3.3 : Research Publications and Awards

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

3.3.1.1 Number of research papers in the journals notified on UGC website during the last five years

Year	2019-2020	2020-2021	2021-2022	2022-2023	2023-2024
Number	0	7	0	1	4

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3.3.1 Number of papers published per teacher in the Journals notified on UGC website during the year						
Title of paper	**Name of the author/s**	**Department of the teacher**	**Name of Journal**	**Year of publication**	**ISSN number**	**Link to the recognition in UGC enlistment of the Journal**
Ameliorative potential of methanolic twigs and leaves extract of Nyctanthes Arbortristis on Diabetes induced neuropathic pain in Albino wistar rats.	Cheshta Rawat, Arti Seti, Sonia Ranwat, Shivani Bhardwaj, Kanchan Singh, Akhilesh Nautiyal, Damit Kumar, Manvi Bhatt, Priyanka Sharma, Diksha sharma.	Pharmaceutics	European Chemical Bulletin	2023	5766-5794	ISSN 2063-5346 (Online) | European chemical bulletin | The ISSN Portal
Phytochemical and therapeutic potential of herbal cognitive enhancer	Abhishek Bharti, Kalpana Kashyap, Rutika, Akhil Moudgil, Kundan Singh Bora, Dinesh Kumar	Pharmacology	Journal of Natural Remedies	2023	0972-5547	Journal of Natural Remedies (informaticsjournals.com)
Nanosuspension as a promising Drug Delivery approach for the antidiabetic drug: An inclusive review on technology and future aspects.	Pooja Sharma, Sujit bose, Akhil Moudgil, Divya Arora, Sushila, Manish Vyas, Shivalika, Mamta Devi, Bhupendera Tomar	Pharmacology	AIP Conference Proceedings	2023	1551-7616	ACP - Abstracting and Indexing (A+I) | AIP Conference Proceedings | AIP Publishing
Critical review of current animal models of nephrotoxicity	Kunal Manshara, Akhil Moudgil, Aman Thakur	Pharmacology	International Journal of Pharmacy and Life Sciences	2023	0976-7126	ijplsjounal.com-Issues (ijplsjournal.com)
Review on Diabetic foot ulcers its Pathogenesis, epideminology and emerging treatments	Sanjay Kumar, Kamaljeet, Anjana Devi, Madhu Bala, Kiran Thakur, Akhil Moudgil	Pharmacognosy	YMER	2022	0044-0477	YMER – An International Peer-Reviewed Journal (ymerdigital.com)

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An update on Biodegradable microspheres loaded with Naltrexone	Madhu Bala, Akhil Moudgil, Sanjay Kumar	Pharmaceutics	International Journal of Pharma Research and Health Sciences	2020	2348-6465	https://portal.issn.org/resource/issn/2348-6465
Antidibetic activity of chemically synthetic compound on Alloxan Induced Diabetes in mice	Akhil Moudgil, Sanjay Kumar, Madhu Bala	Pharmacology	International Journal of Pharma Research and Health Sciences	2020	2348-6465	https://portal.issn.org/resource/issn/2348-6465
Marketing Regulation of Drugs in India	Narinder Nath Sharma, Vipin Kumar Bhulal, Sanjay Kumar	Pharmaceutics	Science, Technology and Development	2020	0950-0707	Science, Technology and Development Journal – UGC CARE GROUP -2 JOURNAL//editorstdjournal@gmail.com (journalstd.com)
Method Development and Validation for the Simultaneous estimation of in Ambroxol and Levocetrizine Bulk and Pharmaceutical Dosage form by using RP-HPLC method	Sanjay Kumar, Darsh Gautam, Poonam Talwan	Pharmaceutical Chemistry	International Journal of Research in Pharmacy and Chemistry	2020	2231-2781	IJRPC
Method Development and Validation for the Simultaneous estimation of in Atorvastatin and Fenofibrate Bulk and Pharmaceutical Dosage form by using RP-HPLC method	Poonam Talwan, Sanjay Kumar, Darsh Gautam	Pharmaceutical Chemistry	International Journal of Research in Pharmacy and Chemistry	2020	2231-2781	IJRPC

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Formulation and Evaluation of Mirtazapine Oral Thin Film	Sanjay Kumar, Darsh Gautam, Poonam Talwan	Pharmaceutics	International Journal of Research in Pharmacy and Chemistry	2020	2231-2781	IJRPC
Recent advances in particle characterization and its application in pharamaceutical industry	Poonam Dogra, Shikha atteri, Sanjay Kumar	Pharmacognosy	International Journal of Pharma Research and Health Sciences	2020	2348-6465	https://portal.issn.org/resource/issn/2348-6465

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List of Publication in 2023

S. No.	Title of Paper	Name of the authors	Department of teacher	Name of Journal	Year of Publication	ISSN number	Impact Factor	Link to website of journal	Link to article/paper/abstract of the article	Is it listed in UGC care list/Scopus/ Web of Science/other, mention
1	Ameliorative potential of methanolic twigs and leaves extract of Nyctanthes Arbortristis on Diabetes induced neuropathic pain in Albino wistar rats	Cheshta Rawat, Arti Seti, Sonia Ranwat, Shvani Bhardwaj, Kanchan Singh, Akhilesh Nautiyal, Damit Kumar, Manvi Bhatt, Priyanka Sharma, Diksha sharma	Pharmaceutics	European Chemical Bulletin	2023	5766-5794	0.24	ISSN 2063-5346 (Online) | European chemical bulletin | The ISSN Portal	(2) (PDF) AMELIORATIVE POTENTIAL OF METHANOLIC TWIGS AND LEAVES EXTRACT OF NYCTANTHES ARBOR-TRISTIS ON DIABETES INDUCED NEUROPATHIC PAIN IN ALBINO WISTAR RATS AMELIORATIVE POTENTIAL OF METHANOLIC TWIGS AND LEAVES	Scopus
2	Phytochemical and therapeutic potential of herbal cognitive enhancer	Abhishek Bharti, Kalpana Kashyap, Rutika, Akhil Moudgil, Kundan Singh Bora, Dinesh Kumar	Pharmacology	Journal of Natural Remedies	2023	0972-5547	0.35	Journal of Natural Remedies (informaticsjournals.com)	Phytochemical and Therapeutic Potential of Herbal Cognitive Enhancer | Journal of Natural Remedies (informaticsjournals.com)	Scopus
3	Nanosuspension as a promising Drug Delivery approach for the antidiabetic drug. An inclusive review on technology and future aspects	Pooja Sharma, Sujit bose, Akhil Moudgil, Divya Arora, Sushila, Manish Vyas, Shivalika, Mamta Devi, Bhupendra Tomar	Pharmacology	AIP Conference Proceedings	2023	1551-7616	0.16	ACP - Abstracting and Indexing (A+I) | AIP Conference Proceedings | AIP Publishing	Nanosuspension as a promising drug delivery approach for the antidiabetic drug. An inclusive review on technology and future aspects | AIP Conference Proceedings | AIP Publishing	Scopus
4	Critical review of current animal models of nephrotoxicity	Kunal Manshara, Akhil Moudgil, Aman Thakur	Pharmacology	International Journal of Pharmacy and Life Sciences	2023	0976-7126	1.4	ijplsjournal.com-Issues (ijplsjournal.com)	https://www.ijplsjournal.com/issues%20PDF%20files/Archives-2023/June-July%202023/2.pdf	SCOPUS, UGC APPROVED

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AMELIORATIVE POTENTIAL OF METHANOLIC TWIGS AND LEAVES EXTRACT OF *NYCTANTHES ARBOR-TRISTIS* ON DIABETES INDUCED NEUROPATHIC PAIN IN ALBINO WISTAR RATS

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ABSTRACT

Background: *Nyctanthes arbor-tristis* is a small ornamental tree renowned for its anti-diabetic activity. Being a rich source of all useful phytoconstituents, traditionally, it's also used in treating many other diseases. However, its role in curing diabetic neuropathy is still not clear. The main objective of this study is to investigate the potential effect of *Nyctanthes arbor-tristis* against streptozotocin (STZ)-induced diabetic neuropathy in rat.

Method: The study was planned with 36 animals and 6 animals in each group. Group 1 (Control group), Group 2 (Diabetic Control), Group 3 (Active Control), Group 4(Test Group-1), Group 5(Test Group-2) & Group-6 (Test Group-3). STZ (50mg/kg) was given intraperitoneally to induce diabetes in Albino wistar rats. After 21 days animals' were assessed for diabetic neuropathy. Rats with diabetic neuropathy were treated for 3 weeks with methanolic extract of *Nyctanthes arbor-tristis* leaves & twigs (100,200,400mg/kg p.o.).,Glibenclamide (10mg/kg p.o.) and amitryptiline (10mg/kg i.p) were used as standard drug. Treatment outcomes were based on metabolic, physiological & biochemical changes.

Result: Treatment with methanolic extract of *Nyctanthes arbor-tristis* significantly decreases blood sugar levels and neuropathic pain as compared to the disease control

Nanosuspension as a Promising Drug Delivery Approach for the Antidiabetic Drug: An Inclusive Review on Technology and Future Aspects

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Abstract. Nanosuspension is a part of nanotechnology which is a submicron colloidal dispersion of pharmaceutically active ingredients in a liquid phase having a size range below 1 um, and which is stabilized by surfactants and polymers. Most of the newly developed drugs are water-insoluble, show poor bioavailability. Glimepiride is an anti-diabetic drug that belongs to the sulfonylurea class, which is used to treat type II diabetes mellitus. Glimepiride increases insulin secretion by acting on the β-cells of the pancreas. Glimepiride binds to sulphonylurea receptors which are present on β-cell on the plasma membrane, which close the ATP-sensitive potassium channel leading to depolarization of the cell membrane. So there is the opening of voltage-gated calcium channel due to which there is an influx of calcium ions causes the secretion of the preformed insulin molecule. It is categorized under biopharmaceutical classification system class II drug, having poor solubility and high permeability. In this review, different methods were studied to formulate the nanosuspension of glimepiride to increase the solubility of glimepiride.

Keywords-Glimepiride, Nanosuspension, Anti-Diabetic, Solubility, Polymers, Drug Deliver

INTRODUCTION

Diabetes mellitus (DM) is a chronic, life-long endocrine, and metabolic disorder that occurs due to a defect in insulin secretion and insulin action. Insulin is the hormone that is produced by a specialized cell called β-cells present on the organ pancreas. Normally our body breakdown the carbohydrates and sugars which convert into glucose molecule and act as fuel for our body, but for utilization of glucose, hormones insulin is required. The deficiency of insulin leads to an increase in the blood glucose level in a body along with disturbances in the metabolism of carbohydrates, fats, and proteins. If diabetes is uncontrolled then it leads to severe diabetic complications like retinopathy, neuropathy, and various cardiovascular complications.

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Critical review of current animal models of nephrotoxicity

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Abstract

Nephrotoxicity occurs when the renal blood is exposed to a nephrotoxic drug or toxin that causes damage to the kidneys. This may lead to acute kidney failure. In this condition the kidney function deteriorates and may lead to chronic kidney failure. If unchecked, the kidney failure may lead to the death. When kidney damage occurs, the kidney fails to remove excess urine and waste leading to retention of nitrogenous waste products of metabolism in the blood. The biochemical parameters commonly used to evaluate kidney function are serum urea, creatinine, uric acid, potassium, sodium and chloride. The animal models play a very important role for understanding the mechanism of nephrotoxicity and development of effective therapy for its optimal management. Since there are many pathways for induction of renal failure, therefore, a large number of animal models have been developed to produce the clinical conditions of renal failure. The present review will help to find an appropriate model to evaluate the new drug or molecule that can protect from nephrotoxicity.

Keywords: Animal, Model, Nephrotoxicity

Introduction

Nephrotoxicity can be defined as a renal disease or dysfunction produced by medication of drugs and other environmental factors and it is directly related to the (ARF) Acute renal failure (Lakshmi and Kiran, 2012) and (AKI) Acute renal injury is a reversible loss of function of renal cells in kidney that result in rapid fall in glomerular filtration rate (GFR) as well as retention of minerals and water (C. Late, 1996).

It has been found that drugs are responsible for 20% of all cases for (ARF) acute renal failure. Drug like antibiotics, anticancer, anti-inflammatory, NSAIDS, aminoglycoside exhibit and adverse effect on renal function and couse lose of immune system responses in the body. So in recent time, interest in drug-induced nephrotoxicity has been increased with increasing number of drugs to affect the renal cells (Ganguli and Prakash, 2003; Ogunnowo, 2015).

Most of the drugs are found to be harmful nephrons produce one or more pathogenic mechanism in the kidney. Pathological conditions include: hemodynamic, changes tubular cells toxicity, nephritis syndrome, urinary tract infection, chronic intestinal nephritis, and (Singh et al., 2014).

The present comprehensively required the methodology information regarding various animal models of nephrotoxicity.

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JOURNAL OF NATURAL REMEDIES
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SHORT COMMUNICATION

Phytochemical and Therapeutic Potential of Herbal Cognitive Enhancer

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Abstract

Memory is the most significant factor in distinguishing one person from another, as it is necessary to recognise one's own self. The brain can encode, store, and retrieve information using three different types of memory. Individuals who lack these basic forms of memory are unable to create personal relationships, acquire new knowledge, and perform basic everyday duties. Memory refers to a person's ability to encode, store, retain, and recall knowledge and past events in his or her brain. Memory gives a person the ability to learn from and adapt to previous experiences, as well as the ability to recall previously taught facts, skills, and habits. Today, poor memory, weak recall, and low retention are all typical issues. Memory deteriorates primarily because of stress and exhaustion. Memory loss, often known as age-related memory impairment, is frequent in those over the age of 40. This could be linked to the loss of hormones and proteins (growth factors) that repair brain cells as people get older. Herbs were employed to improve memory power in India throughout ancient times. Indian and Chinese cultures developed many traditional medicines from herbs to treat diminishing cognition, reverse memory loss, and improve learning power. Nootropic herbs are known for their brain-acting; herbs and smart medications, which are derived from their isolated ingredients and aid to improve blood circulation in the brain. The focus of this review is on natural agents and herbs that work as memory enhancers. By using one of the herbs at a time, one can improve his or her memory.

Keywords: Acetylcholine, Alzheimer's Disease, Herbs, Memory, Nootropics

1. Introduction

Memory is a typical learning ability that indicates long-term changes in the nervous system caused by short encounters. Short-term memory and long-term memory are the two types of memory. There are a variety of drugs available in the market for maintaining memory or enhancing memory but some of them have huge side effects also especially in the case of synthetic drugs[1]. *Bacopa monniera*, also called *Bacopa monnieri*, *Herpestis monniera*, and *Brahmi*, has been used in Ayurvedic medicine for millennia[2] in the case of study about memory the brain is the most important, the forebrain, midbrain, and hindbrain are the three fundamental sections of the human brain. It includes the hypothalamus, thalamus, cerebellum, cerebral cortex, hippocampus, midbrain, and several other glands, with the Hippocampus being important for memory. Memory is a very significant aspect for recalling situations, information, and experiences, but because of certain conditions like stress, negative emotions cause various illnesses such as amnesia, memory loss, high blood pressure, anxiety, and several serious life treatments in that individuals can record events, information, and stimuli over a time. Thus, over recent decades, herbs and natural cures are very useful in the promotion of intelligence such as *Medhya* herbs related

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List of Publication in 2022

S. No.	Title of Paper	Name of the authors	Department of teacher	Name of Journal	Year of Publication	ISSN number	Impact Factor	Link to website of journal	Link to article/paper/abstract of the article	Is it listed in UGC care list/Scopus/ Web of Science/other, mention
1	Review on Diabetic foot ulcers its Pathogenesis, epideminology and emerging treatments	Sanjay Kumar, Kamaljeet, Anjana Devi, Madhu Bala, Kiran Thakur, Akhil Moudgil	Pharmacognosy	YMER	2022	0044-0477	5.7	YMER – An International Peer-Reviewed Journal (ymerdigital.com)	YMER210522.pdf (ymerdigital.com)	Scopus

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REVIEW ON DIABETIC FOOT ULCERS ITS PATHOGENESIS, EPIDEMIOLOGY AND EMERGING TREATMENTS

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Abstract

Diabetic foot complications aren't exactly a hot topic. Diabetic nephropathy, heart attack and stroke aren't as common as diabetic foot complications although they are still the most common complications of diabetes. As a result of diabetic foot infections and lesions, the majority of diabetics are hospitalised and require long-term hospitalizations. In the case of diabetic foot ulcers (DFUs), which can lead to amputations of the limb, as well as significant social, psychological, and economic effects. A DFU can develop in up to 25% of diabetic people throughout the course of their lives, and more than half of those patients become infected. As a result, in order to avoid undesirable results, infection and ulcer recovery must be carefully managed. Doctors and patients alike should be aware of the latest developments in DFU treatment. An overview of the current assessment and treatment options for DFUs is provided here in order to assist clinicians in making educated decisions, including molecular and regenerative medicine; energy-based antimicrobial therapies; plant extracts; antimicrobial peptides; growth factors; devices; and nanomedicine.

Keywords: *Diabetic foot ulcers, Antimicrobial activity, Neuropathy, Therapeutic treatment*

List of Publication in 2021

S. No.	Title of Paper	Name of the authors	Department of teacher	Name of Journal	Year of Publication	ISSN number	Impact Factor	Link to website of journal	Link to article/paper/abstract of the article	Is it listed in UGC care list/Scopus/ Web of Science/other, mention
1	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil

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List if Publication in 2020

S. No.	Title of Paper	Name of the authors	Department of teacher	Name of Journal	Year of Publication	ISSN number	Impact Factor	Link to website of journal	Link to article/paper/abstract of the article	Is it listed in UGC care list/Scopus/ Web of Science/other, mention
1	An update on Biodegradable microspheres loaded with Naltrexone	Madhu Bala, Akhil Moudgil, Sanjay Kumar	Pharmaceutical Chemistry	International Journal of Pharma Research and Health Sciences	2020	2348-6465	Nil	https://portal.issn.org/resource/issn/2348-6465	https://www.pharmahealthsciences.net/pdfs/volume8-issue2/2020/2-vol8-issue2-2020-MS-15790-Review2.pdf	Google Scholar
2	Antidibetic activity of chemically synthetic compound on Alloxan Induced Diabetes in mice	Akhil Moudgil, Sanjay Kumar, Madhu Bala	Pharmacology	International Journal of Pharma Research and Health Sciences	2020	2348-6465	Nil	https://portal.issn.org/resource/issn/2348-6465	https://www.pharmahealthsciences.net/pdfs/volume8-issue2/2020/4-vol8-issue2-2020-MS-15791.pdf	Google Scholar
3	Marketing Regulation of Drugs in India	Narinder Nath Sharma, Vipin Kumar Bhalal, Sanjay Kumar	Pharmacognosy	Science, Technology and Development	2020	0950-0707	6.1	Science, Technology and Development Journal – UGC CARE GROUP -2 JOURNAL(editorstdjournal@gmail.com) (journalstd.com)	32-april2020.pdf - Google Drive	UGC Group-II
4	Method Development and Validation for the Simultaneous estimation of in Ambroxol and Levocetrizine Bulk and Pharmaceutical Dosage form by using RP-HPLC method	Sanjay Kumar, Darsh Gautam, Poonam Talwan	Pharmaceutical Chemistry	International Journal of Research in Pharmacy and Chemistry	2020	2231-2781	6.2	IJRPC	03.pdf (ijrpc.com)	Google Scholar
5	Method Development and Validation for the Simultaneous estimation of in Atorvastatin and Fenofibrate Bulk and Pharmaceutical Dosage form by using RP-HPLC method	Poonam Talwan, Sanjay Kumar, Darsh Gautam	Pharmaceutical Chemistry	International Journal of Research in Pharmacy and Chemistry	2020	2231-2781	6.2	IJRPC	(PDF) Method Development and Validation for the Simultaneous Estimation of in Atorvastatin and Fenofibrate Bulk and Pharmaceutical Dosage Form by Using RP-HPLC Method	poonam talwan - Academia.edu	Google Scholar
6	Formulation and Evaluation of Mirtazapine Oral Thin Film	Sanjay Kumar, Darsh Gautam, Poonam Talwan	Pharmaceutics	International Journal of Research in Pharmacy and Chemistry	2020	2231-2781	6.2	IJRPC	05.pdf (ijrpc.com)	Google Scholar
7	Recent advances in particle characterization and its application in pharamaceutical industry	Poonam Dogra, Shikha atteri, Sanjay Kumar	Pharmacognosy	International Journal of Pharma Research and Health Sciences	2020	2348-6465	Nil	https://portal.issn.org/resource/issn/2348-6465	(2) Recent Advances in Particle Characterization and its Application in Pharmaceutical Industry	Request PDF	ResearchGate.net	Google Scholar

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Int J Pharma Res Health Sci. 2020; 8 (2): 3136-38
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CODEN (USA)-IJPRUR, e-ISSN: 2348-6465

PHS Scientific House

International Journal of Pharma Research and Health Sciences

Available online at www.pharmahealthsciences.net

Review Article

An Update on Biodegradable Microspheres Loaded with Naltrexone

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ABSTRACT

The use of biodegradable polymers for microencapsulation of naltrexone using techniques like solvent evaporation is the need of the hour. The naltrexone microspheres for the preparation of matrix devices will help to understand the microencapsulation. Nowadays, the emphasis is being laid on the development of controlled release dosage forms. Interest in this technology has been increasing steadily over the past few years. Although the oral administration of drugs is a widely accepted route of drug delivery, the bioavailability of drugs often varies as a result of gastrointestinal absorption, biodegradation by the first-pass effect. There are many ways of achieving long-term drug delivery of parental origin; biodegradable microspheres are one of the better means of controlling the release of the drug over a long time. Likewise, emulsions, stability on a long-term basis, and in suspensions, rheological changes during filling, injecting, and storage possess a limiting factor. The extent of release rate in these systems cannot be tailor-made to the needs of the patient. Injectables formulations based on biodegradable microspheres can overcome these problems and can control the release of the drug over a predetermined period. In the order of days to weeks and even to the months. The effect of different process parameters, such as drug/polymer ratio and stirring rate during the preparation of microspheres, on the morphology, size distribution, and in vitro drug release of microspheres. The review mainly covers various molecules encapsulated in biodegradable microspheres for parenteral delivery.

Keywords: Biodegradable Microspheres, Naltrexone, polymers.

1. INTRODUCTION

Microspheres are characteristically free-flowing powders consisting of proteins or synthetic polymers, which are biodegradable and ideally having a particle size less than 200 μm [1] and which can be injected by 18 or 20 number needle [2]. The drug absorption and side effects due to irritating drugs against the gastrointestinal mucosa are improved because the biodegradable microsphere is made up

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Akhil M *et al.*
CODEN (USA)-IJPRUR, e-ISSN: 2348-6465

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International Journal of Pharma Research and Health Sciences

Available online at www.pharmahealthsciences.net

Review Article

Antidiabetic Activity of Chemically Synthetic Compound on Alloxan Induced Diabetes in Mice

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ARTICLE INFO

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Accepted: 20 Apr 2020

ABSTRACT

Alloxan a nitrosourea derivative is one of the most universally accepted diabetogenic agents. The selective β-cell toxicity of alloxan depends on the degree of DNA alkylation and subsequent activation of poly ADP ribose synthetase in the base excision repair pathway, this stimulated activation of poly ADP ribose synthetase triggers exhaustion of NAD+ in the pancreatic islets that will lead to β-cell death through necrosis. In the present study, the objective was to study the evaluation of the antidiabetic activity of the chemically synthetic compound on alloxan-induced diabetes in mice. Chemically synthetic compounds were given to the mice after the administration of alloxan and glucose levels were estimated using a semi-auto analyzer at a range of 505/670nm. The hyperglycaemic levels due to alloxan administration lead to the development of diabetes. Treatment with chemically synthetic compounds significantly lowers the elevated glucose levels in alloxan-induced diabetic mice. Hence compound number 1321,05152,0717 has potential antidiabetic activity. To explore further exhaustive study is required for the mechanism behind the anti-diabetic activity of their chemical compounds.

Keywords: Alloxan, diabetogenic agent, antidiabetic activity, hyperglycaemic levels.

1. INTRODUCTION

Diabetes mellitus (DM), commonly referred to as **diabetes**, is a group of metabolic diseases in which there are high blood sugar levels over a prolonged period. Symptoms of high blood sugar include frequent urination, increased thirst, and increased hunger. If left untreated, diabetes can cause many complications. Acute complications include diabetic ketoacidosis and nonketotic hyperosmolar coma. Serious long-term complications include cardiovascular disease,

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MARKETING REGULATION OF DRUGS IN INDIA-REVIEW

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ABSTRACT

The pharmaceutical industry is one of the most regulated industries; no drug would be marketed without the teams of medical researchers and other specialists who worked to make sure it receives regulatory authority's approval. A regulatory authority is an agency of the government that is responsible for protecting public health in safety aspects. A Approval of the drug product for import, manufacturing and marketing in India, its demonstration for safety and efficacy in humans is essential. The Rules 122A, 122B and 122D, 122 DA, 122DAA, 122E and Appendix I, IA and VI of Schedule Y of the Drugs & Cosmetics Act, 1945, describes the information/data required for approval of clinical trial and/or to import, manufacture, or market any new drug in the country. Marketing of drug products is major concern issue now days. So every country has its own guidelines and own regulatory bodies for any drug approval and for marketing of the drug products. India is emerging as an important player in pharmaceutical field, but to maintain this growth and to emerge as a key player on the global market, a strong and supportive regulatory framework is essential or the advantage gained so far would be lost

INTRODUCTION

The current global economic climate is placing tremendous pressure on pharmaceutical companies to maximize the value of their assets. Sponsors with novel therapies seek to speed up time-to-market and introduce their products in multiple countries as quickly as possible. Companies with established products want to increase sales by expanding into additional markets to offset impending patent expirations. Confronted with these marketplace challenges, no pharmaceutical company can afford first-round submission failures or other regulatory delays that prevent its products from reaching their targeted markets in a timely fashion.

A proactive, regulatory filing strategy helps any pharmaceutical company large or small gets the most from its product portfolio by accelerating global product introductions while avoiding regulatory pitfalls. By understanding the differences in regulatory processes for countries around the world, and taking advantage of the Common Technical Document defined by the International Conference on Harmonization, pharmaceutical companies can significantly improve the speed and efficiency of preparing regulatory submissions while reducing the risk of costly delays.

Drug Regulatory Affairs:

Regulatory Affairs in a Pharmaceutical industry, is a profession which acts as the interface between the pharmaceutical industry and Drug Regulatory authorities across the world.It is mainly involved in the registration of the drug products in respective countries prior to their marketing.

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Research Article

METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF IN AMBROXOL AND LEVOCETIRIZINE BULK AND PHARMACEUTICAL DOSAGE FORM BY USING RP-HPLC METHOD

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ABSTRACT

A simple, accurate, economical and reproducible reverse phase high performance liquid chromatographic (RP-HPLC) method was developed and validated for the determination of Ambroxol and Levocetirizine in bulk and pharmaceutical formulations. The separation was achieved on a phenomenex C18 column (150 × 4.6 mm i.d, particle size of 5µ) using a mixture of 0.01M Potassium dihydrogen orthophosphate (pH 5.0 ± 0.05) & Acetonitrile (60:40 v/v) as mobile phase in an isocratic elution mode, at a flow rate of 1 ml/min. The detection was monitored at 230 nm. The retention time of was found to be around 3.60min (Levocetirizine) 4.68min (Ambroxol) respectively. Excellent linearity range was found between12-120 µg/ml for Ambroxol and 1-10µg/ml for Levocetirizine, n. The method was validated with respect to linearity, robustness, precision and accuracy and was successfully applied for the simultaneous determination of Ambroxol and Levocetirizine from the combined dosage formulation.

1. INTRODUCTION

Amroxol (AMB) is chemically Trans-4-(2-Amino-3,5- dibromobenzylamino)- cyclo hexan-1-ol AMB is Mucolytic ,respiratory agent and used in the treatment of the upper respiratory tract diseases. With its mucolytic activity, AMB facilitates the breakdown of acid muco polysaccharide fibres in the mucous thus making it thinner and less viscous for expectoration. As well it stimulates the production of pulmonary surfactant, a substance fiund to play a major role in the lung defense mechanism and thereby further protect it against inflammation and infection. Levocetirizine(LCTZ) is chemically (2-(4-[(R)-(4-chlorophenyl) (phenyl)methyl]- piperazin-1-yl) ethoxy)acetic acid.Levocetirizine is a third generation non-sedative antihistamine developed from the second generation antihistamine cetirizine. It is the R-enantiomer of the cetirizine which functions to block histamine receptors. More specifically, LCTZ does not prevent the actual release of histamine from mast cells but prevents its binding to its receptors. This in turn prevents the release of other allergy chemicals and increases the blood supply to the area providing relief from the symptoms of hay fever. Literature survey revealed that AMB and LCTZ has been estimated individually or in combination using UV, HPLC and HPTLC. The present work describes the development of a simple, precise, accurate and reproducible spectrophotometric method for the simultaneous estimation of AMB and LCTZ in Pharmaceutical dosage form[1-14].

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METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF IN ATORVASTATIN AND FENOFIBRATE BULK AND PHARMACEUTICAL DOSAGE FORM BY USING RP-HPLC METHOD

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ABSTRACT

A simple, accurate, economical and reproducible reverse phase high performance liquid chromatographic (RP-HPLC) method was developed and validated for the determination of Atorvastatin and Fenofibrate in bulk and pharmaceutical formulations. The separation was achieved on a Thermo Scientific BDS C18 column (250 × 4.6 mm i.d 5m) using a mixture of 25mMSodium acetate (pH adjusted to 5.0 With 1.0 M Glacial acetic acid): Acetonitraile (10::90 % v/v)as mobile phase in an isocratic elution mode, at a flow rate of 1 ml/min. The detection was monitored at 254 nm. The retention time of Atorvastatin and Fenofibrate was found to be around 2.672±0.05 min (Atorvastatin) 4.971±0.07 min (Fenofibrate) respectively. Excellent linearity range was found between 1-5 µg/ml for Atorvastatin and 1-5 µg/ml for Fenofibrate. The method was validated with respect to linearity, robustness, precision and accuracy and was successfully applied for the simultaneous determination of Atorvastatin and Fenofibrate from the combined dosage formulation.

1. INTRODUCTION

Atorvastatin (ATOR) is chemically7[2(4fluorophenyl)3phenyl4(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoate. Atorvastatin is a HMG-COA reductase inhibiter actas anti- hyper lipidemic drug clinically effective drug in the treatment of Hyper cholestrimia . It issoluble in methanol, ethanol, and acetonitrile. Practically insoluble in water. Fenofibrate (FENO),propan2-yl2-{4-[(4-chlorophennyl)carbonyl] phenoxy}-2methyl ropionate is a widely used asAnti-cholesrtimic agent as ppar receptor inhibiter. Atorvastatin and Fenofibrate is available incombined dosage forms as film coated tablets (LIPIKIND). Each tablet contains 10mg of Atorvastatin and 160 mg of Fenofibrate. It is used for the treatment of Hyper Cholestrimia.

For this combination derivative spectroscopic methods and reverse phase liquid chromatographic methods are reported. However, there is no work reported on combination of these drugs by standard addition simultaneous equation method. Hence fast, simple, and accurate and validated spectrophotometric method was developed by standard addition of both drugs by applying simultaneous equation method, the developed method was simple, accurate, precise, specific, sensitive and reproducible which can be efficiently and easily applied to pharmaceutical dosage forms.

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Research Article

FORMULATION AND EVALUATION OF MIRTAZAPINE ORAL THIN FILM

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ABSTRACT

The aim of this present investigation was to develop a rapid dissolving oral polymeric film, using the solvent casting method, having good mechanical properties, instant disintegration and dissolution, an acceptable taste in the oral cavity. Mirtazapine is a tetracyclic antidepressant drug mainly in patients affected by depression The present investigation was undertaken with the objective of formulating of the Mirtazapine rapid dissolving oral thin films allowing fast reproducible drug dissolution in oral cavity thus bypassing first pass metabolism, to enhance the convenience and compliance by the elderly and pediatric patients .Nine formulation of films with drug were prepared using both natural and synthetic polymers like HPMC E6 and Sodium Alginate. Propylene glycol was used as plasticizers. Citric acid was used as a saliva stimulating agent. Synthetic Aspertame was used as sweetening agent. The resultant films were evaluated for weight variation, assay, content uniformity, folding endurance, thickness, tensile strength, percent elongation, surface pH, *in vitro* disintegration and *in vitro* dissolution. The F4 formulation showing the best results. the disintegration time is only 3.5 second. and was releasing upto 100.8% of drug within 20 minutes.

Keywords: Mirtazapine , solvent casting method. Oral thin film and HPMC E6.

INTRODUCTION

More recently, fast-dissolving films are gaining interest as an alternative to fast-dissolving tablets to definitely eliminate patients' fear of chocking and overcome patent impediments. Fast-dissolving films are generally constituted of plasticized hydrocolloids or blends made of thereof that can be laminated by solvent casting or hot-melt extrusion

The oral route is one of the most preferred routes of drug administration as it is more convenient, cost effective, and ease of administration lead to high level of patient compliance. The oral route is problematic because of the swallowing difficulty for pediatric and geriatric patients who have fear of choking. Patient convenience and compliance oriented research has resulted in bringing out safer and newer drug delivery systems. Recently, fast dissolving drug delivery systems have started gaining popularity and acceptance as one such example with increased consumer choice, for the reason of rapid disintegration or dissolution, self-administration even without water or chewing.

Mirtazapine is a tetracyclic antidepressant used mainly in patients affected by depression[1,2]. The novel antidepressant mirtazapine has a dual mode of action. It is a noradrenergic and specific serotonergic antidepressant (NaSSA) that acts by antagonizing the adrenergic alpha2-autoreceptors and alpha2-heteroreceptors as well as by blocking 5-HT2 and 5-HT3 receptors[3,4]. It enhances, therefore, the release of nor epinephrine and 5-HT1A-mediated serotonergic transmission. Increased activation of the central 5-HT_{1A} receptor is thought to be a major mediator of efficacy of Mirtazapine .This dual mode of action may conceivably be responsible for mirtazapine's

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Review Article

Recent Advances in Particle Characterization and its Application in Pharmaceutical Industry

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ABSTRACT

Particle size characterization is a area of analytical chemistry which is required in a great number of industries where the product's end-use is affected by particle size distribution. The Particles can be in the form of solids, liquids, or gases or an aggregation of molecules as in the case of micelles. Particularly In some instances, especially in the area of pharmaceuticals finished forms, analyses are done to ensure the absence of particulate matter in the product. Particle size characterization helps in monitoring the environment accurately for particulate matter as well as particle size distributions, concentrations for full assessment of health hazard substances. The growing interest in particle size characterization and analysis, especially among analytical chemistry researchers, the subject is mainly emphasized on the application. The number of techniques available for particle size analysis is confounding. More than 250 methods have been reported by the analytical researchers for understanding and assessing the particle size.. Because of the broad scope of this area in terms of techniques and analytical approaches, products, and size ranges major technique areas have been discussed. which have received the most attention in recent years: radiation scattering and chromatographic techniques. The new and growing areas are rapidly becoming techniques of choice especially for the rapid analysis of submicrometer particles.

Keywords: Particle Size Characteristics, Analytical Technique, Size, Chromatographic techniques

1. INTRODUCTION

Particle size characterization techniques currently in use within pharmaceutical industry and academia. It assumes no prior knowledge of particle characterization theory or instrumentation and should be ideal for those new to particle

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