to 3.2 with dilute orthophosphoric acid. The detection was carried at 264 nm by maintaining mobile phase at flow rate of 1.0ml/min, while the temperature of column was maintained at 30°C. The injection volume was - 20µl and run time for each sample is 20 min.

Preparation of Standard and Sample Solutions

1. Standard Preparation

Transfer 300 mg of ledipasvir and 3.35 mg of N-Boc-2-Azabicyclo impurity of working standard into 100 ml volumetric flask, dissolve and dilute to volume with diluents (water:acetonitrile 60:40). Take 5 ml of above solution and dilute to 50 ml in a volumetric flask with diluent.

2. Test Solution

Transfer 1000 mg of Harvoni formulation into a 100 ml volumetric flask, dissolve and dilute to volume with diluent. Take 5 ml of above solution and dilute to 50 ml with diuent in a volumetric flask.

Development and Optimization of Method

Under the experimental condition, the method was optimized for their different mobile phase solvent ratio, column temperature, flow rate, pH of inorganic mobile phase. Reverse phase HPLC determination was performed with liquid chromatograph equipped with variable wave length UV detection and LC solution software. The wave length was selected for this experiment after scanning the standard solutions in mobile phase in the range of 190 – 380 nm. The detection wave length of 264 nm was chosen because the maximum absorption of ledipasvir and its related impurity was obtained. Chromatographic analysis was carried out at 30°C on Zorbax eclipse XDB C18 column (250 X 4.6 mm, 5µ).

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Research Article

DEVELOPMENT OF BILAYER TABLETS OF LOSARTAN POTASSIUM AND METFORMIN HYDROCHLORIDE LAYER USING NATURAL GUMS AS POLYMERS

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ABSTRACT

Objective: The aim of this research work was to develop and evaluate a bilayer formulation of losartan potassium and metformin hydrochloride for the treatment of diabetic patients with hypertension. In the present study, losartan potassium as immediate-release (IR) layer and metformin hydrochloride as a sustained-release (SR) layer were selected.

Methods: The polymers selected were fenugreek gum, sweet potato starch, and ispaghula gum as natural disintegrants for IR layer and guar gum, xanthan gum, and pectin for SR layer. Bilayer tablets were developed by employing the two layers.

Results: For IR layer, L4 formulation with 5% ispaghula gum as natural disintegrant showed 98.94% drug release was selected as an optimized layer. For sustained layer, F2 formulation with 18.75% guar gum as drug retardant showed 97.17% drug release was selected as optimized layer. Optimized formulation followed zero-order kinetics. When the release data was plotted into Higuchi and Korsmeyer-Peppas equations, then it was confirmed that the optimized formulation exhibited a Fickian diffusion type drug release.

Conclusion: Tablets prepared with 5% ispaghula gum and 18.75% guar gums as drug retardants were found to be useful for bilayer tablet formulation with desired drug release characteristics.

Keywords: Sustained release layer, Immediate-release layer, Losartan potassium and metformin hydrochloride layer.

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INTRODUCTION

Oral ingestion has been the most convenient and commonly employed route of drug delivery due to its ease of administration. The design of a modified release drug product is usually intended to optimize a therapeutic regimen by providing slow and continuous delivery over the entire dosing interval [1-3]. Bilayer tablet is the novel drug delivery system where a combination of two or more drugs in a single unit having different release profiles improves patient compliance; prolongs the drug action resulting in effective therapy along with better control of plasma drug levels. Bilayer tablets [4-6] can be the primary option to avoid chemical incompatibilities between active pharmaceutical ingredients by physical separation and to enable the development of different drug release profiles. Immediate release (IR) dosage forms are those for which ≥85% of the labeled amount dissolves within 30 min. Sustained-release (SR) drug delivery systems can be defined as any dosage form that prolongs the therapeutic activity of the drug by continuously releasing medication over an extended period of time. The approach decreases the pill burden on the patient. Treat different ailments in the same patient (co-morbidity) at the same time with only one tablet. Bilayer tablets also allow for synergistic combinations. These tablets will also provide elegance to the product.

The drug losartan potassium [7-9] was selected for IR layer. As the drug undergoes extensive first-pass metabolism (F=0.33) that can be overcome by formulating the drug as an IR layer because the entire drug releases in the region of the stomach and absorbs completely before entering into liver. The drug also has a biological half-life of 6–9 h that suits the drug for IR part. For SR layer, metformin hydrochloride layer (HCl) [10-12] is selected because of having large dose (500 mg) and $t_{1/2}$ of around 2 h where frequent administration of drugs can be minimized. Hence, this work was aimed to release losartan potassium within 30 min and metformin HCl for a period of 10 h.

In this work, various natural polymers, namely, pectin, sweet potato starch, fenugreek gum, and ispaghula gum, were employed for the preparation of bilayer tablets. These polymers are natural origin, bio-processed, and biodegradable, whereas synthetic polymers derived from chemical reactions are found to be hard and are not biodegradable. These natural polymers have antioxidant and anti-aging properties compared to synthetic polymers. The natural polymer pectin that is extracted from orange peel has antioxidant, anti-diabetic, and reduces gastroesophageal reflux disease. Fenugreek gum has multiple uses such as treatment of obesity, hypertension, and reduction blood glucose levels. Ispaghula gum can be employed in the treatment of bladder problems and hypertension and can be employed for skin irritations. These polymers have super disintegrating properties (pectin, fenugreek gum, and ispaghula gum) as well as SR characteristics (xanthan gum and guar gum).

MATERIALS AND METHODS

Materials

Losartan potassium was obtained as a gift sample from Hetero Labs, Hyderabad. Metformin HCl was obtained from Apogen Remedies, Bapatla. All the remaining chemicals used were of analytical grade.

Methods

Preparation of gums

Extraction of pectin

One hundred grams of orange peels were mixed with 500 ml water and 2.5 ml HCl. Boiled for 45 min and filtered. The filtrate was washed with 250 ml of boiled water. Later, it was cooled to 25°C. Extract was precipitated by adding 200 ml 95% ethanol. It was subjected to thorough stirring and left it for 30 min to allow pectin float on the surface. Extracted pectin was purified by washing with 200 ml of ethanol [13].

Extraction of sweet potato starch

The fresh sweet potato tubers were washed and peeled using a stainless steel knife. Peeled sweet potatoes were grinded and passed through a sieve of diameter 150 μm. The slurry was allowed to sediment for 3 h.

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Synthesis, characterization, analgesic and anti-inflammatory activity of new pyrazole derivatives

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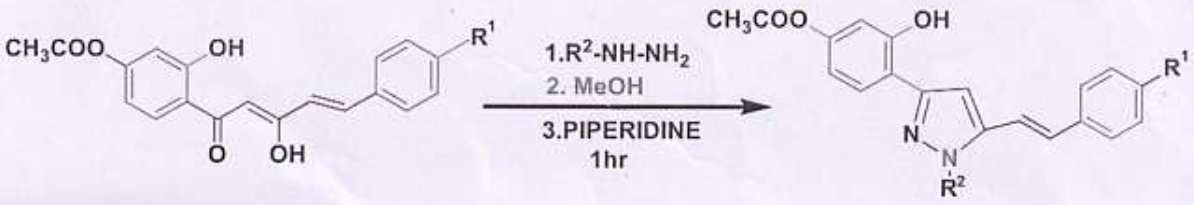
Abstract

The synthesis of nine new pyrazole derivatives was achieved from β-hydroxy enones and hydrazines by using a trace of piperidine in methanol at room temperature. The use of piperidine provides more yield and purity of products in lesser time when compared to the other reagents. All synthetic compounds were characterized by their physical properties, NMR and LC mass spectral data. The pyrazole derivatives were screened for their analgesic and anti-inflammatory activities *in vivo*. The derivatives exhibited moderate to significant activities in comparison to control, and most of the pyrazoles were competent with standard drugs (Pentazocine and Indomethacin).



9 examples

R^1 = Cl, NO_2, OCH_3, R^2= H, C_6H_5, 2,4-DNP

Keywords: Pyrazoles, β-hydroxy-enones, hydrazines, piperidine, anti-inflammatory activity, analgesic activity

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DESIGN AND CHARACTERIZATION OF CHRONOPHARMACEUTICAL DRUG DELIVERY OF PROPRANOLOL HYDROCHLORIDE

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Keywords:

Propranolol hydrochloride, Hypertension, Pulsatile, Pellets, Hydrogel plug, Fluidized Bed Wurster

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ABSTRACT: Objectives: In the present study, an effort was made to develop a novel pulsatile dosage form for the treatment of hypertension using Propranolol hydrochloride as a model drug. A time-delayed capsule was prepared by sealing the pellets inside the insoluble hard gelatin capsule body with an erodible hydrogel plug. **Methods:** The pellets were prepared by the Fluidized Bed Wurster (bottom spray) technique. The entire device was enteric coated so that the variability in gastric emptying time can be overcome and a colon-specific release can be achieved. Hydrogel plug (HPMCK4 and lactose in 1:1 ratio) having 4.5 kg/cm^2 hardness and 100 mg weight was placed in the capsule opening and found suitable to avoid the drug release in small intestinal fluid and eject the plugin colonic fluid, releasing the pellets into colonic fluid after a lag time criterion of 5 h. Three dissolution media with pH 1.2, 7.4 and 6.8 were consecutively used to simulate the pH changes along the GI tract. **Results:** FTIR study confirmed that there was no interaction between drug and polymer. Among all the formulations Propranolol hydrochloride pellets coated with Eudragit FS 30D in 35% w/w concentrations shown prolonged release for a period of 12 h. **Conclusion:** The obtained results revealed capability of system in controlling drug release for a programmable period of time and prevent a sharp increase in the incidence of blood pressure, during the early morning h, a time when the risk of hypertension attacks is maximum.

INTRODUCTION: Pulsatile drug delivery system is one type of drug delivery system, where the delivery device is capable of releasing drugs after predetermined time-delay (*i.e.,* lag time). The approach is based on the principle of delaying the time of drug release until the system transits through to the colon.

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For drugs required to be targeted in the colonic region (distal organ) the delivery system should prevent the release of drug in the upper two-third portions in the gut. Drugs with idiosyncratic pharmacokinetics or pharmacodynamics or drugs with extensive first-pass metabolism, require the pulsatile release of the drug.

A pulsatile release system is beneficial for the adaptation of drugs to suit circadian rhythms of body functions or diseases [1]. Several functions (*e.g.,* BP, heart rate, stroke volume, cardiac output, blood flow) of the cardiovascular system are subject to circadian rhythms. Cardiac events also occur with a circadian pattern [2].

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Effects of *Aegle marmelos* (L.) Methanolic Leaf Extracts on Cardiovascular Parameters in Diabetic Rats

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Abstract: *Aegle marmelos* (L.) Correa is a widely found plant in India as well as in South Asia. For more than several centuries it is being widely used for its medicinal properties. The objective of the study was to evaluate the cardiovascular changes in alloxan induced diabetic rats treated with methanolic leaf extracts of *Aegle marmelos*. 5 treatment groups (namely control, diseased, low dose (100mg/kg), medium dose (250mg/kg) and high dose (500mg/kg) of methanolic leaf extracts were used in the study. The cardiovascularеffects were evaluated by the determination of Very-Low-Density Lipoprotein (VLDL), Serum Sialic Acid, Glutathione Peroxidase, Serum Catalase, Ascorbic acid, Sodium, Potassium, and Chloride levels. High dose treatment group showed significant decrease in Very-Low-Density Lipoprotein (VLDL), Serum Sialic Acid, Glutathione Peroxidase, Serum Catalase, Ascorbic acid, Sodium, Potassium, and Chloride levels when compared with the diseased treatment groups. Though Low and medium dose treated animals showed insignificant decrease in these cardiovascular parameters when compared with high dose treatment group as well as diseased group. The effects of high dose treatment on cardiovascular parameters were very significant as that of control group. Through the cardiovascular parameters it is evident that the highdose of methonolic leaf extract of *Aegle marmelos* can be used the treatment of diabetes and its cardiovascular complications.

Keywords: *Aegle marmelos*, Rutaceae, Bael, Alloxan, Diabetes, Cardiovascular Parameters

1. Introduction

Natural products have a very special place in drug research and development. Plants as a source of therapeutically useful drugs have been proved the evidence of high economic importance. Search for new drugs from various plant sources occurs throughout the globe. In India though there are certain limitations or challenges in the resources, standardization of medicinal plants has gained significance in the recent times [1].

Aegle marmelos (L.) Correa is a widely found medicinal plant in India and South Asia. It is being commonly used for its therapeutic properties [2]. Antinociceptive activity [3], hepatoprotective activity [4, 5], antioxidant activity [4, 10, 17-20], antimicrobial activity [6], antibiofilm activity [6], cytotoxic activity [6, 10], antifeedant activity [6], larvicidal activity [6], antiproliferative activity [7, 13, 19], cholinergic agonist activity [8], serotonergic agonist activity [8], adrenergic agonist activity [8], antifungal activity [9, 11], transcriptome gene activity [12], anticancer activity [13], antidiarrhoeal activity [14], protective effects against fructose induced hepatic insulin resistance [15], immunomodulatory activity [16], proctective effects against chronic fatigue syndrome [20], antilipidemic activity [21, 28], antihypercholestrolemic activity [21, 28], anti ulcer activity [22], detoxifying activity [23], diuretic activity [24], antibacterial activity [25], anti filarial activity [26], antidiabetic activity [27] has been reported in various plant extracts of the plant. Most of the phytocompunds are found be accumulated in the leaves of the plants. Therefore, the present research work was aimed at the evaluation of cardiovascular changes in diabetic rats treated with methanolic leaf extracts from *Aegle marmelos*.

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ORIGINAL ARTICLE

Evaluation of Biochemical Changes in Diabetic Rats Treated with *Aegle marmelos* (L.) Methanolic Leaf Extract

Ravi Babu Birudu, Padmavathi Pamulapati, Sathish Kumar Manoharan[1]

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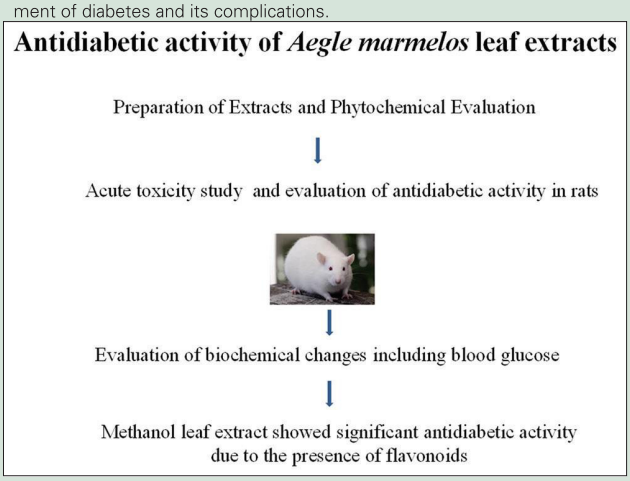
ABSTRACT

Background: *Aegle marmelos* (L.) Correa is a widely found plant in India as well as in South Asia. For more than several centuries, it is being widely used for its medicinal properties. **Objective:** The objective of this study was to evaluate the biochemical changes in alloxan-induced diabetic rats treated with methanolic leaf extracts of *A. marmelos*. **Materials and Methods:** Six treatment groups, namely control, diseased, standard (glimepiride), low dose (100 mg/kg), medium dose (250 mg/kg), and high dose (500 mg/kg) of methanolic leaf extracts, were used in the study. The biochemical effects were evaluated by the determination of bodyweight, blood glucose, serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), total proteins, serum albumin, serum creatinine, and alkaline phosphatase. **Results:** A significant increase in the bodyweight of the animals was observed in the high-dose treated animals (350.0 ± 6.15) when compared to the diseased group animals (241.0 ± 7.23). A significant decrease in the blood glucose, SGOT, and SGPT levels was observed in the high-dose treated animals (142.3 ± 20.52, 71.6 ± 4.8, and 24.5 ± 2.42) when compared to the diseased group animals (292.8 ± 29.34, 146.3 ± 11.12, and 74.5 ± 2.88), respectively. Similarly, total proteins, serum albumin, serum creatinine, and alkaline phosphatase levels of the high-dose treated animals were also significantly decreased (6.1 ± 0.26, 4.2 ± 0.22, 0.4 ± 0.18, and 109.2 ± 14.58) when compared to the diseased group animals (9.7 ± 0.27, 5.4 ± 0.26, 1.0 ± 0.22, and 257.2 ± 8.22), respectively. **Conclusion:** Through the biochemical changes, it is evident that the high dose of methanolic leaf extract of *A. marmelos* can be used in the treatment of diabetes and its complications.

Key words: *Aegle marmelos*, alloxan, bael, diabetes, rutaceae

SUMMARY

- The presence of flavonoids in the methanolic leaf extracts of *Aegle marmelos* has yielded the antidiabetic activity and therefore can be used in the treatment of diabetes and its complications.



Abbreviations Used: SGPT: Serum glutamic pyruvic transaminase; SGOT: Serum glutamic oxaloacetic transaminase.

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INTRODUCTION

Natural products have a special place in pharmaceutical research. During their long evolution and selection, they have acquired qualities mostly in connection with biological functions of animal or plant organisms. In addition, natural products are noted for their highly complex molecular architectures, and they show amazing arrangements of functional groups, strained ring systems, and other attractive structural attributes. Traditional knowledge of medicinal plants has always guided the search for new cures. In spite of the advent of modern high-throughput drug discovery of valuable drugs, traditional plants are often economical, locally available, and consumable raw or as simple medicinal preparation. Many vegetable drugs are used in preparations prescribed by practitioners of indigenous medicine in different regions; the common people use others as household remedies.[1]

Aegle marmelos (L.) Correa is a widely found plant in India as well as in South Asia. For more than several centuries, it is being widely used for its medicinal properties. Several phytocompounds have been isolated and characterized by various plant parts, namely alkaloids, terpenoids, tannins, phenols, cardiac glycosides, steroids, flavonoids, and saponins. These phytocompounds are reported to possess therapeutic potential for various diseases and disorders.[2] Analgesic, antioxidant, anti-bacterial, antifungal, anticancer, antidiarrheal, immunomodulant, antihyperlipidemic, antiulcer, diuretic, antifilarial, and hepatoprotective activities have been reported in various plant extracts of the plants.[3-28] Leaves are considered to be the most common sites of accumulation of phytocompounds in plants. Therefore, the present research work was aimed at the evaluation of biochemical changes in diabetic rats treated with methanolic leaf extracts from *A. marmelos*.

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Relationship between Dopamine and Serotonin on the Effect of *Ginkgo biloba* Extract in the Treatment of Obsessive-compulsive Disorder in Rodents

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In this study, the effect of EGb-761, the standardized extract of *Ginkgo biloba* at dose levels of 50, 100 and 200 mg/kg was investigated on experimental models of obsessive-compulsive disorder such as quinpirole-induced compulsive checking in rats and marble burying behaviour in mice. Water maze test was used to evaluate the effect on spatial memory and the underlying mechanisms were predicted based on rat brain dopamine and serotonin levels. EGb-761 at 100 and 200 mg/kg showed significant improvement against quinpirole-induced compulsions. A protective effect on memory task was observed in EGb-761-treated rats. This could be attributed to the increase in serotonin and decrease in the dopamine levels. The protective effect of EGb-761 in the treatment of obsessive-compulsive disorder is apparent through the performance in the open field and marble burying behaviour.

Key words: Obsessive-compulsive disorder, *Ginkgo biloba*, EGb-761, quinpirole, memory, serotonin, dopamine

Obsessive-compulsive disorder (OCD) is a diagnostic and statistical manual of mental disorders-5 and is one of the most common forms of psychological disorder with about 2 % of the population suffering from it at any point of life, all over the world[1]. OCD, is a disorder of obsessions that generates recurrent and persistent unwanted thoughts, images or impulses leading to develop compulsions, it can also be defined as a chronic illness causing disability with symptoms that vary in intensity and impair quality of life (QOL), various factors associated with poor QOL such as; comorbid depression, obsessions, low social support, adverse effects of concomitantly used medications such as mood stabilizers and feeling of low social status[2,3] are further making it more debilitating.

The primary loci of these pathological changes are the regions that communicate with basal ganglia and are involved in error detection of brain circuits i.e. hippocampus, globus pallidus, orbitofrontal cortex (OFC), anterior cingulate cortex (ACC), right premotor cortex, left superior temporal gyrus and left dorsolateral prefrontal cortex[4,5]. Various theories explaining the neurobiology of OCD, reinstate that repeated stimulation of ACC and OFC result in messages that are excessive and erroneous to the basal ganglia[6], this also leads to comorbidities such as attention deficit hyperactivity disorder and bipolar disorder, general memory deficit[7] and reduced memory confidence[8]. Many neurotransmitters play a key role in the aetiology of OCD, of which serotonin's involvement[9,10] is of great importance.

Many medicinal plants such as *Rhodiola rosea*, *Scutellaria lateriflora*, *Matricaria recutita*, *Ginkgo biloba*, *Piper methysticum* and *Crocus sativus* were reported to possess adequate beneficial effect in the treatment of various anxiety disorders and are reported to act through multitude of mechanisms such as altering the neurotransmitter reuptake,

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Research Article

DESIGN AND DEVELOPMENT OF RIZATRIPTAN BENZOATE ORAL DISPERSIBLE FILMS

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ABSTRACT

Aim: The present work was to formulate and evaluate the Rizatriptan benzoate oral dispersible films by using solvent casting method. Materials and methods: The formula was optimised with different polymers like sodium CMC, HPMC and sodium alginate by using different plasticizers like propylene glycol, N-dibutyl phthalate, PEG400 and PEG 200 by using different concentrations of optimised plasticizer i.e PEG 200 like 15%, 20%, 25%, 30% and 35% at different temperatures like 55˚c, 60˚c, 65˚c, 70˚c and finally by different base levels of film casting machine i.e 0.5, 1, 1.5, 2 mm by solvent casting method. The formulations were characterized for weight variation, thickness, folding endurance, disintegration time, content uniformity and in vitro drug release studies and drug polymer interactions were studied by using Fourier transform infrared spectroscopy. Results: The films prepared with 8% sodium alginate with plasticizer PEG 200 at 30% at 60˚c with 0.5mm base level dispersion shown the best results compared to different polymers and conditions by obtaining 97% of drug release. Conclusion: Based on the evaluation of different parameters it was concluded that formulation of Rizatriptan benzoate oral dispersible films was successfully done and F12 shows 97.5% drug release at 60˚c temperature.

Keywords: Rizatriptan benzoate, oral dispersible films, N-dibutyl phthalate, PEG200, PEG 400, Propylene Glycol.

INTRODUCTION

The oral cavity has been investigated as a site for drug delivery for a long period of time. In 1847 Sombrero found that nitroglycerine was absorbed from the oral cavity[1]. Since then various active substances have been investigated for local or systemic use[2]. Drug delivery through the oral cavity offers many advantages. The oral mucosa is conveniently and easily accessible and therefore allows uncomplicated application of dosage forms. Furthermore, the oral mucosa is robust against local stress or damage and shows fast cellular recovery after such incidents[3]. Oral dispersible film is a new drug delivery system. Oral dispersible film has gained popularity due to its availability in various size and shape. Oral dispersible films are intended to disintegrate or dissolve within seconds. They offer advantages such as administration without water, ease of swallowing, rapid onset of action and convenience of dosing. For fast dissolving active pharmaceutical ingredients, absorption is possible through the oral mucosa and may improve bioavailability. Oral dispersible film is an ideal dosage form for the patients who difficult to swallow the tablet. Due to its ease of usage and high acceptability, fast dissolving films were formulated in the present study.

Rizatriptan benzoate was selected as a model drug for the study which is an anti migraine drug, a selective 5 Hydroxy tryptamine $(5\text{-HT})_{1B/1D}$ agonist and used for the acute treatment of migraine attacks with or without aura. Rizatriptan benzoate has oral bioavailability of 45% due to hepatic metabolism. Rizatriptan benzoate oral dispersible film is alternative to oral dispersible tablets to eliminate the patients fear of chocking and overcome the patients impediments. This formulation was optimised by taking so many criteria i.e by studying the effect of different hydrophilic polymers (Sodium CMC, HPMC and Sodium alginate), plasticizers (Propylene glycol, N-dibutyl phthalate, PEG 400 and PEG 200) by varying the concentrations (15%, 20%, 25%, 30% and 35%) with wider temperature ranges (55˚c, 60˚c, 65˚c, 70˚c) at base levels (0.5mm, 1mm, 1.5mm, 2 mm) on film casting machines it can be effectively used in case of migraine patients as it can be administered without the intake of water.

MATERIALS AND METHOD

Rizatriptan benzoate was a gift sample from Natco pharma, Hyderabad. PEG 200, PEG 400 were obtained from Loba chemie pvt., Limited. Hydroxy propyl methyl cellulose, sodium alginate were obtained from Himedia, Mumbai. Carboxy methyl cellulose sodium 200-300 cps and N-dibutyl pthalate were supplied from S.D. Fine-Chem Ltd, Mumbai. Potassium chloride, sodium hydroxide and potassium di ortho phosphate were purchased from Qualigens, Mumbai.

Construction of calibration curve

100 mg of Rizatriptan benzoate was dissolved in 6.8 phosphate buffer in a 100 ml volumetric flask and the solution was made up to the volume with 6.8 phosphate buffer to prepare a standard solution. The standard solution of Rizatriptan benzoate was subsequently diluted with 6.8 phosphate buffer to obtain a series of dilutions containing 2, 4, 6, 8 and 10 µg of Rizatriptan benzoate per ml of solution. The absorbance of the above dilutions was measured in ELICO Double beam SL 210 Uv-visible Spectrophotometer at 227 nm using in 6.8 phosphate buffer as blank. The absorbance values were plotted against concentrations of Rizatriptan benzoate as shown in Figure 1.

MAT JOURNALS

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Influence of Kollidon SR on Ondansetron HCl pH Independent Drug Release from Hydroxypropyl Methyl Cellulose Matrix Tablets

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Abstract

The Polymers are tools used in novel drug delivery system to modify the drug release of pharmaceutical dosage form. Ondansetron HCl is a weakly basic drug belongs to BCS class-II; it is showing distinct pH dependent solubility. The major intention of the current study was to develop a pH independent controlled released system for pH dependent poorly soluble Ondansetron HCl. The effect of combination of polymers on parameters like release pattern, release mechanism of the drug were studied. A 3^2 full factorial design was used to study the effect of Kollidon SR on Ondansetron HCl Drug Release from Hydroxypropyl Methyl Cellulose Matrix Tablets. The release rate from formulated matrix tablets was studied at both SGF (pH 1.2) and SIF (pH 6.8). Drug release from Kollidon SR and Methocel (1:1) based matrix system based tablets was found to pH independent controlled drug release up to 24h with >90% drug release. Kollidon SR has a distinctive character of maintaining tablets geometric shape until the end of dissolution test, this is mainly due to the water insoluble content, polyvinyl acetate, forming 80% (w/w) of Kollidon SR, while the remaining content 20% (w/w) is the water soluble, polyvinylpyrrolidone, responsible for pore formation causing a diffusion controlled release The similarities in Release profiles were evaluated by applying the model independent (f2) similarity factor. The Optimized formulation characterized by DSE, X-RD and FT-IR studies was found not having any interaction with polymer and drug. The Optimized Formulation followed zero order with non-Fickian diffusion method. In conclusion, Kollidon SR and Methocel k100 were found to be novel potential candidates for the development of pH independent controlled delivery system of Ondansetron HCl.

Keywords: *Ondansetron hydrochloric acid; pH independent controlled drug delivery system, Kollidon® SR, METHOCEL K100M*

INTRODUCTION

The oral drug delivery is by far the most preferable route of drug delivery system, due to ease of administration, patient compliance and flexibility in formulation. Most of the active pharmaceutical ingredients are weak acids And weak bases these salts showed variable drug release pattern in different areas of GIT, weakly basic drugs are highly soluble in acidic pH and the solubility was reduced to increase the pH shift to the intestinal pH 6.8 Phosphate medium, due to pH dependent solubility, such a type of drugs is not easy to formulate a controlled release dosage form to the formulator [1]. Ondansetron hydrochloride is a serotonin sub type-3 (5-hydroxytryptamine-3) receptor antagonist [2]. It is a widely used drug for the treatment of several

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Research Article

Prescribing Patterns of Drugs in Pregnant Women Among Outpatients and Inpatients in Obstetrics & Gynecology Department

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ABSRACT

A Prospective cross-sectional study was carried out in order to assess the prescription pattern in pregnant women. Attending Antenatal In & Outpatient Department of a Tertiary Care Hospital. A cross sectional study was conducted by reviewing the antenatal care In &outpatient department case papers of 230 random pregnant women. The prescription pattern was assessed and the drugs were classified based on the US FDA Risk Classification. Out of 230 prescriptions, only 177 prescriptions had drugs other than iron, folic acid and calcium lactate. In this study most of the drugs prescribed falls under category B (26.6%) , a fair number of drugs falls under category A (16.60%) and C (16.60%) and a few drugs falls under category D (6.66%). No drugs belonging to category X were prescribed. The present study reveals that the drug use during pregnancy in and around Bapatla region were minimal and the most of the drugs were prescribed by their generic names. Prescribing by generic name is known to reduce the cost of drug treatment, rationalized drug therapy and avoids confusion.

Keywords: Pregnant women, Prescribing pattern, US FDA, Drug treatment, Generic names, Confusion.

INTRODUCTION

Pregnancy[1]

Pregnancy is a special physiological state where medication intake presents a challenge and a concern due to altered drug pharmacokinetics and drug crossing the placenta possibly causing harm to the fetus. Medication treatment in pregnancy cannot be totally avoided since some pregnant women may have chronic pathological conditions that require continuous or interrupted treatment (e.g., asthma, epilepsy and hypertension). Also during pregnancy new medical conditions can develop and old one can worsen (e.g., migraine, headache, hyperacidity, nausea, vomiting) requiring drug therapy. However, before taking any drug (including over the-counter drugs) or dietary supplements (including medicinal herbs), a pregnant woman should consult her health care practitioner. A health care practitioner may recommend that a woman take certain vitamins and minerals during pregnancy. Health care practitioners also consider of the benefits to the mother and the risk to the fetus while prescribing drugs during pregnancy. It is not possible to avoid drugs during pregnancy, so women with certain chronic medical conditions such as epilepsy, diabetes, inflammatory bowel disease and asthma, the use of drugs is essential and benefits for mother and child may well outweigh the teratogenic risk of the drug. Other nonchronic diseases related or unrelated to the pregnancy may require medical treatment. The drugs prescribed to pregnant mothers for therapeutic purposes may cause serious structural and functional adverse effects in the developing child. Reducing medication errors and improving patient safety are the important areas of discussion. It is essential to consider several factors before prescription of drugs during pregnancy. Such as,

Dose and duration of drug exposure is important. The larger the dose is more likely the effects. The longer the duration of drug exposure is greater chance of susceptible periods of organogenesis and developmental problem.

Timing of exposure is very crucial. Certain organ systems may have only limited period of susceptibility for damage.

Pathogenetic mechanism, teratogen produces their adverse effect by specific mechanism.

Host susceptibility, variability in the genetic factors related to mechanism of certain drugs. All drugs can affects the health of the mother and fetus, therefore any drugs should be administer with care during pregnancy.

The FDA, in 1979 developed a classification system which groups drugs under category A, B, C, D & X, according to the degree of their potential risk of foetal teratogenicity during pregnancy[2].

US-FDA Pregnancy Risk Factor Categories

The USA Food and Drug Administration (FDA) classify the drugs for use in pregnancy using 5-letters system.

A = adequate Controlled studies in pregnant women fail to demonstrate a risk to the fetus. Very few drugs are seen in this category.

B = "Best" No risk seen in animals, but no controlled trials in pregnant women.

C = "Caution" "Adverse fetal effects in animals, no controlled trials in humans." Most drugs are category C.

D = "Danger" "Evidence of human fetal risk should be reserved for life-threatening disease."

X = strong evidence of fetal abnormality, No therapeutic indication in pregnancy.

Teratogenic Drugs: "Most Teratogenic FDA-approved

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Open Access to Pharmaceutical and Medical Research

Open Access Research Article

Comparative in vivo study of pure drug and fast dissolving tablets of Simvastatin

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ABSTRACT

The objective of this study was to investigate differences in the pharmacokinetic patterns between pure drug and an optimized formulation of fast dissolving tablets of Simvastatin. The formulations were administered to 2 groups of white New Zealand rabbits (n=6) following cross over design pattern and the plasma levels were measured using LC-MS/MS method. Pharmacokinetic parameters were determined for each formulation. The comparison of the plasma time curves of the dosage forms showed that each dosage form caused significant differences in the drug plasma levels. The highest mean C_{max} value was observed for optimized fast dissolving tablets (68.33 ± 0.42ng/ml) compared to pure drug (27.72 ± 0.31ng/ml). The mean time taken to peak plasma concentration for *(Tmax)* following administration of pure drug was 11.53 ± 0.011hours, while it was 6.09 ± 0.072 hour following administration of selected optimized fast dissolving tablets.The elimination rate constant (Kel) for pure drug and optimized fast dissolving tablets were found to be 0.58 ± 0.012h^{-1} and 0.53 ± 0.014 h^{-1} respectively. The absorption rate constant (Ka) for pure drug and optimized fast dissolving tablets were found to be 1.68 ± 0.01h^{-1} and 5.53 ± 0.02h^{-1} respectively. The $AUC_{0-\infty}$values observed with optimized fast dissolving tablets686.1±2.07 nghr/ml in compared to pure drug values 191 ± 1.43 nghr/ml. Thus, the results of pharmacokinetic studies indicated rapid and higher oral absorption of Simvastatin when administered as its fast dissolving tablets. Both Ka and AUC were markedly increased by fast dissolving tablets.

Keywords: LC-MS/MS, Simvastatin, fast dissolving, In-vivo studies, pharmacokinetic parameters.

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INTRODUCTION

Simvastatin (SIM), a crystalline compound, is practically insoluble in water and hence poorly absorbed from the GI tract . It is a potent and specific inhibitor of 3-hydroxy-3-methyl-glutaryl coenzyme A (HMG CoA) reductase , which catalyzes the reduction of HMG CoA to mevalonate. Thus, simvastatin arrests a key step for cholesterol biosynthesis in the liver and is widely used in the treatment of hypercholesterolemia and dyslipidemia as an adjunct to diet. After oral administration, simvastatin is metabolized to its β-dihydroxy acid form (simvastatin acid) by the cytochrome-3A system in the liver, where it inhibits the rate-limiting step in cholesterol biosynthesis. This leads to up-regulation of low-density lipoprotein (LDL) receptors and an increase in catabolism of LDL cholesterol. Being a BCS Class II drug, it often shows dissolution rate-limited oral absorption and high variability in pharmacological effects. The major problem of Simvastatin is its very low water solubility, which results into poor dissolution rate. The pharmacokinetic performance of Simvastatin fast dissolving tablets was studied in a comparison with that of pure drug in rabbits [4].

Materials and Methods: The *in vivo* study of the optimized formulations were performed as per the guidelines approved by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Ministry of social Justice and Empowerment, Government of India. Prior approval by Institutional animals ethics committee was obtained for conduction of experiments (Ref:VIPER /IAEC/I-7/ 2017-2018, Dated 21-9-2017). Pure Simvastatin and optimized fast dissolving tablets were selected based on in-vitro release studies and stability conditions were chosen as dosage forms for administration.

Subject selection: The pharmacokinetic performance of Pure Simvastatin and optimized Simvastatin fast dissolving tablets were studied in a randomized crossover study design in rabbits. Twelve New Zealand healthy rabbits with a mean

ORIGINAL ARTICLE

Topical Combination Delivery of Benzoyl Peroxide and Adapalene Niosomal Gel for Acne Treatment

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Abstract

Aim and Objective: Adapalene (ADP) is very effective in 0.01% strength, but it causes skin erythema in the applied area. ADP and benzoyl peroxide (BPO) are the most commonly used drugs in treatment of acne. ADP acts as keratolytic agent and BPO acts as potent antibacterial agent, both the drugs are used individually in a cyclic manner. The combination of both drugs if used judiciously can be used to cure mild to moderate acne effectively by acting on pathogenetic site. The successful treatment of acne depends on the maintenance of effective drug concentration levels at the affected site. The main benefit over liposome is that the lipids are replaced by non-ionic vesicles and hence the preparation is totally non-antigenic. **Materials and Methods:** The non-ionic surfactants like SPANs are obtained from synthetic sources, and hence the quality is maintained same all the time. The ADP was incorporated into niosomes using SPAN 60 and cholesterol was used as a stabilizer. Various ratios of SPAN 60, cholesterol, Stearic acid, BPO, and ADP were tried and optimized. Various process parameters were also optimized for the rotary flask evaporation method. The present study investigates the effect of niosomal coadministration of BPO and ADP in term of *in vitro* skin retention study and *in vivo* antiacne effects. These vesicular carriers, because of their improved percutaneous delivery and better skin retention, have proved to be very useful in enhancing therapeutic index of drugs used for tropical diseases. The niosomal dispersion was incorporated into Carbopol gel. The gel was kept for 3 months accelerated stability studies. **Results and Discussion:** The niosomal dispersion was evaluated for various parameters such as vesicle size, shape, and morphology by transmission electron microscopy. *In vitro* and *in vivo* studies were carried out. The drug release pattern from gel was evaluated on the basis of *in vitro* studies and skin irritation studies on rabbit skin. **Conclusion:** The *in vitro* study shows sustained release gel effects whereas the *in vivo* study shows no signs of irritation on the applied skin area.

Key words: Adapalene, benzoyl peroxide, niosomes, SPAN 60

INTRODUCTION

Skin and topical drug delivery[1]

The skin is the largest and most readily accessible organ of the human body, accounting for approximately 16% of total body mass of an adult and spanning an average surface area of 2 m^2. This large area of skin offers many convenient sites for administration of topical as well as systemic drugs.

Transdermal drug delivery presents many advantages over other routes of administration. Active pharmaceutical ingredients (APIs) applied topically avoid hepatic first-pass metabolism. Better patient compliance exists due to noninvasive and painless aspects of the formula which can be applied repeatedly without the complications that exist with oral or parental daily dosing. The major pharmacokinetic advantages include elimination of dose dumping, sustained API delivery, steady plasma levels, and reduction in dosage frequency, and systemic toxicity. Although a number of advantages exist, formulators are still challenged to overcome the natural barrier function of the skin for optimal transdermal drug delivery.

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SENSITIVE HPLC-MS/MS METHOD FOR ESTIMATION OF ELAGOLIX IN HUMAN PLASMA SAMPLES

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ABSTRACT

In the present work, a rapid, sensitive, specific, precise and accurate liquid chromatography-tandem mass spectrometry method for determination of Elagolix in human plasma was developed and validated with a large calibration curve range (10-4000 pg/mL) which can be used for routine drug analysis and bioequivalence studies. Liquid-liquid extraction method was used to extract the analyte from the human plasma. The separation was achieved using Xbridge Zorbax Eclipse XDB - C18 (150 x 4.6 mm, 5 µ) column with Acetonitrile: 20mM Ammonium formate (pH-3.0) (50: 50, v/v) as a mobile phase. A flow rate of 1.0 mL/min, no splitting and run time 10.0 min was used for the chromatographic analysis of Elagolix . Sensitivity of this method was found to be 10 pg/mL. The analyte was analyzed by mass spectrometry in the multiple reaction monitoring mode. A Turbo-Ion spray source was interfaced between the HPLC and triple quadrupole mass spectrometer (MDS Sciex API 4000). Where the acquired masses for Elagolix sodium 654.5 → 529.1 m/z and Elagolix-D6 was 638.4 → 529.1 m/z were used for quantification of an analyte and its IS. The method was validated in terms of accuracy, precision, selectivity, recovery, freeze-thaw stability, bench-top stability, stock solution stability and re-injection reproducibility. The within and between-batch precision was obtained within the range 0.31 to 8.55 and 0.26 to 6.16. The mean recovery for drug was obtained 87.79%, where as the mean recovery of IS was 84.97%. The %RSD value at higher concentration and lower concentration in all stability experiments was within 15%. This method is free from ion suppression, ion enhancement and any type of abnormal ionization.

Keywords: Elagolix, Deuterated, LC-MS/MS, Human plasma

INTRODUCTION

Elagolix sodium (Figure-1), the sodium salt of the active moiety elagolix. Elagolix sodium is a nonpeptide small molecule, GnRH receptor antagonist [1-5].

Elagolix sodium is chemically described as sodium 4-({(1R)-2-[5-(2-fluoro-3-methoxyphenyl)-3-{[2-fluoro-6-(trifluoromethyl)phenyl]methyl}-4-methyl-2,6-dioxo-3,6-dihydropyrimidin-1(2H)-yl]-1-phenylethyl}amino)butanoate. Elagolix sodium has a molecular formula of $C_{32}H_{29}F_5N_3O_5Na$ and a

ગુજરાત સંશોધન મંડળનું ત્રૈમાસિક

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Benzoyl Peroxide and Adapalene Niosomal Gel for Treatment of Acne by Topical Combination Delivery System in vitro & in vivo studies

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V.Sai Kishore

Abstract

Aim and Objective: Adapalene andbenzoyl peroxide are used in treatment of acne. The combination of both drugs if used judiciously can be used to cure mild to moderate acne effectively by acting on pathogeneticsite. The successful treatment of acne depends on the maintenance of effective drug concentration levels at the affected site. Material and Methods: Nisomal gel preparation was carried by the combination of two chemical constituents Benzoyl Peroxide and Adapalene by mixing with stereac acid, Span-60, Span-40, and Carbopol 940 by using thin film hydration method.

Results and Discussion: Results obtained from the histological studies showed that the prepared niosomal formulation was effective in the treatment of acne. Comparison of the control sample and treated pinna showed that there was a marked increase in volume of the sebaceous gland and several units of comedowns present in the treated pinna Conclusion: Niosomes in comparison to other conventional dosage forms in terms of a better therapeutic efficacy at the affected site at lower doses of drugs present in the niosomal gel formulation.

Research Article

Wound healing activity of *Euphorbia antiquorum* stem extract on rats

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Abstract

Background: Wounds are inescapable events of life which are due to physical, chemical and microbial infections. Medicinal plants came into prominence having good wound healing activity with low adverse drug reactions than the synthetic drugs. **Objective:** The present study was designed to evaluate the wound healing activity of *Euphorbia antiquorum* ethanol stem extract formulation on the wistar rats by using excision wound model. **Materials and Methods:** Animals were divided into four groups containing six animals each. Excision wound was made on the back of rats near the neck region about 2mm diameter. The *Euphorbia antiquorum* ethanol extracts were formulated into ointment by using hydrophilic base containing 2.5 and 5 percentage strength. The formulations were applied on the wounds twice a day and wound healing was observed on the 5, 10, 15, 20th days. Wound contraction period, percentage of inhibition and bio chemical parameters were observed. **Results:** The wound contraction for the *Euphorbia antiquorum* 2.5% ointment was 45.76% ±3.07 to 98.05% ±0.24 and 5 % ointment was 72.45% ±3.43 to 99.13% ± 0.25. Significant wound contraction was observed in 5% strength containing formulation when compared with control and standard. **Conclusion:** Thus from the present study *Euphorbia antiquorum* ethanol formulation (5% ointment) showed significant wound healing activity compared with standard and control groups.

Keywords: Wound healing, *Euphorbia antiquorum*, excision wound model, ethanol extract

Introduction

Wound is defined as disruption of the cellular and anatomical continuity at a tissue. It may be produced by physical, chemical, thermal and microbial damage to tissue. A large number of herbs are used as a folklore medicine for the treatment of cuts, wounds, and burns. In India there is a surplus number of variety of species of plants present which can be used in the treatment of various wounds (Biswas et al., 2003).

The wound healing process consists of three phases. First phase includes homeostasis which often occurs immediately after the wound occurs with vascular constriction and aggregation of platelets. Second phase is inflammatory phase characterized by the five common signs i.e redness, pain, heat, swelling and loss of function. All the inflammatory mediators are produced in this phase cause chemotaxis of monocytes, lymphocytes and initiates epithilisation process. The last phase is remodeling phase characterized by increasing the strength of scar and cause complete reepithilisation (Mutsaers et al., 1997). Various factors like oxygen, age, sex hormones, stress, will affect the wound healing process (Sabale et al., 2012).

The *Euphorbia antiquorum* stem consists of various phytochemical constituents that may responsible for wound healing. This plant is topical plant widely distributed over the world ranging from annual weeds to trees. The plant contains latex, green stem, ribs are prominent generally three. The characteristic feature is triangular in shape. Flowers are cyathia yellowish green to pinkish in colour (Wine et al., 2011). Male flowers with one stamen, female flower lies at the center of cyathium. Fruits are yellowish to orange in colour. It contains various chemical constituents like flavonoids, di & tri terpenes which shows a significant activity of antimicrobial, anti HIV and cytotoxic properties (Sivaraj et al., 2011; Sumathi et al., 2012). The latex shows the lavicidal and mosquitocidal activity(Vimal et al., 2014; Vimal et al., 2015).

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Hypoglycemic and antidiabetic activity of tuberous roots of *Cyanotis cristata* in normal and Alloxan induced diabetic rats.

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Abstract

The present study was aimed to verify the claims and for exploring the hypoglycemic and antidiabetic activity of tuberous roots of *Cyanotis cristata* in normal and Alloxan induced diabetic rats. Alcoholic and aqueous extracts of tuberous roots of *Cyanotis cristata* were prepared and given individually, orally at different doses to different groups of rats fasted for18 h. The serum glucose levels were estimated initially at 0 h (before treatment) and at 0.5, 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 h after the treatment. The alcoholic extract of tuberous roots of *Cyanotis cristata* (ALETRCC) at higher dose (320 mg/kg) produced maximal serum glucose lowering effect in both normal and alloxan induced diabetic rats. The aqueous extract of tuberous roots of *Cyanotis cristata* (AQETRCC) produced maximal percent reduction in serum glucose levels with higher dose (400 mg/kg). ALETRCC and AQETRCC produced hypoglycemic and antidiabetic activities at 4 h, in a dose dependent manner. The effect produced by ALETRCC was found better than that of standard metformin (45 mg/kg) an oral hypoglycemic agent. The ALETRCC has exhibited higher and better hypoglycemic and anti diabetic activity for a prolonged period than that of the AQETRCC. The study results suggested that tuberous roots of *Cyanotis Cristata* possess potential anti-diabetic activity.

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Original Article

Phytochemical, *in vitro* Antioxidant and *in vivo* Safety Evaluation of Leaf Extracts of *Tragia plukenetii*

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ABSTRACT

Objective: To investigate the phytochemical properties, *in vitro* antioxidant and *in vivo* safety profile of leaf extracts of *Tragia plukenetii* (TP). **Methods:** TP leaves were obtained from the south part of India (Guntur District, Andhra Pradesh) and it was extracted with different solvents (Benzene Extract (BE), Chloroform Extract (CE) and methanolic extract (ME)). These TP extracts were analyzed for the *in vitro* antioxidant activity by DPPH reducing power, β-carotene-linoleic acid complex and iron chelation assays followed by *in vivo* acute oral and dermal toxicities using Swiss mice and Wistar rats respectively. **Results:** The present study results revealed ME exhibited an effective and powerful antioxidant activity when compared to a standard antioxidant, Butylated hydroxytoluene (BHT). ME was found to be effective in DPPH, β-carotene-linoleic acid complex and iron chelation assays respectively. *In vivo* acute oral toxicity study revealed that mice treated with up to 5000 mg/kg of BE, CE and ME did not show any signs of toxicity. Furthermore, similarly, acute dermal toxicity study demonstrated that BE, CE and ME did not exhibit any signs of dermal toxicity up to 1000 mg/kg in rats. **Conclusion:** TP extracts possess an excellent antioxidant activity with a devoid of any signs of acute oral and dermal toxicities.

Key words: β-carotene-linoleic acid complex, Dermal toxicity, DPPH assay, Iron chelation, Oral toxicity, *Tragia plukenetii*.

INTRODUCTION

The use of herbal products, in whole or their aerial parts have been gaining considerable attention as therapeutic or prophylactic measures for many disorders and/or diseases in our daily life throughout the world. Severe adverse effects, higher cost, insufficiency and ineffectiveness of many allopathic drugs have led the researchers to focus more on herbal medicines to combat many diseases including neurological diseases.[1] Oxidative stress owing to the imbalance between Reactive Oxygen Species (ROS) generation and innate antioxidant defense mechanism in our body plays an imperative role in numerous diseases including Alzheimer's,[2] cancer,[3,4] Parkinson's disease,[5] diabetes,[6] acute lung injury,[7] cataracts and cardiovascular diseases such as atherosclerosis and hypertension.[8] The detailed mechanisms of cellular damage mediated through ROS and preventive pathways are well documented in the literature.[9] Plant derived products like flavonoids, anthraquinones, carotenoids, tannins and others protect cellular damage due to their significant free radical scavenging property.[10,11] Recently, phytomedicines are in huge demand in the developed and the developing world, as they could able to combat many diseases.[4] These phytomedicines provide an excellent contribution to modern therapeutics with potential innate natural antioxidants. There is a wide scope for researchers to focus more on the development of natural efficacious antioxidants. Many of the plant derived antioxidants are available in various parts of the world but the specific treatments with these substances are yet to be validated.

Tragia (Family: Euphorbiaceae) is comprised of more than hundred species. Interestingly, most of the research has been done using only five Tragia species, namely, *Tragia involucrate, Tragia cannabina, Tragia spantulata, Tragia plukenetii* and *Tragia benthamii*. The detailed phytochemical and pharmacological properties of these species were reviewed and reported elsewhere.[12] Briefly, the different solvent extracts of different parts of *Tragia plukenetii* (TP) have been reported for antiulcer,[13] antioxidant and antitumor,[14] wound healing, antimicrobial,[15-17] antipyretic, diuretic, antiasthmatic, antispasmodic,[18] antidiabetic, treatment in polio, male impotency and elephantiasis,[19] treatment of uterine complaints and skin irritation,[20] antinociceptive[21] and treatment of gastroenteritis, stomach ache, gonorrhea and tapeworm infestation.[22,23] The above-mentioned virtues are due to the presence of valuable phytochemicals such as sterols, alkaloids, flavonoids,

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RESEARCH ARTICLE:

Development of Metoprolol Tartrate Sustained Release Formulations by using Modified Starches

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ABSTRACT:
The present study was under taken to develop sustained release formulations for Metoprolol tartrate , a β-blocker for the treatment of Hypertension. The tablets were prepared by wet granulation technique by using modified starches as release retardant polymers. The evaluation involves 3 stages i.e. pre-compression, post compression parameters and in-vitro release kinetics assessment of tablets. The USP-II paddle method was selected to perform the dissolution test and 500ml of 6.8 pH phosphate buffer was used as dissolution medium at 50rpm at 37 C ∟ 0.5. The release kinetics was analyzed. All the formulations followed Peppa's release mechanism. When the release data was plotted into korsmeyer-Peppas equation (log cumulative % of drug release Vs log time), it was observed that all formulations (F2 to F11) (formulated with modified starches) followed Anamalous (non-Fickian) type of mechanism. The in-vitro release studies revealed that the formulation F5(formulated with Potato Starch containing 1:4 drug :polymer ratio), F8(formulated with Corn Starch containing 1:3 drug :polymer ratio) and F11 formulated with Rice Starch containing 1:3 drug :polymer ratio) can be taken as ideal or optimized formulations for sustained release formulations as it fulfills all the requirements.

KEYWORDS: Sustained release formulations, Metoprolol tartrate, Potato starch, Corn starch , Rice starch , Calcium starch , In-vitro release kinetics.

INTRODUCTION:

Starch is a natural, cheap, available, renewable, and biodegradable polymer produced by many plants as a source of stored energy. It is the second most abundant biomass material in nature. It is found in plant leaves, stems, roots, bulbs, nuts, stalks, crop seeds, and staple crops such as rice, corn, wheat, cassava, and potato.

From serving as food for man starch has been found to be effective in drying up skin lesions (dermatitis) especially where there are watery exudates consequently starch is a major component of dusting powders, pastes and ointments meant to provide protective and healing effect on skins. Starch mucilage has also performed emollient and major base in enemas. Because of its ability to form complex with iodine, starch has been used in treating iodine poisoning. Acute diarrhea has also been effectively prevented or treated with starch based solutions due to the excellent ability of starch to take up water. In Pharmacy, starch appears indispensable; It is used as excipients in several medicines. Its traditional role as a disintegrant or diluent is giving way to the more modern role as drug carrier; the therapeutic effect of the

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Comparative in Vivo Evaluation of Delayed Release Pellets and Oral Solution Containing Fenofibric Acid

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Abstract— *Fenofibrate is a third-generation fibric acid derivative indicated for the treartment of primary hyper-lipidemia or mixed dyslipidemia. Fenofibric acid delayed release (DR) pellets were successfully developed and optimized using wurster process. The present investigation aimed to evaluate the pharmacokinetic properties of Fenofibric acid DR pellets using rabbits as animal model. Blood samples were collected at various time intervals. The plasma concentration of Fenofibric acid was estimated by ultra-high performance liquid chromatography (UHPLC-UV) method. The pharmacokinetic parameters were calculated from the plasma concentration of Fenofibric acid vs. time profile. The sustained Tmax, lower Cmax and prolonged Mean residence time (MRT) indicate an delayed extended release of Fenofibric acid DR pellets compared to Fenofibric acid (as choline salt) API. From the obtained results, it is concluded that the test formulation was provided extend the delivery of Fenofibric acid in desired rate.*

Keywords— *Delayed release; Fenofibric acid; formulation variables; Pellets; Pharmacokinetics; process parameters.*

I. INTRODUCTION

Pharmaceutical invention and research are increasingly focusing on delivery systems which enhance desirable therapeutic objectives while minimizing side effects. Now a days, the multiparticulate drug delivery systems are notably relevant for attaining controlled or delayed release oral formulations with reduced risk of local irritation, low risk of dose dumping, increased bioavailability as well as reproducible and short gastric residence time.

Multiple-dose units have many kinetic and therapeutic advantages over single-dose sustained release units, such as improved bioavailability, easy administration, reproducible gastric residence time, low risk of dose dumping, low intra and inter subject variability, flexibility of blending of different release profile and divided into various dose strengths without formulation changes. The most commonly used pelletization techniques are Suspension/solution layering, extrusion spheronization and powder layering. However, suspension/solution layering (Wurster) technique is most preferable in the pharmaceutical industry owing to its advantages like continuous process, less manual interruption and batch to batch reproducibility [1-3].

Fenofibrate is a third-generation fibric acid derivative indicated for the treartment of primary hyper-lipidemia or mixed dyslipidemia. Fenofibrate is a prodrug and requires enzymatic cleavage via first pass metabolism, hydrolysis at the ester bond to form fenofibric acid, which is the active metabolite. Insolubility of fenofibrate in water was negatively impact the in vivo performance of the product. Hence, novel fenofibrate formulations were developed with different approaches to overcome the challenges with solubility, to prevent the recrystallization of drug in acidic pH and to improve bioavailability. Choline fenofibrate is a newly developed choline salt of fenofibric acid and is more hydrophilic than fenofibrate. It does not require first pass hepatic metabolism to become active, as it dissociates to free fenofibric acid within the gastrointestinal tract and rapidly absorbed throughout the gastrointestinal tract [4].

Impact of various formulation variables and critical process parameters on Fenofibric acid DR pellets were statistically interpreted and significant variables were optimized in our earlier investigation [5-6]. The present study aimed to evaluate the pharmacokinetic parameters of optimized formulation of Fenofibric acid DR pellets.

II. MATERIALS AND METHODS

Materials

Choline fenofibrate was obtained from RA CHEM Pharma Ltd., Hyderabad as gift sample, Sugar spheres (Arun pharma, Hyderabad), Povidone (BASF, Mumbai), Polyethylene glycol (Clariant, Hyderabad), Hypromellose (Dow chemical's, Mumbai), Ethocel 45 cps (Colorcon, Goa), Eudragit L 30 D55 (Evonik), Triethyl citrate (Merck, Mumbai), Talc (Luzenac, Mumbai), Isopropyl alcohol (Avantor, Hyderabad), Purified water and empty hard gelatin capsule shells size 0 (ACG, Hyderabad) were used as received.

Methods

Preparation of Fenofibric acid DR Pellets

Fenofibric acid DR Pellets were prepared by employing bottom – spray fluid bed (Wuster) coating process (Glatt GPCG 1.1). The dosage form was designed to obtain the delayed extended release. Drug loaded pellets were prepared by spraying the aqueous drug dispersion over non pariel seeds (Sugar spheres (20#- 25# ASTM)) employing wurster process (Bottom spray fluid bed coating technology). The drug dispersion was coated on to sugar spheres using 1.0 mm of spray nozzle with a spray rate of 2-6 g/min, 0.8-1.2 Kg/cm^2 of atomization air pressure, 50-65 cfm of air volume and product

Bala Vishnu Priya Mukkala, Murthy TEGK, and Prameela Rani A, "Comparative in Vivo Evaluation of Delayed Release Pellets and Oral Solution Containing Fenofibric Acid," *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 1, Issue 3, pp. 37-40, 2018.

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Formulation Development Evaluation and Optimization of Orodispersible Tablets of Frovatriptan for The Treatment of Migraine

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ABSTRACT

The aim of present research work is to formulate and evaluate Oral dispersible tablets of frovatriptan using various diluents and superdisintegrants and to optimize the formulation. Frovatriptan is a triptan drug used for the treatment of migraine headaches. The drug excipient compatibility study was done and no interactions were found, DSC & XRD studies were carried out. The tablets were formulated by direct compression method using Spray dried lactose, Manito, Microcrystalline cellulose (MCC), Starch as diluents and Crospovidone, Cross-Carmel lose sodium, Sodium starch glycol ate as superdisintegrants. The pre-compression parameters like bulk density, tapped density, Carr's Index, Haunters ratio and angle of repose were determined and all the formulations were found to be within IP limits. The post compression parameters like the hardness, thickness, friability, weight variation, and disintegrating time, wetting time, water absorption ratio and drug content for all the formulations were carried out and results were found to be as per USP limits. *In-vitro* drug release and kinetics studies were carried out for all the formulations, of those the formulation F_{33} containing Cross providing (5%) and mannitol as diluent, has shown better release and follows first order kinetics. The formulations were optimized by 2^2 factorial design and the ANOVA study was carried out and normal plot, half normal plot and overlay plot were plotted. The tablets were stored at 40±2°C/75 ± 5% RH for three months to assess the stability of optimized formulation.

Keywords: Frovatriptan, Crospovidone, Crosscarmellosesodium, Sodium starch glycolate, MCC, Spray dried lactose, starch, Magnesium stearate, Talc, Aerosil and aspartame.

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Research Article

FORMULATION AND EVALUATION OF ESOMEPRAZOLE FAST DISSOLVING BUCCAL FILMS

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ABSTRACT

Objective: The present study deals with the formulation and evaluation of fast dissolving buccal films for effective treatment option in the gastroesophageal reflux disease.

Methods: Esomeprazole fast dissolving buccal films are a convenient formulation of which can be taken with or without water. In the present investigation, polyvinyl alcohol and polyvinylpyrrolidone were used as film-forming agents and polyethylene glycol 400 is taken as plasticizer. Solvent evaporation method was used for the preparation of fast dissolving buccal films.

Results: The films were prepared and evaluated for film thickness, folding endurance, dispersion test, drug content, and dissolution. The *in vitro* dissolution studies were carried out using simulated salivary fluid (pH 6.8 phosphate buffer).

Conclusion: Among all the formulations, Formulation E7 was released up to 99.6% of the drug from the film within 5 min of time which exhibits faster absorption and also shows desirable characteristics of the film. The drug-excipient interaction studies WERE carried out by Fourier-transform infrared studies, differential scanning calorimetry analysis-X-diffraction studies, and scanning electron microscopic studies and the results revealed that there were no major interactions between the drugs and excipients used for the preparation of films.

Keywords: Fast dissolving buccal films, Esomeprazole, Polyvinyl alcohol, Polyvinylpyrrolidone, Polyethylene glycol 400 solvent evaporation method.

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INTRODUCTION

Esomeprazole, the new S-isomer of omeprazole, is introduced to reduce gastric acid secretion more efficiently. Esomeprazole exhibits significantly higher bioavailability, leading to the greater inhibition of gastric acid secretion compared to omeprazole [1]. Esomeprazole, the stereospecific S-isomer of Omeprazole, is the first proton-pump inhibitor to be developed as a single isomer for use in the treatment of acid-related diseases [2]. The intragastric pH-monitoring data for esomeprazole, 20 mg once daily, show improvement over omeprazole, 20 mg once daily, but the esomeprazole, 40 mg once daily, intragastric pH data show a further convincing gain in control of gastric pH [3]. Early studies have shown that esomeprazole achieves greater and more sustained acid control than omeprazole, with a similar tolerability and safety profile. Furthermore, esomeprazole shows a more rapid onset of acid-suppression effect than omeprazole and less interindividual variation in acid control. In addition, a recent crossover study demonstrated that esomeprazole at a standard dose of 40 mg once daily provides more effective control of gastric acid at steady state than standard doses of pantoprazole, lansoprazole, and rabeprazole in patients with symptomatic gastroesophageal reflux disease (GERD) [4]. In addition, esomeprazole treatment yields higher erosive esophagitis healing rates and provides sustained resolution of heartburn in more patients than any other [5]. GERD is a condition in which the digestive acid in the stomach comes in contact with the esophagus (food pipe). The irritation caused by this disorder is known as heartburn. Long-term contact between the acid and esophagus can cause permanent damage to the esophagus [6,7]. Esomeprazole reduces the production of digestives acids, thus minimizing their effect on the esophagus. Esomeprazole is combined with the antibiotics clarithromycin and amoxicillin (or metronidazole in penicillin-hypersensitive patients) in the 7– 14-day eradication triple therapy for *Helicobacter pylori*. Infection by *H. pylori* is the causative factor in the majority of peptic and duodenal ulcers [5].

METHODS

Esomeprazole was procured as gift sample from M/S Aurobindo Pharmaceuticals, Hyderabad. Polyvinyl alcohol (PVA) and polyvinylpyrrolidone (PVP) were commercially procured from M/S Yarrow Chem Products, Mumbai. Polyethylene glycol (PEG) was procured commercially from Sisco Research Laboratories Pvt. Ltd., Mumbai. Saccharin sodium was procured commercially from High-Pure Fine Chemicals, Chennai. All the materials used in the formulation were of pharmacopoeial standards.

Preparation of esomeprazole fast dissolving buccal films (EFDBF)

Fast dissolving buccal films of esomeprazole were prepared by solvent evaporation method. Film-forming agents such as PVA and PVP were prepared in the form of aqueous solutions individually in 100 ml beakers to attain clear solutions Then, the solution of PVP was added to PVA aqueous solution and stirred well to get homogenous solution which is marked as solution A. Accurate quantities of esomeprazole and saccharin sodium were weighed individually and dissolved in suitable quantity of PEG 400 to get a drug and plasticizer solution which is marked as solution B. The solution B was added to aqueous solution A and mixed continuously. The obtained solution was drawn on the non-adhesive base plate and dried under infrared (IR) lamp for 24 h. After drying, the films were cut into suitable sizes [8]. Various trials were conducted to carried out optimize formula for the preparation of EFDBF. The various compositions of EFDBF are given in Table 1.

Evaluation of fast dissolving films

Film thickness

The film thickness was measured using screw gauge with a least count of 0.01 mm at different locations on the film. The film thickness was measured at three different locations, and the average weight was determined. The obtained results are given in Table 2.

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DESIGN AND DEVELOPMENT OF SPHERICAL AGGLOMERATED CRYSTALS LOADED FAST DISSOLVING TABLETS FOR ENHANCING THE SOLUBILITY OF IBUPROFEN

V.PavanKumar* and V.Saikishore

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Abstract:

The main focus of this work was to enhance the solubility and bioavailability of Ibuprofen by using spherical crystallization technique. This technique was developed by Kawashima and their coworkers in 1986, by which crystallization and agglomeration can be carried out at once in a single step to convert crystals straight into compressed spherical form. Spherical agglomerates were obtained by the quasi-emulsion solvent diffusion method, in which ibuprofen was dissolved in the mixture of methanol (good solvent), dichloromethane (bridging liquid) and poor solvent (distilled water containing polymer PVP K-30) with a stirring rate of 500 rpm at room temperature and filtered through Whatman filter paper no.42. Evaluation of agglomerates showed that drug content ranged from 98.18% to 99.27% and agglomerates prepared with ibuprofen and PVP K-30 in 1:1 ratio showed the highest drug release in 60 minutes. This technique enhanced the Physico-chemical properties such as solubility and also enhanced the bioavailability of Ibuprofen as compared with the plain drug, which indicates that the spherical agglomerates can suitable for direct compressible tablet process. Direct compression is a modern method in tablet manufacturing which involves simple mixing and compression and it is both efficient and economical, well suited to the production of high-quality tablets. The formulation prepared with crospovidone was offered the rapid release of ibuprofen when compared to other superdisintegrants. Evaluation tests of tablets exhibit hardness, low friability, excellent dissolution rates and also improve the physical and chemical stability of tablets as compared to wet granulation technique.

Keywords: *Spherical agglomerates, Physico-chemical properties, Bioavailability, Direct compression, superdisintegrant*

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Original Article

Development of pH Independent Drug Release System for Dipyridamole

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ABSTRACT

Introduction: Dipyridamole is an Anti-platelet agent exhibits release problems at higher pH of small intestine due to its pH dependent solubility and precipitation followed by interruption of drug release from dosage form. To overcome this extended release formulation was developed by using pH modulating agent (tartaric acid). **Objective:** Present study was undertaken with a view of the formulations evaluated by performing dissolution testing on developed extended released tablets. **Method:** development of dissolution method at different time points and USP Apparatus 1 (basket) and 2 (paddle) at rotating speeds of 50 or 100 rpm used to evaluate the release characteristics of the formulations. Furthermore, solubility and *in vitro* dissolution studies of formulated tablets were performed at pH values of 1.2 and 5.5. **Results:** In this study we found increasing volume of dissolution medium pH 5.5 phosphate buffers drug precipitation is increased. The developed dissolution method was validated according to ICH guidelines for various parameters such as specificity, accuracy, precision, and stability. The dissolution method was confirmed by determining the dissolution rate of extended released Dipyridamole tablets containing pH modulating agent. The best *in vitro* dissolution profile was obtained using pH 5.5 phosphate buffer as the dissolution medium (500 ml) stirred at 100 rpm. A comparison of the dissolution profiles in official and developed media showed significant differences based on f1 and f2 values. **Conclusion:** The developed dissolution test exhibited a higher capacity than the compendia methods in differentiating the release profiles of pH independent extended release tablets. It can be applied during formulation development and quality control analysis of pH independent extended release tablets for evaluation of the effects of pH modifier in dissolution medium and processing parameters.

Key words: Tartaric acid, Dissolution media, Extended release Dipyridamole Tablets.

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INTRODUCTION

Dissolution testing has been a key tool during drug development process and in the marketable preparation of the formulation.[1] At the formulation development process, dissolution testing is used to evaluate stability of the product consistency, and evaluate the effect of variables on the characteristics of the final drug product.[2] For commercial dosage form, dissolution testing is used to confirm manufacturing and product consistency and to evaluate different process variables.[3] In dissolution test development, the process should focus on assessing relevant physical and chemical properties of the API and dosage form design, because these will guide the choice of the dissolution medium and apparatus.[4] Most of the drugs have pH-dependent solubility exhibiting varying release rates with changing pH in the gastrointestinal tract.[5] Weakly basic drugs are highly soluble in acidic pH (1-3) to increase the pH solubility, it will be decreased. It causes conversion of the more ionizable drug to a less soluble form. Therefore the diffusion rate of the drug through the matrix is reduced. This conversion into an

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Research Article

EFFECT OF FORMULATION FACTORS ON ORODISPERSIBLE TRIPTAN FORMULATIONS – NOVEL APPROACH IN TREATMENT OF MIGRAINE

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ABSTRACT

Objective: The present research work is an attempt to determine the effect of various diluents and superdisintegrants on drug release of eletriptan orodispersible tablets and designs an optimized formulation using 2^2 factorial design. Further, evaluate the tablets for various pre-compression and post-compression parameters.

Methods: The drug excipient compatibility study was conducted by infrared spectroscopy, differential scanning colorimetry and X-ray diffraction studies were conducted to test the purity of the drug. The tablets were formulated by direct compression method using spray dried lactose, mannitol, microcrystalline cellulose, starch as diluents and crospovidone, croscarmellose sodium, and sodium starch glycolate as superdisintegrants. The powder formulations were evaluated for pre-compression parameters such as bulk density, tapped density, Carr's Index, Hausner's ratio, and angle of repose. The tablets were evaluated for post-compression parameters such as the hardness, thickness, friability, weight variation, and disintegrating time in the oral cavity, *in vitro* drug release kinetics studies, and accelerated stability studies. The formulations were optimized by 2^2 factorial design.

Results: The drug and excipients were compatible, and no interaction was found. The drug was pure, and all the pre-compression parameters were within Indian Pharmacopoeial Limits. Post-compression parameters were also within limits. The disintegration time was found to be 27 s for the formulation F_{29} containing Croscarmellose sodium (5%) and Mannitol as diluent, and *in vitro* drug release was found to be 99.67% in 30 min and follows first-order kinetics. This was also the optimized formulation by 2^2 factorial design with a p=0.013.

Conclusion: The orodispersible tablets of eletriptan were successfully formulated, and the optimized formulation was determined that can be used in the treatment of migraine.

Keywords: Eletriptan, Crospovidone, Croscarmellose sodium, Sodium starch glycolate, Microcrystalline cellulose, Lactose, Starch, Magnesium stearate, Talc, Aerosil, Aspartame.

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INTRODUCTION [1]

Oral route of drug administration is perhaps most useful and important route for drug delivery. Tablets are the most favored oral solid dosage form mainly because of several advantages such as ease of administration, good chemical and microbiological stability, lowest cost among all another solid dosage form, dose precision and least content variability, ease of packing, self-medication, and patient compliance. Orodispersible tablets are solid unit dosage forms like conventional tablets, but are composed of superdisintegrants, which help them to dissolve the tablets within a minute in the mouth in the presence of saliva without any difficulty of swallowing. In such cases, bioavailability of the drug is significantly greater than those observed from the conventional tablet dosage form. Migraine is a neurological disease characterized by recurrent moderate to severe headaches often in association with a number of autonomic nervous system symptoms. Triptans are a family of tryptamine-based drugs used as abortive medication in the treatment of migraines and cluster headaches. Thus, the aim of present research work was to formulate oral disintegrating tablets of Eletriptan to overcome the adverse effects of conventional tablets in the treatment of migraine.

METHODS

Eletriptan was obtained as a gift sample from Sun pharma ltd, Hyderabad, croscarmellose sodium, sodium starch glycolate, cross-povidone, microcrystalline cellulose, mannitol, spray-dried lactose, and starch were obtained from Signet chemical corp. Mumbai, aspartame, aerosil, talc, and magnesium stearate were obtained from S.D fine chemicals, Mumbai, and potassium dihydrogen orthophosphate and sodium hydroxide were obtained from Narmada chemicals.

Calibration curve for eletriptan in 6.8 phosphate buffer [2]

About 100 mg of Eletriptan was accurately weighed into 100 ml volumetric flask and dissolved in a small quantity of methanol. The volume was made up to 100 ml with pH 6.8 phosphate buffer to get a concentration of (1000 µg/ml) SS-I. From this, 1 ml was withdrawn and diluted to 100 ml with 6.8 phosphate buffer to get a concentration of (10 µg/ml) SS-II. From the standard stock solution (SS-II), 2 ml, 4 ml, 6 ml, and 8 ml were withdrawn, and volume was made up to 10 ml with 6.8 phosphate buffer to give a concentration of 2,4,6, and 8 µg/ml. Absorbance of these solutions was measured against a blank of 6.8 phosphate buffer at 221 nm, and values are tabulated in Table 4 and shown in Fig 1.

Drug-excipient compatibility studies by infrared (IR)[3]

IR spectroscopy is one of the most powerful analytical techniques to identify functional groups of a drug. The pure drug and its formulation were subjected to IR studies. In the present study, the potassium bromide disc (pellet) method was employed. The graphs are shown in Fig. 2 and 3.

Formulation of orodispersible tablets of Eletriptan[3]

All the ingredients were weighed accordingly and passed through#60 mesh sieve separately. The drug and diluents were mixed by adding a

RESEARCH ARTICLE

Formulation and Evaluation of Lansoprazole Fast Dissolving Buccal Films

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Abstract

Aim: The aim of the study deals with the formulation and evaluation of fast dissolving buccal films of which is an effective and well-tolerated treatment option in the management of acid-related disorders. Lansoprazole fast dissolving buccal films are a new, patient-friendly, and more convenient formulation of which can be taken with or without water. **Materials and Methods**: In the present investigation, polyvinyl alcohol and polyvinylpyrrolidone were used as film-forming agents, and polyethylene glycol 400 is taken as plasticizer. Solvent casting method was used for the preparation of fast dissolving buccal films. **Results and Discussion:** The films were prepared and evaluated for film thickness, folding endurance, dispersion test, drug content, and dissolution. The *in vitro* dissolution studies were carried out using simulated salivary fluid (pH 6.8 phosphate buffer). **Conclusion:** Among all the formulations, formulation L7 was released up to 99.8% of the drug from the film within 5 min of time which exhibits faster absorption and also shows desirable characteristics of the film. The drug-excipient interaction studies carried out by Fourier-transform infrared studies, differential scanning calorimetry analysis–X-diffraction studies, and scanning electron microscopic studies, and the results revealed that there were no major interactions between the drugs and excipients used for the preparation of films.

Key words: Fast dissolving buccal films, Lansoprazole, Polyethylene glyol 400, Polyvinyl alcohol, Polyvinylpyrrolidone, Solvent casting method

INTRODUCTION

Lansoprazole is a proton-pump inhibitor (PPI) which inactivates the final step in the gastric acid secretion pathway in gastric parietal cells in a dose-dependent manner. Bioavailability is 85% after the first dose - the highest among PPIs,[1-5] and acid inhibition is swift, resulting in rapid relief of symptoms.[6] Lansoprazole also exhibits antibacterial activity against *Helicobacter pylori in vitro*.[7-9] 17 years of clinical experience worldwide have shown lansoprazole to be an effective and well-tolerated treatment option in the management of acid-related disorders, including gastric and duodenal ulcers and gastroesophageal reflux disease and the treatment or prevention of gastroduodenal lesions induced by non-steroidal anti-inflammatory drugs.[10] Lansoprazole is also effective in combination with different regimens for *H. pylori* eradication and is included in the first-line PPI-based options for this purpose.[7,8,11-13]

Lansoprazole fast dissolving buccal film (LFDBF) is an orally dissolving film and is a new, patient-friendly, and more convenient formulation of lansoprazole which can be taken with or without water. LFDBF, which has an artificial strawberry flavoring, disintegrates rapidly in the mouth and is swallowed easily with the patient's saliva. It is the first PPI that can be taken orally without water. This formulation represents an improved alternative presentation for all patients requiring lansoprazole, offering the benefits of a choice of administration options. LFDBF maintains the same pharmacological properties as lansoprazole capsules and can be taken by any patient who is currently prescribed lansoprazole. The ability to take a tablet either

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DEVELOPMENT OF FENOFIBRIC ACID DRUG LOADED PELLETS BY EXTRUSION SPHERONIZATION: A STATISTICAL DESIGN FOR OPTIMIZATION OF PROCESS VARIABLES

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ABSTRACT

The objective of the present investigation was to develop a drug loaded pellets of Fenofibric acid employing Extrusion spheronization process. This study evaluates the impact of certain process variables of extrusion spheronization technique in the feasability of producing Fenofibric acid drug loaded pellets. Impact of various process variables were assessed by using statistical interpretation such as ANOVA. A 3^3 (three factor, three level) face centered central composite design was employed to study the effect of independent variables on dependent variables. The selected process variables such as % Fluid uptake, Spheronizer speed and Spheronization time were studied, as well as their influences on the properties of Bulk density, % fines and % retains were determined. Optimization was done by fitting experimental data to the software program (Design Expert). The design space for process variables and its influence on responses was developed. Low fluid uptake, Higher spheronization speed and time leads to fines generation as well as high fluid uptake, low spheronization speed and time results in agglomerates. Water content and spheronizer speed interaction influence the sphere density. Fabricated pellets were characterized for various physico-chemical parameters. The optimized formulation showed desired drug release profile. The information acquired in this

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Multi-particulate Drug Delivery Systems of Fenofibric Acid: Optimization of Formulation Using Statistical Experimental Design

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Abstract

The objective of the present research work was to develop a multi-particulate modified release system of Fenofibric acid using Wurster (Bottom spray fluid bed coating) process. Impact of various formulation variables was assessed by using statistical interpretation such as ANOVA. A 3^3 (three factor, three level) face centered central composite design was employed to study the effect of independent variables (concentration of ER Polymer, plasticizer and pore former), on dependent variables (drug release at 2.5^{th} h & 6^{th} h). Optimization of the formulation variables was done by fitting experimental data to the software program (Design Expert). The design space for formulation variables was developed. Fabricated pellets were characterized for various physico-chemical parameters. *In vitro* release data of the optimized formulation was fitted into various kinetic equations. The optimized formulation showed a desired drug release at both 2.5^{th} h and 6^{th} h as 17.5 ± 2.28% & 87.1 ± 0.75% respectively. The drug release from the capsules followed first order kinetics and controlled by non fickian transport. The information acquired in this study recommends that the multi-particulates of Fenofibric acid can be effectively intended to give a delayed release of Fenofibric acid and thus enhanced bioavailability.

1 Introduction

Pharmaceutical research and development are increasingly focusing on advance drug delivery systems, which enhance desirable therapeutic intent while minimizing side effects. Now a days, the multiparticulate drug delivery systems are notably relevant for attaining controlled or delayed release oral formulations with reduced risk of local irritation, low risk of dose dumping, increased bioavailability and less inter and intra subject variability.

Bottom spray fluid bed (Wurster) process is one of the most favourable techniques for fabrication of pellets, as it promotes uniform coating, which leads to an systematic and predictable drug release[1-3].

Quality by design (QbD) is a comprehensive and proactive approach to support the pharmaceutical development in a more scientific, risk based manner, by restricting the flexibility in the manufacturing process to ensure predetermined product specifications. It helps to determine the critical material attributes (CMAs) and critical process parameters (CPPs) that influencing the predefined critical quality attribute (CQAs)[4].

Response surface methodology (RSM) is one of the desired methods in the development and optimization of drug delivery systems. Three level factorial design, Central composite design (CCD), D-optimal design and Box Behnken design are the various types of RSM designs available for statistical optimization of the formulations. Central composite design is one type of RSM design allows, all factors to be varied simultaneously, allowing quantification of the effects caused by independent variables and interactions between them.

Face centered central composite design contribute relatively high quality predictions over the entire design space and do not require using points outside the original factor range. Hence

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DEVELOPMENT OF FENOFIBRIC ACID DELAYED RELEASE PELLETS: OPTIMIZATION OF PROCESS VARIABLES IN FLUID BED PROCESS

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Abstract:

The objective of the present study was to optimize the process of Fenofibric acid delayed release (DR) pellets. Wurster (Bottom spray fluid bed coating) process was employed to develop the Fenofibric acid DR pellets. This study assesses the impact of various process variables on drug layering by using statistical interpretation such as ANOVA. A face centered central composite design (CCD) was employed to study the effect of independent variables (product temperature, atomization air pressure, fluidization air volume and spray rate) on dependent variables (Fines, agglomerates, coating efficiency and assay). Fabricated pellets were characterized for various physico-chemical parameters and stability studies. Optimization was done by fitting experimental results to the software program (Design expert). The design space for process parameters and its influence on %fines, % agglomerates, coating efficiency and assay was developed. From the obtained results, 40°C ± 3°C as product temperature, 0.8 -1.2 kg/cm^2 as atomization air pressure, 50 -65 cfm as fluidization air volume and 2-6 g/min as spray rate were selected as the operating ranges for robust coating process, desired yield and quality of the product. The drug release from the optimized formulation followed first order kinetics and controlled by non fickian transport. There is no significant change observed during stability. It was concluded that the face centered central composite design facilitated the process optimization of Fenofibric acid DR pellets. The Fenofibric acid DR pellets were successfully developed by employing bottom spray fluid bed coating (Wurster) technique.

Key-Words: *Fenofibric acid, Pellets, Fluid bed process, Process parameters, CCD.*

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COMPARATIVE IN VIVO EVALUATION OF EXTENDED RELEASE PELLETS AND ORAL SOLUTIONCONTAINING METHYLPHENIDATE HYDROCHLORIDE

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ABSTRACT

Methylphenidate Hydrochloride (HCl) is used to treat Attention deficit hyperactivity disorder (ADHD). Methylphenidate HCl Extended release (ER) pellets were successfully developed and optimized using wurster process. The present investigation aimed to evaluate the pharmacokinetic properties of Methylphenidate HCl ER pellets using rabbits as animal model. Blood samples were collected at various time intervals. The plasma concentration of Methylphenidate HCl was estimated by reverse phase liquid chromatography/ tandem mass spectroscopy (LC/MS/MS) method. The pharmacokinetic parameters were calculated from the plasma concentration of Methylphenidate HCl vs. time profile. The sustained T_{max}, lower C_{max} and prolonged Mean residence time (MRT) indicate an extended release of Methylphenidate HCl ER pellets compared to Methylphenidate HCl API. From the obtained results, it is concluded that the test formulation was provided extend thedelivery of Methylphenidate HCl in desired rate.

Key words: Methylphenidate HCl, Extended release, Pellets, Pharmacokinetics, formulation variables, process parameters

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INTRODUCTION

Multiple-dose units have many kinetic and therapeutic advantages over single-dose sustained release units, such as improved bioavailability, easy administration, reproducible gastric residence time, low risk of dose dumping, low intra and inter subject variability, flexibility of blending of different release profile and divided into various dose strengths without formulation changes. The most commonly used pelletization techniques are Suspension/solution layering, extrusion spheronization and powder layering. However, suspension/solution layering (Wurster) technique is most preferable in the pharmaceutical industry owing to its advantages like continuous process, less manual interruption and batch to batch reproducibility [1-3].

Methylphenidate HCl is an amphetamine like CNS Stimulant, commonly used to treat Attention deficit hyperactivity disorder (ADHD) in children, adolescents and adults. Its hydrochloride salt is freely soluble in water, stable and well absorbed from the intestinal tract, with a short elimination half life (i.e. 3 to 4 h). These favorable properties combined with a low dose and also need to decrease the dosing frequency, make methylphenidate as an ideal

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FORMULATION AND EVALUATION OF IMMEDIATE RELEASE TABLETS OF PIOGLITAZONE HYDROCHLORIDE BY EMPLOYING MODIFIED SUPERDISINTEGRANTS

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Keywords:

Pioglitazone Hydrochloride, Disintegration, Anti-Diabetic, Bioavailability

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ABSTRACT: The aim and objective of the present work is to design and develop immediate release tablets of pioglitazone hydrochloride to improve the patient compliance and desired bioavailability by selected delivery system by following immediate release mechanism. In the present investigation, super disintegrants used in the combination of 1:1 ratio were modified using co-processed technology with the solvents like acetone and methanol using solvent evaporation technique. The dissolution rate of the drug was significantly increased which reaches closer to the dissolution profile of marketed product. This was due to an increase in surface area of drug available for dissolution. The physical modification of super-disintegrants using co processing technique and selection of processed material with particle size specificity made the drugs to possess required characteristics as fast dispersible. The pre compression and post compression properties are determined as per the procedure prescribed. The drug release studies and kinetics indicate that the prepared tablets with co-processed superdisintegrants were best at its release in the entire tract of GIT due to their change in bio pharmaceutical property like dissolution. Optimized formulations were selected for stability concern and *in-vivo* performance. The best formulations retain its properties within the stability period of 3 months. The *in-vivo* properties evaluated confirmed the approach of good bioavailability by the drug with the help of the design of drug into immediate release product.

INTRODUCTION: A drug delivery system which dissolves FPst, in extreme cases, is a solid tablet that dissolves or disintegrates in oral cavity without water or chewing". Many of FPst-dissolving drug delivery system like films should include other excipients to mask the bad taste of the active compounds.

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All these are called as melt-in-mouth tablets, repi melts, porous tablets, oro - dispersible, quick dissolving or rapid disintegrating tablets [1] or immediate release tablets which makes to overcome the disadvantages of tablets like hand tremors, dysphasia occurrence in geriatric patients, the semi developed muscular systems in children and in case of bedridden, the problem of swallowing is very common phenomenon leads to very poor patient compliance [2].

Direct compression is selected as the technique where a group of ingredients can be blended, placed onto a tablet press, and made into a perfect tablet without any of the ingredients having to be

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RESEARCH ARTICLE

Design and Development of Oral Modified Release Formulations for Losartan Potassium with Natural and Modified Gums

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ABSTRACT:
The present study was under taken to develop oral modified release formulations for Losartan Potassium, an angiotensin-ii antagonist for the treatment of Hypertension. The tablets were prepared by wet granulation technique by using natural (Guar gum, Xanthan, Gum karaya, Gum kondagogu, Olibanum) and modified [CMGG (Carboxy methylated guar gum), CMGG-I (Carboxy methylated guar gum-Iodine), BG-C (Borax Guar gum- Cross linked), BG-F (Borax Guar gum- Films)] gums as release retardant polymers. The evaluation involves 3 stages i.,e. pre-compression, post compression parameters and in-vitro release kinetics assessment of tablets. The USP-II paddle method was selected to perform the dissolution test and 900ml of water was used as dissolution medium at 100rpm at 37^{0}C ± 0.5. The release kinetics was analyzed. All the formulations followed Peppa's release mechanism. When the release data was plotted into korsmeyer-Peppas equation (log cumulative % of drug release Vs log time), it was observed that formulations F1, F4, F5 (formulated with selected gums), F6 (formulated with modified gums)followed Anamalous (non- Fickian) type of mechanism whereas the formulations F2, F3 (formulated with selected gums) followed case II mechanism and formulations F7 to F9 (formulated with modified gums) followed Anamolous(Fickian) type of mechanisms. The in-vitro release studies revealed that the formulation F1 can be taken as ideal or optimized formulation for modified release formulations as it fulfills all the requirements.

KEYWORDS: Oral modified release formulations, Losartan potassium, Guar gum, Xanthan, Karaya, kondagogu, Olibanum, CMGG, CMGG-I, BG-C, BG-F, In-vitro release kinetics.

INTRODUCTION:

Sustained release formulations describe the slow release of a drug substance from a dosage form to maintain therapeutic response for extended period (8-12 h) of time. In long term therapy for the treatment of chronic disease conditions, conventional formulations are required to be administered in multiple doses and therefore have several disadvantages.

Sustained release formulations are preferred for such therapy because they maintain uniform drug levels; reduce dose and side effects, show better patient compliance, and increase the safety margin for high potency drugs. Introduction of matrix tablets as sustained release has given a new breakthrough for Novel Drug Delivery System (NDDS) in the field of pharmaceutical technology. The hydrophilic polymer matrix is widely used for formulating a sustained release dosage form. Drug release retardant materials are the key performers in the matrix systems. Natural polymers are economical, readily available, non-toxic and capable of chemical modifications, potentially biodegradable and biocompatible. Losartan Potassium (LP) is a potent, highly specific Angiotensin II Type 1 (AT1) receptor

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Study on Antirheumatoid Arthritis Activity

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Abstract: In recent years much attention was paid on role of polysaccharides isolated from natural sources.This study was carried out to investigate the effects of polysaccharide extracted from the green seaweed Cladophora indica Marten (Ci-ps) on collagen induced arthritis. To investigate these effects of Ci-ps of 2 varying test doses (test-200mg/kg , test-400mg/kg) in comparision to standard dexamethasone (0.1 mg/kg/day/po) ,assessment of various parameters such as body weight changes, arthritis index, paw volume and haematological parameters were performed. The body weight was fallen for all the arthritis induced groups, but. Ci-ps of Test -400mg/kg treated group had shown steady increase in bwt throughout the study period. Assessment of arthritis score revealed that high dose of Ci-ps extract has shown remarkable reduction in score when compared to arthritic control group. Test-400mg had shown remarkable decrease in paw volume on day 5 7, and 9 respectively. Haematological results revealed that there is a significant reduction in elevated WBC count, CRP & RF values. The study shows that Ci-ps extract (preferentially test-400mg/kg bwt) could effectively ameliorate CIA and significantly suppress the immune response against Collagen. Hence it can be concluded the polysaccharides of this green seaweed has potential antirhuematoid arthritic activity as they had shown promising results in ameliorating the disease associated altered parameteters.

Keywords: anti-rheumatoid, seaweeds, Green algae, Collagen induced arthritis and polysaccharides

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I. INTRODUCTION

Rheumatoid arthritis is a condition defined with imprecise etiology characterized by progressive joint destruction,bone deformities and can lead to premature death. The consequent morbidity and mortality have a substantial socioeconomic impact. The pathological condition of RA are well known such as the leucocyte infiltration, chronic inflammation, pannus formation and extensive destruction of the articular cartilage and bone.

In particular it was reported that the inflammatory cytokines ,such as TNF-α,IL-1β and IL-6,play key roles in inflammation and joint damages during the development of RA.Epidemilogy of RA in female to male is 3:1 and the prevalence is 1% of the world population. Drug therapy used in most cases is represented by: adrenocorticoid hormones, anti-rheumatic and immunosuppressive agents that can cause severe adverse effects such as liver and renal dysfunction,cortisol dependence,stomach problems. In spite of tremendous development in the field of synthetic drugs during recent era, they are found to have some or other side effects, It has been demonstrated by several research workers that the seaweed extracts exhibited anti-inflammatory,antioxidant ,antiarthritic activity [1]. Green seaweeds have been repeatedly used as natural materials from which to extract bioactive substances over the past 20 years because of their widespread distribution and large biomass. They are usually grown or collected for food consumption and especially known for their high nutritional value and health benefits. Marine green algae remain largely unexploited among the three main divisions of macroalgae (*i.e.*, Chlorophyta, Phaeophyta, and Rhodophyta). Interest in utilizing green seaweeds as natural resources has recently increased because of their many active ingredients, particularly those that may be used for medical purpose [2]. Green seaweeds reportedly contain lipid fractions, proteins, peptides, polysaccharide, carotenoids, phenolic compounds, alkaloids, thallus, holdfast, mucilaginous, and whole plants .Among all these active ingredients, polysaccharides are the components most intensively investigated for medical purposes[3].Considering the features described above the production and application of original polysaccharides as therapeutic agents have become increasingly important topics of research.in this context our study focuses on antirhematoid arthritis activity of green seaweed belonging to the order *Cladophorales*

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Design and in Vitro Evaluation Studies of Tramadol Hydrochloride Lozenzes for Treatment of Pain in Childreans

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Abstract: The oral route is the most preferred route of administration of drugs because of low cost of therapy, ease of administration, patient compliance and flexibility in formulation. The illness are associated with fever, head ache and body aches so to cure the above/relief from the above, there was need to adminster the drugs to the individuals but in case of pediatric patients it was difficult to administer the dosage forms like tablets, capsules, etc. In the present investigation an attempt has been made to prepare and evaluate the sugar based medicated tramadol hydrochloride hard lozenzes for pediatrics to overcome the administration. They were prepared by heating and congealing method on laboraty scale with malt syrup as base. All the formulations were subjected to various physico-chemical parameters such as hardness, friability, content uniformity, weight variation, thickness, drug content and in vitro dissolution studies. Drug-excipients compability stuidies were conducted by FT-IR spectroscopy and results revealed that no interactions were found between drug and excipients. The results of in vitro drug release studies showed that formulations F3, F6 and F9 releases the drug 96.72,95.32 and 98.66 percentage at the end of 30 mins. The hard lozenge can provide an attractive alternative formulatin in the treatment of pain in pediatric patiants.

Keywords: Tramadol Hydrochloride, Lozenges, HPMC: Hydroxy Propyl Methyl Cellulose, Na CMC: Sodium Carboxy Methyl Cellulose, MC: Methyl Cellulose

1. Introduction

In oral drug delivery, the mucosa of the mouth may appear to differ little from the rest of the moist lining of the gastro intestinal tract[1,2]. In fact, with the notable exceptions of the esophagus and uterine cervix, this tissue is remarkably different from all other mucosa of the body, and probably has more in common with skin, with which it is forms, a junction at the lips, than with the intestinal mucosa. The use of the oral mucosa for drug delivery has led to the tendency, at least in the dermatological literature, to regard oral mucosa as a highly permeable tissue. There are many dosage forms like Lozenges, tablets, inhalers, and syrups, are in markets for the treatment of the various diseases. The "Lozenges are flavoured medicated dosage forms intended to be sucked and hold in the mouth or pharynx. These preparations are commonly used for the purpose of local or systemic effect [3, 4]". Advantages of the Lozenges as dosage forms include increasing bioavailability, reduction in gastric irritation, bypass of first pass metabolism and increase in onset of action. New drug design to this area always benefit for the patient, physician and drug industry. There are several dosage forms like in the market, there is a need for more dosage forms which acts effectively and locally asa well as systemically. Oral thrush is a disorder caused by infection of the mouth due to fungus (yeast) candida albicans. In babies it may be a severe infection sometimes causing epidemics in schools by cross-infection[5].

Tramadol hydrochloride tablet lozenges are flavoured medicated dosage forms intended to be sucked and hold in mouth/pharynx. The present investigation is designed to improve patient compliance and these preparations are commonly used for the purpose of local or systemic effects through the buccal mucosa. Advantages of the Lozenges [6,7]as dosage forms includes increases in bioavailability, reduction in dose size, and reduces gastric irritation, bypass first pass metabolism. When it is not effectively treated, oral thrush often leads to hospitalization, limitations on