DVV Clarification

3.3.1_2 Screenshots of research articles clearly showing the title of the article, affiliation, name of the journal, year and authors name

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

Title of paper	**Name of the author/s**	**Department of the teacher**	**Name of journal**	**Calendar Year of publication**	**ISSN number**	**Link to the recognition in UGC enlistment of the Journal /Digital Object Identifier (doi) number**		
						Link to website of the Journal	Link to article / paper / abstract of the article	Is it listed in UGC Care list
Drug Delivery and Therapeutic Approaches to Prostate Cancer	**Jameel Ahmed S Mulla**	Pharmaceutics	Indian Journal of Novel Drug Delivery	2018	0975-5500	https://www.ijndd.in/	https://www.ijndd.in/drug-delivery-and-therapeutic-approaches-to-prostate-cancer/	Yes
Formulation and Standardization of Asava of Syzygium Cumini	**Patil S. V., Aralelimath V.** R., Mahajan V. A., Inamdar N. R. and Shinde S. S.	Pharmaceutics Pharmacology	Indian Drugs	2018	0019-462X	https://www.indiandrugsonline.org/	https://www.indiandrugsonline.org/issuesarticle-details?id=ODM4	Yes
Formulation and Evaluation of Fast Dissolving Oral Films of Domperidone	**Jameel Ahmed S Mulla**, Utkarsh A Chopade, Suraj B Kumbhar, Pallavi S	Pharmaceutics	Indian Journal of Novel Drug Delivery	2018	0975-5500	https://www.ijndd.in/	https://www.ijndd.in/formulation-and-evaluation-of-fast-dissolving-oral-films-of-domperidone/	Yes

	Marathe, Priyanka V Ware							
Effect of Polyethylene Glycol on Physiochemical Properties of Spherical Agglomerates of Antidiabetic Drug	**Aralelimath V. R., Patil S. V., Patrakar R. G.**	Pharmacology Pharmaceutics Pharmacognosy	Current Pharma Research	2018	2230-7842	https://jcpr.humanjournals.com/	https://jcpr.humanjournals.com/effect-of-polyethylene-glycol-on-physiochemical-properties-of-spherical-agglomerates-of-antidiabetic-drug/	Yes
Development and Characterization of Rapidly Disintegrating Tablets of Amlodipine Besylate	Shivani D Jadhav, **Jameel Ahmed S Mulla**	Pharmaceutics	Indian Journal of Novel Drug Delivery	2018	0975-5500	https://www.ijndd.in/	https://www.ijndd.in/development-and-characterization-of-rapidly-disintegrating-tablets-of-amlodipine-besylate/	Yes
Formulation and Evaluation of Chitosan Based Transdermal Patches of Lornoxicam for Prolonged Drug Release and to Study the Effect of Permeation Enhancer	Adhikrao Vyankatrao Yadav, **Mukund Namdeo Urade**	Pharmacology	Indian Journal of Pharmaceutical Education and Research	2019	0019-5464	https://www.ijper.org/	https://www.ijper.org/article/909	Yes
Formulation and In Vitro, In Vivo Evaluation of Proniosomal Gel of Neomycin Sulphate	Amol Shete, **Priyanka Thorat**, Rajendra Doijad, Sachin Sajane	Pharmaceutics	International Journal of Applied Pharmaceutics	2019	0975-7058	https://journals.innovareacademics.in/index.php/ijap/index	https://journals.innovareacademics.in/index.php/ijap/article/view/30614	Yes
Optimizatio	Shivratna	Pharmac	Turkish	2019	2148-	https://www.	https://www.t	Yes

n of Thiazolidone Scaffolds Using Pocket Modeling for Development of Potential Secretory System Inhibitors of *Mycobacterium tuberculosis*	V. Khare, Sujata P. Choudhari, Siddharth P. Phalle, Santosh S. Kumbhar 1, Prafulla B. Choudhari, Sambhaji R. Masal, Aakash K. Patil, Rakesh P. Dhavale, Durgacharan A. Bhagwat, **Atul M. Kadam**	eutics	Journal of Pharmaceutical Sciencesa		6247	turkjps.org/	urkjps.org/archives/archive-detail/article-preview/optimization-of-thiazolidone-scaffolds-using-pocke/26306	
Analytical method development and validation of Valacyclovir to estimate from its formulation	**P. D. Lade, S. V. Patil,** S. S. Kadam, O. B. Tipugade, P. G. Nakhare	Pharmaceutical Chemistry Pharmaceutics	Current Pharma Research	2019	2230-7842	https://jcpr.humanjournals.com/	https://jcpr.humanjournals.com/analytical-method-development-and-validation-of-valacyclovir-to-estimate-from-its-formulation/	Yes
Design, Development and Characterization of Fast Dissolving Oral Film of Clonazepam	Govind G Nikam, **Jameel Ahmed S Mulla**	Pharmaceutics	Indian Journal of Novel Drug Delivery	2020	0975-5500	https://www.ijndd.in/	https://www.ijndd.in/design-development-and-characterization-of-fast-dissolving-oral-film-of-clonazepam/	Yes
A Novel Corticosteroid Cubosomes – For Ocular	Snehal Shashaikant Chakorkar, **Jameel Ahmed**	Pharmaceutics	Indo American Journal of Pharmaceutical Research	2020	2231-6876	https://www.iajpr.com/	https://zenodo.org/records/3923714	Yes

Drug Delivery	**S. Mulla**							
Formulation and Evaluation of Teneligliptin-Loaded Mucoadhesive Microspheres	**Jameel Ahmed S Mulla**, **Vijayanand R Aralelimath**, Omkar Tipugade, Shreyasi S Shinde, Nisha G Tetgure, Ayesha A Mulla, Dinesh D Gavali	Pharmaceutics Pharmacology	Indian Journal of Novel Drug Delivery	2020	0975-5500	https://www.ijndd.in/	https://www.ijndd.in/formulation-and-evaluation-of-teneligliptin-loaded-mucoadhesive-microspheres/	Yes
Characterization, antioxidant, antimicrobial and cytotoxic activities of green synthesized silver and iron nanoparticles using alcoholic *Blumea eriantha* DC plant extract	Chavan, R. R., Bhinge, S. D., Bhutkar, M. A., Randive, D. S., Wadkar, G. H., Todkar, S. S., & **Urade, M. N.**	Pharmacology	Materials Today Communications	2020	2352-4928	https://www.sciencedirect.com/journal/materials-today-communications	https://www.sciencedirect.com/science/article/abs/pii/S2352492820323312X	Yes
Microemulsion Based Hydrogel Formulation for Topical Drug Delivery - A Concise Review	**Jameel Ahmed S Mulla** and Biradev S Karande	Pharmaceutics	Indian Journal of Novel Drug	2021	0975-5500	https://www.ijndd.in/	https://www.ijndd.in/microemulsion-based-hydrogel-formulation-for-topical-drug-delivery-a-concise-review/	Yes
Effect of polymers and process parameters	Sandip Honman, **Atul Kadam**,	Pharmaceutics	Journal of Drug Delivery Science	2021	1773-2247	https://www.sciencedirect.com/journal/journal-of-	https://www.sciencedirect.com/science/article/abs/pii/S177	Yes

in augmenting the compactability and dissolution behaviour of oxcarbazepine spherical agglomerates	Sujata Choudhari, Raviraj Patil, Siddique Akber Ansari, Vinod Gaikwad		and Technology			drug-delivery-science-and-technology	3224721002586	
Formulation and Characterization of Rapidly Dissolving Buccal Films of Montelukast Sodium	Ankita B Hogale, **Jameel Ahmed S Mulla**	Pharmaceutics	Indian Journal of Novel Drug	2021	0975-5500	https://www.ijndd.in/	https://www.ijndd.in/formulation-and-characterization-of-rapidly-dissolving-buccal-films-of-montelukast-sodium/	Yes
Ecopharmacovigilance: Perspectives, concepts, applications, and relationships in modern context	Prachi Khamkar, Debarshi KarMahapatra, **Atul Kadam**	Pharmaceutics	Journal of Pharmacovigilance and Drug Research	2021	2582-7235	https://www.jpadr.com/index.php/jpadr	https://jpadr.com/index.php/jpadr/article/view/19	Yes
Regulatory challenges and myths in pharmaceutical 3D printing	**Atul Kadam,** Prachi Khamkar	pharmaceutics	European Pharmaceutical Review	2021	1360-8606	https://www.europeanpharmaceuticalreview.com/	https://www.europeanpharmaceuticalreview.com/article/143008/regulatory-challenges-and-myths-in-pharmaceutical-3d-printing/	Yes
Formulation and Process Validation of Clarithromycin Loaded Immediate Release Tablets	Ketaki S. Shinde, Dr. R. C. Doijad, **Dr. J. S. Mulla** and Sachin S. Mali	Pharmaceutics	World Journal of Pharmacy and Pharmaceutical Sciences	2022	2278-4357	https://www.wjpps.com/wjpps_controller/index	https://www.wjpps.com/Wjpps_controller/abstract_id/16195	Yes

Basic Aspects of Pharmaceutical Process Validation of Solid Dosage Forms: Quality Assurance Point of View	Ketaki S. Shinde, Dr. R. C. Doijad, **Dr. J. S. Mulla** and Sachin S. Mali	Pharmaceutics	European journal of pharmaceutical and medical research	2022	2394-3211	https://www.ejpmr.com/	https://www.ejpmr.com/home/abstract_id/9508	Yes
Floating Microspheres: A Novel Drug Delivery System	Omkar B Tipugade, **Jameel Ahmed S Mulla**	Pharmaceutics	Indian Journal of Novel Drug Delivery	2022	0975-5500	https://www.ijndd.in/	https://www.ijndd.in/floating-microspheres-a-novel-drug-delivery-system/	Yes
Periplaneta americana L. a potential source of traditional medicine: chemometric analysis, *in vitro* and *in silico* study	Suchismeeta Behera, Amulyaratna Behera, Suman Kumar Mekap, Chinmaya Chidananda Behera, **Atul Kadam** & Prafulla K. Mohanty	Pharmaceutics	Journal of Biomolecular Structure and Dynamics	2022	1538-0254	https://www.tandfonline.com/journals/tbsd20	https://www.tandfonline.com/doi/abs/10.1080/07391102.2021.1938681	Yes
Non-Ionic Surfactant Vesicle (Niosome): A Novel Drug Delivery System	Sandhya S Shewale**,** **Jameel Ahmed S Mulla**	Pharmaceutics	Indian Journal of Novel Drug Delivery	2022	0975-5500	https://www.ijndd.in/	https://www.ijndd.in/non-ionic-surfactant-vesicle-niosome-a-novel-drug-delivery-system/	Yes

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IJNDD

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Review Article

Drug Delivery and Therapeutic Approaches to Prostate Cancer

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Liposomes,
Nanoparticles

ABSTRACT

According to the global cancer statistics, prostate cancer is the second most often diagnosed cancer in males worldwide and it ranks in fifth place among cancer-related deaths. Localized prostate cancer is usually treated by surgical removal of the prostate (radical prostatectomy) or by radiation therapy. Both treatment options are frequently associated with severe side effects. Drug delivery to prostate through conventional route is associated with pharmacokinetics based and side effects related problems. This review briefly highlighted about prostate structure and its cancer. Different therapeutic approaches such as radiotherapy, chemotherapy, immunotherapy, androgen deprivation therapy (ADT), focal therapies and systemic therapies; and drug delivery approaches such as liposomes, polymeric based nanoparticles and micelles, dendrimers, gold nanoparticles, carbon based nanoparticles and magnetic nanoparticles for prostate cancer are also outlined here.

INTRODUCTION

Cancer

Cancer is the second leading cause of death worldwide, and is accountable for a predictable 9.6 million deaths in 2018. Globally, about 1 in 6 deaths is due to cancer. About 70% of deaths from cancer occur in low- and middle-income countries. The most common cancers are; lung (2.09 million cases), breast (2.09 million cases), colorectal (1.80 million cases), prostate (1.28 million cases), skin cancer (non-melanoma) (1.04 million cases) and stomach (1.03 million cases). Cancer arises from the transformation of normal cells into tumour cells in a multistage process that normally progresses from a pre-cancerous lesion to a malignant tumour. These changes are the consequence of the interaction between a person's genetic factors and 3 categories of external agents, including (a) physical carcinogens, such as ultraviolet and ionizing radiation (b) chemical carcinogens, such as asbestos, components of tobacco smoke, aflatoxin (a food contaminant), and arsenic (a drinking water contaminant) (c) biological carcinogens, such as infections from certain viruses, bacteria, or parasites [1].

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Prostate

The prostate is one of the male accessory glands that contribute to the male ejaculate by producing seminal fluid. In mice, elimination of this organ reduces fertility [2]. The understanding of development, maturation and anatomy of prostate has progressed gradually throughout the past century, but it has been moderately hindered by reliance on historical anatomical descriptions [3-5]. Description of prostatic lobes has been replaced by the now widely accepted concept that the human prostate is better described as consisting of zones found within one discrete organ [6].

The prostate is an exquisitely steroid hormone sensitive organ. Considering hormone action throughout the different life stages of prostate organogenesis, puberty, and during adulthood and aging, is critical for understanding prostate anatomy and the different diseases of this organ. Certainly, most of men experience some form of prostate pathology during their lifetime. The focus has been on investigating the long-term impact of disruption of normal prostate development on structural and functional abnormalities related to specific types of prostate disease that often are not recognized until much later in life [7].

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FORMULATION AND STANDARDIZATION OF ASAVA OF *SYZYGIUM CUMINI*

ABSTRACT

Asavas and Arishtaare alcoholic medicaments prepared by allowing the herbal juices or their decoctions to undergo fermentation with the addition of sugar. Standardization of ayurvedic formulation is essential in order to assess the quality of drugs.Inthe present study standardization of asava from *Syzygiumcumini,* known to be effective in diabetics has been performed.Asava formulation was prepared by reported traditional method of ayurveda. Formulation has been standardized by modern scientific quality control procedure for the finished productas. Standardization of asava was achieved by organoleptic study, physicochemical parameters such as pH, specific gravity, total solid content, acid value, alcohol content, refractive index, total reducing sugars and stability study. The results has revealed that the physicochemical parameters were within the limits and the values could be used to establish and formulate procedures for standardization and quality controlling of these ayurvedic formulations.

Keywords: standardization, asava, arishta, *syzygiumcumini*, diabetics

The word Ayurveda is composed of two parts ayur and veda, Ayur means life and veda means knowledge. Ayurveda has long and strong heritageof use of poly herbal drugs and formulations to treat various diseases[1]. Asava and Arishta are alcoholic medicaments prepared by allowing the herbal juices or their decoctions to undergo fermentation with the addition of sugars[2]. Formulation of Asava and Arishta has done by soaking the drugs, either in coarse powder form or in the form of decoction, in a solution of sugar or jaggery, for a specified period of time, during which it undergoes a process of fermentation[3,4]. Aasava have been used as medicines far over 3000 years to treat various disorders & are also taken as appetizers and stimulants. It is liquid preparations containing self generated alcohol, thus contain water soluble as well as alcohol soluble substances of the drugs. Due to their medicinal value, sweet taste, and easy availability people are prone toconsume higher doses of these drugs for longer periods. As per Samhita, Asava is Madya which is prepared with apakwa Aushada.The compound which is prepared by 'asutaprakriya' is called as Asava[5,6]. Asavais a type of Madya, which contains decoction of different drugs, guda, and dhataki, described by Sushruta. Asava is defined as that which is prepared from ikshurasa, described by Sushruta. Vagbhata has also defined Asava as Madya prepared using fresh tubers, roots, fruits etc. and Madya with medicinal properties is called as Asava[7, 8]. But the systematic quality control parameters of such problem is main reason for reproducibility along with control over batch to batch uniformity[9, 10]. The aim of present study was formulation and standardization of the Asava an Ayurvedic formulation to establish typical quality control parameters of such formulations.

All powdered ingredients were collected from Unique Chemicals, Kolhapur, Maharashtra, India. All Chemicals used were of analytical grade.

Approximately 250mL of water taken in to the cleaned fermentation flask (glass;350mL), with hot water and Sugar/Jaggary/Wheat flour, was dissolved in to it. This mixture was boiled for half an hour, cooled to room temperature to have a final mixture. All ingredients as given in Table I were weighed and passed through sieve no 44 and ingredients from 1 to 14 were added to the final mixture. Dhatakipusha (*woodfordia fructicosa*) was then added to the mixture. The vessel was closed with a clean lid followed by wrapping around the lid with clay smeared cloth. The vessel was kept at dark place for 40 days.

After the stipulated period, the vessel was withdrawn. Preparation showed dark brownish fluid, pleasant smelland alcoholic taste. The fluid was filtered through muslin cloth, prepared asava was kept in a container.

Organoleptic characteristics odour, taste, colour and clarity of prepared asava formulation was determined.

Digital pH meter was used to check the pH of formulations. Before the experiment the machine was calibrated by using standard buffer solution of pH4.0, 7.0 and 9.2.

The density and specific gravity were determined by using density bottle method[11].

The viscosity was determined by Ostwald viscometer.

Total solid content determination

20mL of the Asava formulation wastaken in evaporating dish and evaporated to dryness on a water bath and then

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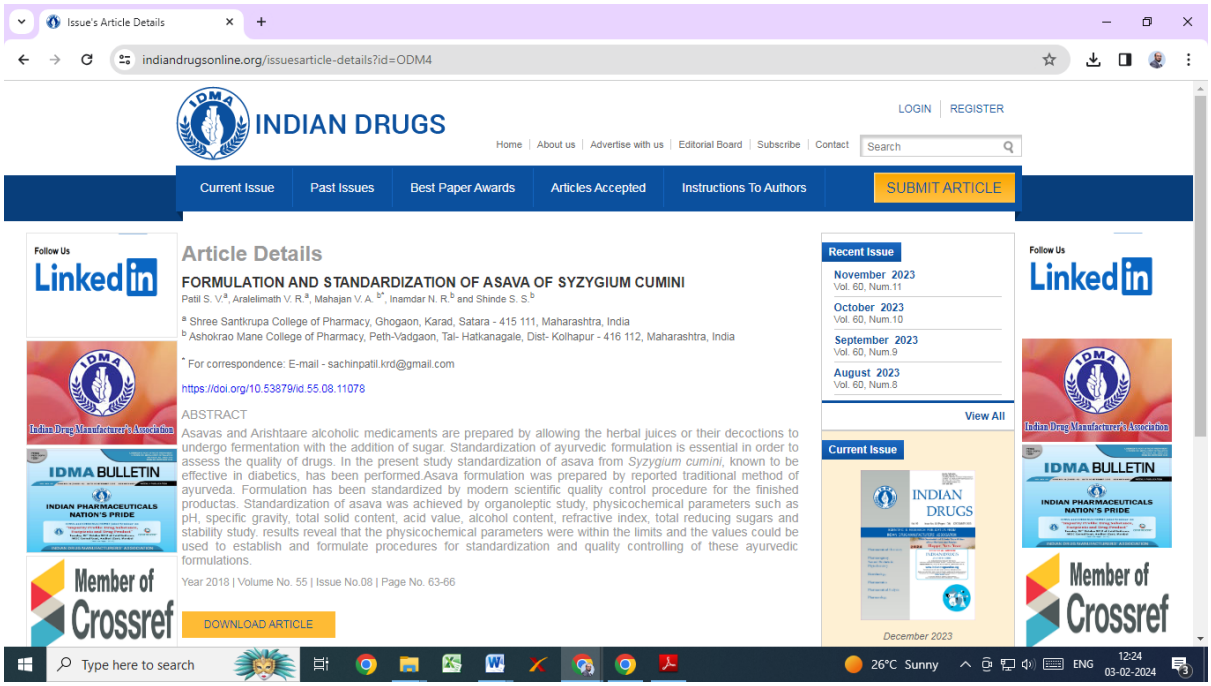

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Research Article

Formulation and Evaluation of Fast Dissolving Oral Films of Domperidone

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Fast Dissolving Oral Film,
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FTIR,
DSC,
Mouth Dissolving Time

ABSTRACT

The oral route remains the most preferred for the general population. This system will provide maximum therapeutic efficacy, increased bioavailability and maximum stability by reducing the frequency of dosage. The present work aims to formulate and evaluate fast dissolving oral films of domperidone using HPMC K100 and HPMC E15 as film forming agents by solvent casting method. The prepared films were characterized for weight variation, thickness, tensile strength, folding endurance, surface pH, *in vitro* disintegration time and mouth dissolving time. Polymer ratio and concentration of superdisintegrants played important role in disintegration and mouth dissolving time. *In vitro* drug release profile exhibited that formulation with higher concentration of superdisintegrants dissolves the oral films faster than the others.

INTRODUCTION

Fast dissolving oral films provide the opportunity to administer medicines and avoid first-pass metabolism [1]. Fast dissolving oral films may also be used in children [2, 3], patients with dysphasia [4], and elderly patients [5]. Although certain products such as paracetamol are available as oral suspension, these contain additives and sugar, which may not be advisable for children [6]. In addition, administrating oral liquid formulations to children is challenging by using syringes [7]. These concerns are triggers for the development of more number of fast dissolving oral films formulations. A fast dissolving oral film has been successfully used to deliver medicines to patients having difficulty in swallowing, those with oral pain due to mucositis or after oral surgery, or those with nausea [8].

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. Recently, fast dissolving films are gaining interest as an alternative of fast dissolving tablets. The films are designed to dissolve upon contact with a wet surface, such as the tongue, within a few seconds, meaning the consumer can take the product without need for additional liquid. It gives quick absorption and instant bioavailability of drugs due to high blood flow and permeability of oral mucosa is 4-1000 times greater than that of skin. This convenience provides both a marketing advantage and increased patient compliance. As the drug is directly absorbed into systemic circulation, degradation in gastrointestinal tract and first pass effect can be avoided. These points make this formulation most popular and acceptable among paediatric and geriatric patients and patients with fear of choking. Over-the-counter films for pain management and motion sickness are commercialized in the US markets.

Fast dissolving films are useful in patients such as paediatric, geriatrics, bedridden, emetic patients, diarrhoea, sudden episode of allergic attacks, or coughing for those who have an active life style. It is also useful whether local action desired such as local anaesthetic for toothaches, oral ulcers, cold sores or teething.

Advantages of fast dissolving films include; Convenient dosing, No water needed, No risk of chocking, Taste masking, Enhanced stability, Improved patient compliance, The drug enters the systemic circulation with reduced hepatic first pass effect, Site specific and local action, Availability of large surface area that leads to rapid disintegration and dissolution within oral

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Research Article

Effect of Polyethylene Glycol on Physiochemical Properties of Spherical Agglomerates of Antidiabetic Drug.

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ABSTRACT
Spherically agglomerated crystals of Pioglitazone hydrochloride (PGH) with improved flowability and compactibility were successfully prepared by emulsion solvent diffusion method. Plane agglomerates and agglomerates with polyethylene glycol 6000 (PEG) 1% and 2% were prepared using methanol, chloroform and water as good solvent, bridging liquid and poor solvent respectively. Particle size, flowability, compactibility and packability of agglomerates were preferably improved for direct tabletting compared with raw PGH. These improved properties of spherically agglomerated crystals were due to their large and spherical shape and enhanced fragmentation during compaction which was well supported by increased tensile strength and less elastic recovery of its compact. X-ray powder diffraction and differential scanning calorimetry study were indicated polymorphic transition of PGH from form II to I during recrystallization but not associated with chemical transition indicated by Fourier transforms infrared spectra.

KEYWORDS
Spherical crystallization, polyethylene glycol 6000, pioglitazone hydrochloride, compatibility, pack ability.

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Research Article

Development and Characterization of Rapidly DisintegratingTablets of Amlodipine Besylate

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Amlodipine Besylate,
Rapidly Disintegrating Tablets,
Superdisintegrants,
Disintegration Time,
In Vitro Drug Release

ABSTRACT

Hypertension is one of the most important causes of premature death worldwide and the problem is growing; in 2025, an estimated 1.56 billion adults will be living with hypertension. Amlodipine besylate is a longacting calcium channel blocker used in the treatment of chronic stable angina, vasospastic angina and hypertension. Recent developments in the technology have prompted scientists to develop Rapidly Disintegrating Tablets (RDTs) with improved patient compliance and convenience. The present study aims to prepare and evaluate amlodipine besylate Rapidly Disintegrating Tablets using superdisintegrants by direct compression method. Amlodipine loaded-RDTs were characterized for weight variation, hardness, thickness, friability, wetting time and disintegration time. In vitro drug release study was performed using United States Pharmacopoeia (USP) II dissolution testing apparatus II (paddle method). The results revealed that Amlodipine loaded-RDTs were successfully formulated with good mouth feel, faster disintegration and better drug release.

INTRODUCTION

Hypertension, also known as high or raised blood pressure, is a condition in which the blood vessels have persistently raised pressure. Blood is carried from the heart to all parts of the body in the vessels. Each time the heart beats, it pumps blood into the vessels. Blood pressure is created by the force of blood pushing against the walls of blood vessels (arteries) as it is pumped by the heart. The higher the pressure the harder the heart has to pump [1].

Globally, nearly one billion people have high blood pressure (hypertension); of these, two-thirds are in developing countries. Hypertension is one of the most important causes of premature death worldwide and the problem is growing; in 2025, an estimated 1.56 billion adults will be living with hypertension. Hypertension kills nearly 8 million people every year, worldwide and nearly 1.5 million people each year in the South-East Asia (SEA) Region. Approximately one-third of the adult population in the SEA Region has high blood pressure [2].

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Amlodipine besylate, chemically described as 3-Ethy l-5-methyl (±)-2-[(2-aminoethoxy) methyl]-4-(2-chlorophenyl)-1, 4-dihydro -6-methyl-3, 5-pyridinedicarboxylate monobenzene sulphonate [3, 4], is a long-acting dihydropyridine calcium channel blocker commonly used in the treatment of hypertension. Amlodipine selectively inhibits transmembrane influx of calcium ions into cardiac and vascular smooth muscle, leading to decreased vascular tone, reduced systemic vascular resistance, diminished after load and coronary vasodilation [5].

The term oral drug delivery, also known as peroral delivery, refers to taking a dosage form by mouth for local action or systemic absorption at any point along the gastrointestinal (GI) tract. Oral drug delivery is the most readily available and widely accepted route of delivery for medications. The most obvious challenge is that many drugs have a bad taste when placed in the mouth or exhibit foul odors, which must be resolved to be acceptable to patients. Apart from this, there are also many barriers and obstacles that inhibit drug absorption via the oral route. These include the acidic gastric environment, digestive enzymes, mucus layer diffusion and tight junctions between epithelial cells that prevent paracellular transport [6, 7]. Many

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Development and characterization of rapidly disintegrating tablets of amlodipine besylate

Shivani D Jadhav, Jameel Ahmed S Mulla

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Abstract:

Hypertension is one of the most important causes of premature death worldwide and the problem is growing; in 2025, an estimated 1.56 billion adults will be living with hypertension. Amlodipine besylate is a long acting calcium channel blocker used in the treatment of chronic stable angina, vasospastic angina and hypertension. Recent developments in the technology have prompted scientists to develop Rapidly Disintegrating Tablets (RDTs) with improved patient compliance and convenience. The present study aims to prepare and evaluate

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Original Article

Formulation and Evaluation of Chitosan Based Transdermal Patches of Lornoxicam for Prolonged Drug Release and to Study the Effect of Permeation Enhancer

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ABSTRACT

Objective: The objectives of present investigation were to develop transdermal system for Lornoxicam using chitosan as rate controlling polymer and Tween 20 as permeation enhancer. Then evaluate the effect of Tween 20 on the physico-chemical properties of the patches and on drug permeation across the membrane. **Methods:** Transdermal patches of Lornoxicam were prepared by solvent casting method. The prepared patches were evaluated for physicochemical characteristics such as *in vitro* drug release, skin irritation studies. The interaction between drug and polymer were investigated by FTIR, DSC, XRPD methods. **Results:** The *in vitro* release studies revealed Formulation L4 containing higher concentration of Tween 20 showed 74.6% diffusion in 12 h and follows Korsmeyer-Peppas drug release kinetics. Respective formulation did not showed any sign of erythema or edema in skin irritation test. FTIR study reveals good compatibility between drug and polymer. **Conclusion:** The prepared transdermal drug delivery system of Lornoxicam using Chitosan had shown good promising results for sustained release matrix transdermal patch formulation.

Key words: Transdermal patches, Chitosan, Lornoxicam, Tween 20, *in-vitro* release studies.

INTRODUCTION

Transdermal drug delivery system provides controlled drug release through skin to reach systemic circulation. Transdermal delivery also has leading edge over oral route by avoiding first pass metabolism of drugs. Transdermal delivery serves variety of advantages compared with the traditional oral route of drug administration. Transdermal drug delivery systems are non-invasive and inexpensive, self-administered, improve patient compliance and can provide release of drugs for long periods of time. The challenge remains for transdermal delivery is that only limited number of drugs is amenable to administration by this route.[1] Treatment of chronic diseases/disorders such as asthma, rheumatoid arthritis by transdermal route of drug administration might prove to have several advantages over other routes of drug administration.[2]

Chitosan is *N*-deacetylated derivative of chitin, semi-rigid polysaccharide, which is composed of *N*-acetyl D-glucosamine and D-glucosamine. Chitosan is a promising biomaterial in view of its biodegradability; biocompatibility and nonantigenecity.[3] Chitosan has bio-adhesive or mucoadhesive property that readily binds to negatively charged surfaces such as mucosal membranes. Chitosan greatly enhances the transport of polar drugs across epithelial surfaces. Chitosan is insoluble in neutral and basic environments due to lack of positive charge. Chitosan has a positive charge under acidic conditions due to protonation of free amino groups which enhances the solubility.[4]

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Formulation and Evaluation of Chitosan Based Transdermal Patches of Lornoxicam for Prolonged Drug Release and To Study the Effect of Permeation Enhancer

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Original Article

FORMULATION AND *IN VITRO, IN VIVO* EVALUATION OF PRONIOSOMAL GEL OF NEOMYCIN SULPHATE

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ABSTRACT

Objective: The objectives of present investigation were to prepare and evaluate proniosomes of neomycin sulphate (NS) by coacervation phase separation method by using sorbitan monostearate (span 60) and lecithin as a surfactant to increase the penetration through the skin and study the effect of concentration of the same.

Methods: Proniosomes of neomycin sulphate (NS) were prepared by coacervation phase separation method by using span 60 and lecithin. The effect of concentration of span 60 and lecithin was studied by factorial design. The prepared proniosomes were converted to gel by using carbopol as a gelling agent. The prepared formulations were evaluated for entrapment efficiency, *in vitro* drug diffusion, *in vitro* antibacterial activity and *in vivo* skin irritation test etc.

Results: All Formulation showed the percentage entrapment efficiency in the range 38.31±0.05% to 77.96±0.06%, good homogeneity and gel was easily spreadable with minimal of shear. Optimized formulation showed enhanced rate of diffusion *in vitro*, increase in zone of inhibition against *staphylococcus aureus*, no skin irritation and showed good stability.

Conclusion: The results of present study indicates that proniosomal gel formulated by using combination of span 60, Lecithin, cholesterol can be used to enhance skin delivery of NS because of excellent permeation of drug. Developed proniosomal gel formulation was promising carrier for NS

Keywords: Proniosomes, Neomycin Sulphate, Sorbitane monostearate (span 60), Lecithin and Cholesterol

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INTRODUCTION

Oral route of administration is most accepted route for majority of drugs but still faces challenges as compared to other routes. Transdermal route gives better control of blood level, reduce systemic toxicity, it protects drug from the hepatic first pass metabolism, better patient compliance and can be a potential option for oral dosage forms. Human skin is the important target site for the application of drug especially in the treatment of local disease. Penetration enhancement with special formulation approaches is mainly based on the usage of colloidal carriers [1]. Colloidal carrier have distinct advantages over conventional drug delivery as it act as drug containing reservoirs, modification of the particle composition or surface can adjusts the release rate to the target site [2]. These carriers accumulate in stratum corneum or other upper skin layers and are not expected to penetrate into viable skin. The penetration enhancement is the most critical factor in the transdermal drug delivery [3]. Hence it is necessary to increase the flux through skin membrane by using different approaches of penetration enhancement. Vesicular systems have been widely studied as vehicles for dermal and transdermal drug delivery. A number of vesicles systems such as liposomes, niosomes, ethosomes, emulsomes and transfersomes have been developed. The vesicular carrier such as niosomes has distinct advantage over conventional dosage forms because these particles can act as drug reservoir [1-2].

Compounds having high molecular weight cannot cross skin, need some amendment owing to the availability of novel methods that might enhance the transport of large molecular weight compounds into or through the skin. Vesicular systems especially niosomes and liposomes are well established system for the transdermal route but the stabilityis the major problem of these carriers. Liposome exhibits some difficulties such as instability of aqueous dispersions on storage and the leakage of the encapsulated drugs. Also the high cost of synthetic phospholipids.

An alternative approach i.e. niosomes that overcomes several of these problems associated with liposomes [3]. Non-ionic surfactant vesicles obtained on hydration of synthetic non-ionic surfactants, with or without incorporation of cholesterol or other lipid [4]. But the proniosomes are more advantageous than nonionic surfactant vesicles i.e., niosomes, in terms of physical stability such as aggregation, fusion and leaking, and provide additional convenience in transportation, distribution, storage, and dosing [5]. Proniosomes encloses both hydrophilic and lipophilic drugs. Proniosomes reduce the toxicity related to drug because of their non-ionic nature of surfactant [6].

Neomycin Sulphate is a bactericidal aminoglycoside antibiotics (or antibacterial agent) is categorized as a BCS class-III i.e. high solubility and poor permeability, and generally it used as topical agent in skin infection. Physicochemical properties of NS like highly polar nature and high molecular weight (908.87D). Poor skin permeability (<3%) of Neomycin sulphate reduces its deeper penetration in skin [7]. That aminoglycoside antibiotic works by binding to the bacterial 30S ribosomal subunit, causing misreading of t-RNA, leaving the bacterium unable to synthesize proteins vital to its growth [8-10]. In present investigation proniosomal gel of NS was prepared by using span 60 and lecithin to increase the skin penetration.

MATERIALS AND METHODS

Materials

Neomycin Sulphate was obtained as a gift sample from Encube Ethical Pvt. Ltd. Goa. Span 60, Cholesterol and carbopol 934 were purchased from Loba Chemicals, Mumbai. Lecithin was purchased from Research lab Mumbai. All other ingredients were of analytical grade.

Formulation of proniosomal gel

Proniosomes were prepared by the modified literature method reported by Fang *et al.* 2001 [11]. Proniosomes prepared by co-acervation phase separation method. Precisely weighed amount of drug, surfactant, cholesterol, lecithin, and organic solvent (Ethanol) taken in wide mouth container. After mixing all ingredients, the open end of glass tube was covered with a lid to prevent loss of solvent from it and warmed on water bath at 60-70 °c for about 10 min, until the surfactants were dissolved completely. Then aqueous

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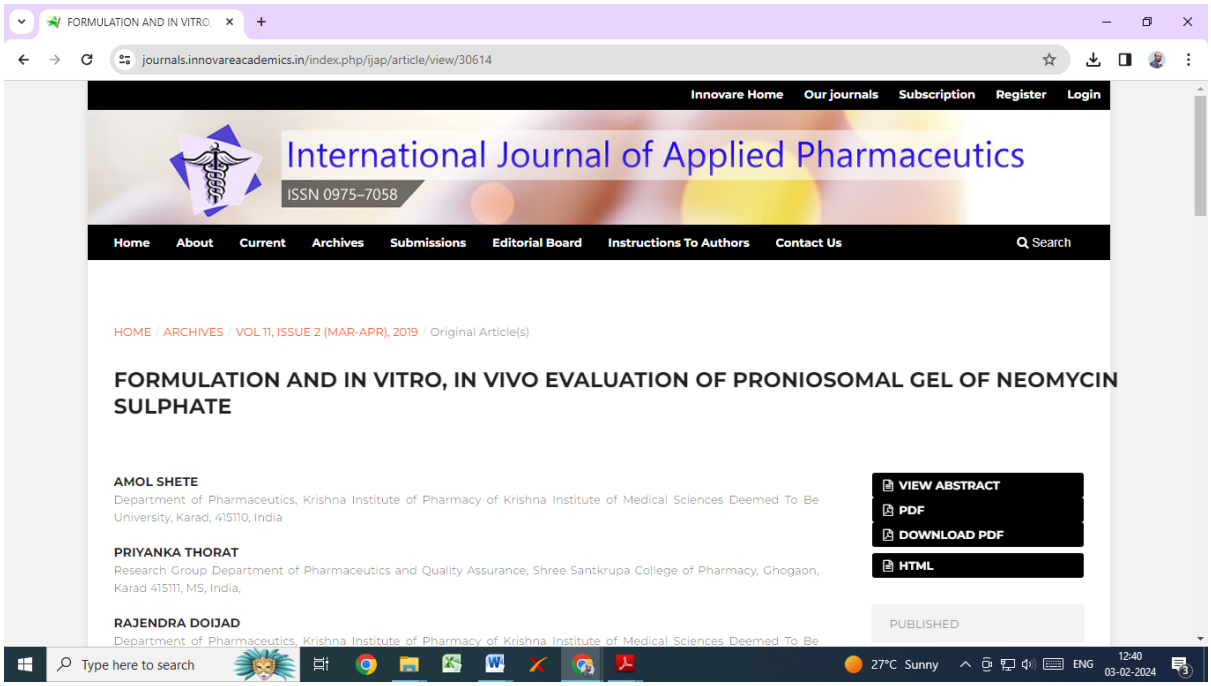

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ORIGINAL ARTICLE

Optimization of Thiazolidone Scaffolds Using Pocket Modeling for Development of Potential Secretory System Inhibitors of *Mycobacterium tuberculosis*

Mycobacterium tuberculosis'in Potansiyel Sekreter Sistem İnhibitörleri Olarak Thiazolidone İskelelerinin Optimizasyonu

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ABSTRACT

Objectives: *Mycobacterium tuberculosis* is the causative organism of tuberculosis, which is the most lethal disease after cancer in the current decade. The development of multidrug and broadly drug-resistant strains is making the problem of tuberculosis more and more critical. In the last 40 years, only one molecule has been added to the treatment regimen. Generally, drug design and development programs target proteins whose function is known to be essential to the bacterial cell. *M. tuberculosis* possesses specialized protein export systems like the SecA2 export pathway and ESX pathways.

Materials and Methods: In the present communication, rational development of an antimycobacterial agent's targeting protein export system was carried out by integrating pocket modeling and virtual analysis.

Results: The 23 identified potential lead compounds were synthesized, characterized by physicochemical and spectroscopic methods like infrared and nuclear magnetic resonance spectroscopy, and further screened for antimycobacterial activity using isoniazid as standard. All the designed compounds showed profound antimycobacterial activity.

Conclusion: We found that Q30, M9, M26, U8, and R26 molecules had significant desirable biological activity and specific interactions with Sec of mycobacteria. Further optimization of these leads is necessary for the development of potential antimycobacterial drug candidates with fewer side effects.

Key words: *Mycobacterium tuberculosis*, Sec, ESX, docking, antimycobacterial, multidrug resistant, pocket modeling

ÖZ

Amaç: *Mycobacterium tuberculosis*, son on yılda kanserden sonra en ölümcül hastalık olan tüberkülozun etkenidir. Çoklu ilaç ve ilaca dirençli suşların gelişimi, tüberküloz problemini daha da kritik kılmaktadır. Son 40 yılda, tedavi rejimine sadece bir molekül eklenmiştir. Genel olarak ilaç tasarım ve geliştirme programları, bakteri hücresi fonksiyonunda önemi olduğu bilinen proteinleri hedeflemektedir. *M. tuberculosis*, SecA2 ve ESX gibi özel protein ihracat sistemlerine sahiptir.

Gereç ve Yöntemler: Bu çalışmada, protein atım sistemini hedefleyen antimikobakteriyel bir bileşiğin rasyonel geliştirilmesi integre cep modelleme ve sanal analiz kullanılarak gerçekleştirilmiştir.

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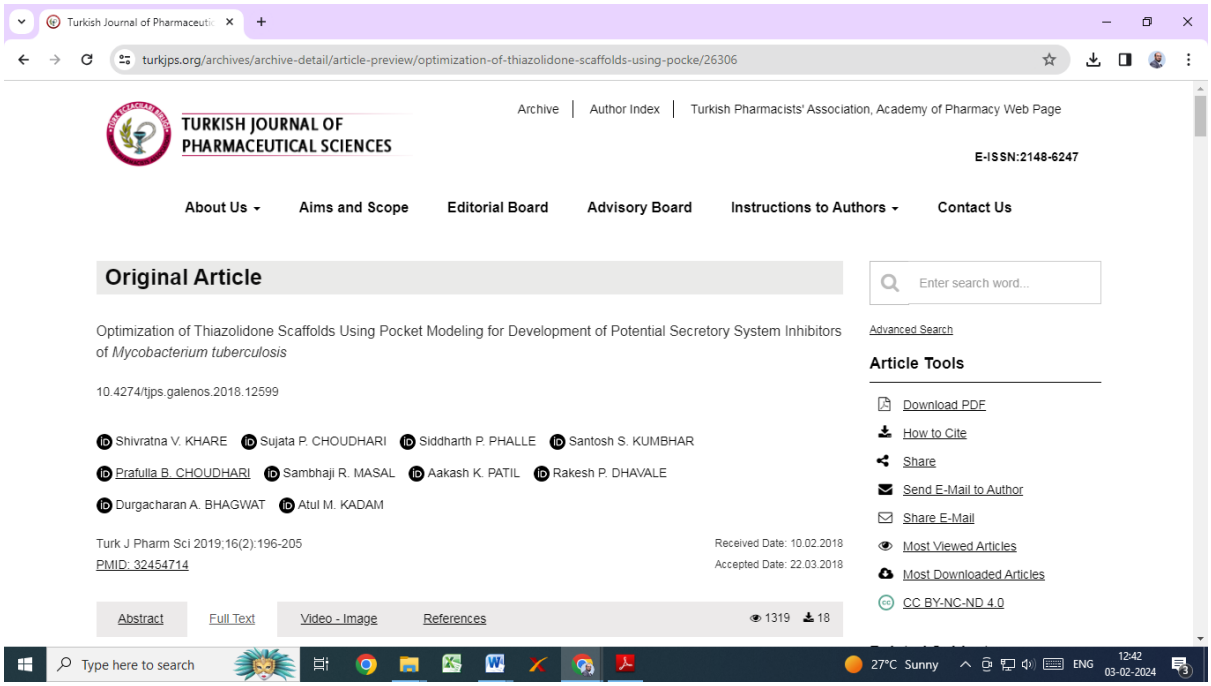

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Research Article

Analytical method development and validation of Valacyclovir to estimate from its formulation.

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ABSTRACT
A simple, rapid and sensitive method has been developed for the quantitative estimation of Valacyclovir hydrochloride in bulk and tablet. The zero order method was developed. The wavelength 254 nm was selected for the concentration range 5-25µg/ml. The accuracy of the method was assessed by recovery studies and was found to be 98.40±0.623. The method was statistically validated for the linearly, precision, accuracy repeatability, LOD, LOQ and ruggedness. The method was successfully applied for routine analysis of this drug in bulk and formulations. The method was validated as per ICH guidelines.

KEYWORDS
Valacyclovir, method development, validation.

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Research Article

Design, Development and Characterization of Fast Dissolving Oral Film of Clonazepam

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ABSTRACT

The present study proposed to prepare fast dissolving oral film containing clonazepam for the treatment of epilepsy. HPMC E15 and PEG 400 were used as film forming agent and plasticizer, respectively. Solvent casting method was used to prepare Clonazepam loaded fast dissolving oral films. The prepared films were characterized for weight variation, thickness, percent elongation, tensile strength, folding endurance, moisture content, content uniformity, surface pH and swelling index. The DSC and FTIR Spectra revealed that drug was compatible with the polymer. The prepared oral films were opaque in nature having good folding endurance. Shows the rapid release of drug in oral cavity. Drug release by diffusion (93.44 %) and by dissolution (98.32%) after 5 minute. All nine batches are rapid release of drug after film contact with saliva.

INTRODUCTION

According to US FDA, fast dissolving oral film is a sort of thin, flexible and non-friable polymeric film containing one or more dispersed active pharmaceutical ingredients. Fast dissolving oral film is intended to be kept in the buccal region for rapid disintegration or dissolution in the saliva before swallowing for drug delivery into the gastrointestinal tract [1].

In the last few decades, fast dissolving oral film has drawn much attention of researchers because of its distinct advantages over the other fast dissolving dosage forms. Fast dissolving oral film can be readily wetted and dissolved by saliva quickly without drinking water or chewing, allowing pediatric, geriatric or bedridden patients who have troubles in swallowing medicine [2, 3].

Fast dissolving oral film as a buccal drug delivery system, can enhance bioavailability by avoiding first-pass metabolism as well; as a result, patients can absorb drugs very fast through the rich vasculature of buccal region. For some special medicines which are vulnerable in gastrointestinal tract environment or have stomach irritation, it is also a good choice [4-7].

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Epilepsy is the most common chronic brain disease and affects people of all ages. Nearly 50 million people around the world have epilepsy, which makes it one of the most common neurological diseases worldwide. Around 80% of people having epilepsy live in countries with lower and middle-income. It is characterized by recurrent seizures, which are short episodes of involuntary movement that may involve one part of the body (partial) or the whole body (generalized) and are sometime accompanied by loss of consciousness, control of bowel or bladder function [8].

Clonazepam (CNZ), a chlorinated derivative of nitrazepam, is an anticonvulsant benzodiazepine widely used in the treatment of epilepsy. It is also effective in the management of some types of neuralgia [9].

It is also used in mycoclonus and associated abnormal movements, also for the treatment of panic disorders [10].

Moreover, it has recently been shown its efficacy also in the therapy of the burning mouth syndrome (BMS), pathology characterized by a painful burning sensation and/or other dysesthesias of the oral mucosa [11].

The present study intended to prepare fast dissolving oral film containing clonazepam for the treatment of epilepsy.

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A NOVEL CORTICOSTEROID CUBOSOMES – FOR OCULAR DRUG DELIVERY

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ABSTRACT

Corticosteroid containing ocular formulation is very exigent tasks faced by the pharmaceutical industry while designing drugs acting on various ocular related diseases. Because ocular drug delivery faces various limitations like complex ocular anatomy and poor ocular bioavailability of drugs due to the high turnover rate of tears, lower corneal permeation, and rapid nasolacrimal drainage, and most important is irritation to the eye caused due to corticosteroid structure. The preferred dosage form for ocular delivery of corticosteroid is a solution or the ointment, but to sustain the level of drug at the target site during therapy is not possible so it is necessary to formulate novel drug delivery techniques. A large number of novel carrier drug delivery systems systems have been developed to overcome the above problems but among them, cubosomal drug delivery is a safe and effective technique for corticosteroid ocular drug delivery. Cubosomes are distinct, sub-micron; self assembles liquid crystalline particles having honeycomb (cavernous) structure which separate two internal aqueous channels and large interfacial area; having particle size ranges from 10-500 nm in diameter. This review briefly describes the ocular administration of corticosteroids with the cubosomal drug delivery system along with various drugs studied in ocular drug delivery, a method used for the preparation of Ocular cubosomes and its evaluation parameter. The benefits of cubosomal drug delivery will likely be applied widely in all treatment, diagnostic, and research aspects of ophthalmology in the future.

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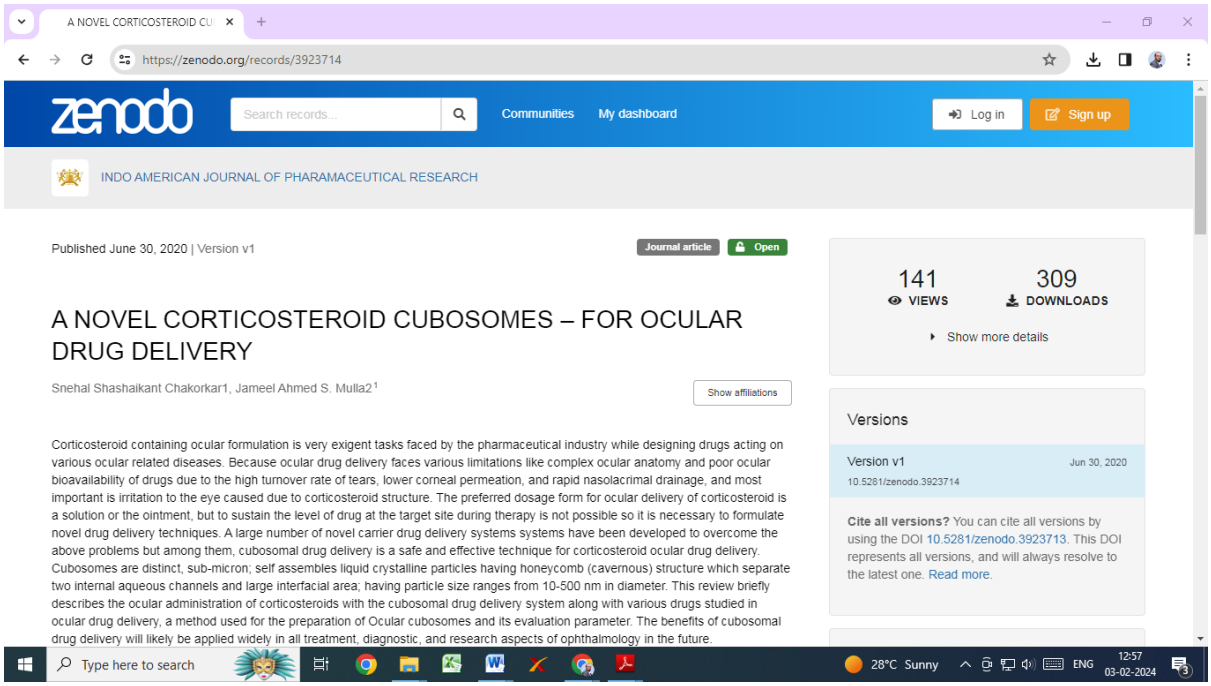

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Research Article

Formulation and Evaluation of Teneligliptin-Loaded Mucoadhesive Microspheres

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ABSTRACT

The mucoadhesive microspheres are one of the most promising novel techniques for drug delivery. Mucoadhesive systems provide a sustained drug release method, enhancing drug absorption in a site-specific manner. This study aims to prepare teneligliptin mucoadhesive microspheres to increase the residence time in the gastric and offers control release. The teneligliptin mucoadhesive microspheres are prepared by ionotropic external gelation technique using sodium alginate, HPMC K4, HPMC K15, HPMC K100, xanthan gum, guar gum, and carbopol 934. All mucoadhesive microspheres after preparation were characterized for percentage yield, particle size, drug entrapment efficiency, mucoadhesive test, and in vitro release. The results obtained are differed depending on the concentration of polymers and ratios of drug to polymers.

INTRODUCTION

Diabetes is a chronic disease that occurs when the pancreas produces insulin inadequately or when the body cannot use the insulin produced by it efficiently. Insulin is a peptide hormone that controls the amount of glucose in the blood, commonly known as blood sugar. Hyperglycaemia, or raised blood sugar, is a common effect of uncontrolled diabetes. Unchecked diabetes, over time, leads to potential complications in various organ systems of the body, which includes heart ailments, kidney damage, and nerve damage. According to The World Health Organization (WHO), about 8.5% of adults aged 18 years and above had diabetes in 2014. During 2016, diabetes was the direct cause of 1.6 million deaths, and in the year 2012, high blood glucose was the leading cause of 2.2 million deaths additionally [1-2]. Nearly half of all deaths attributable to high blood glucose occur before 70 years of age. WHO estimated the diabetes was the seventh leading cause of death in 2016 [2].

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Dipeptidyl peptidase-4 (DPP-4) inhibitors are a comparatively new form of oral diabetes drugs. Also identified as gliptins, they are generally prescribed for people with type-2 diabetes who do not respond well to medications such as metformin and sulphonylureas. DPP-4 is an enzyme that destroys the hormone incretin. DPP-4 inhibitors work by blocking the activity of DPP-4. Incretins help the body produce more insulin only when needed and reduce the liver's amount of glucose when it is not required. These hormones are released during the whole day, and levels are increased at mealtimes [3].

Teneligliptin is one of the newly approved gliptins and is effective in treating type-2 diabetes. It is hypothesized that an oral formulation that could substantially retain in the gastrointestinal tract (GIT) and release the drug in a controlled manner could be highly effective than a single dose conventional dosage form. In this context, mucoadhesive drug delivery systems adhere to certain gastrointestinal segments and would offer various advantages.

The present study aims to prepare mucoadhesive microspheres of teneligliptin to prolong the residence time in the gastric and provide control release.

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Characterization, antioxidant, antimicrobial and cytotoxic activities of green synthesized silver and iron nanoparticles using alcoholic *Blumea eriantha* DC plant extract

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DAPI staining

ABSTRACT

Silver and iron nanoparticles was synthesized, characterized and investigated for biological screening using alcoholic *blumea eriantha* DC plant extract. Equal amount of plant extract was mixed and incubated with silver nitrate and ferric chloride to obtain silver and iron nanoparticles respectively. Formation of silver and iron nanoparticles was confirmed by using UV, FT-IR spectroscopy, SEM, X-ray diffraction, and TEM. The anti-oxidant, antimicrobial, cytotoxic activities of the synthesized nanoparticles were determined by using standard protocols. MCF-7 cells were treated with selected concentrations of extract and prepared nanoparticles. It was observed that the synthesized nanoparticles were spherical in shape with an average particle size of 50 nm. The results of the studies revealed that the synthesized nanoparticles exhibited effective antioxidant, antibacterial and cytotoxic activity. The cell viability was measured for 50 hours after the addition of selected concentration of nanoparticles. The inhibition rate of silver nanoparticles was observed to be 15.45, 20.25 and 28.16 % against concentration 25, 50 and 100 μg mL^{-1} respectively. DPPI staining and Annexin V FITC assay results indicated that silver nanoparticle induce apoptosis in MCF-7 cells as compared with control. Therefore, it may open up a new avenue for anticancer therapies that needs further research.

1. Introduction

Dignified metal nanoparticles are becoming increasingly trendy, more than ever, due to their exceptional biocompatibility [1]. As a new material, silver nanoparticles (AgNPs) are considered as one of the most extensively used metallic nanoparticles in the era due to the wide physicochemical properties. Also their wide physiochemical properties raised much concern in the biomedical field, the pharmaceutical industry etc [1–3]. Moreover, AgNPs are in an alternative quite good agent to carry such effective drug moieties at the targeted area [4]. Iron is mainly plentiful and widely used elements on earth [5]. Silver and iron have been reported to exhibit a wide array of pharmacological activities since ancient times [6–10]. NPs are well known for their beneficial biomedical inhibitory properties such as anticancer, antibacterial, antifungal, antiviral, etc. [11].

Being environmentally friendly, cost-effective and easily scalable, green synthesis is an excellent substitute for the electrochemical, chemical, radiation, photochemical, Langmuir–Blodgett and biological synthesis [12]. However, green synthesis have attracted merit importance due to its one-step, faster, cost-effective, nontoxic and eco-friendly synthetic approach [13]. In addition, earlier methods have already proved the successful synthesis of NPs using bacteria [14,15], plant extract [16,17], fungus [18], panchakavya [19] and cow milk [20]. The use of phytomedicine has become very popular with time owing to its medicinal properties [12]. In nanotechnology the plant extracts are not only a good way to make nanoparticles that are harmless and stable, but also a good way to reduce the use of toxic chemicals or powerful reducing agents.

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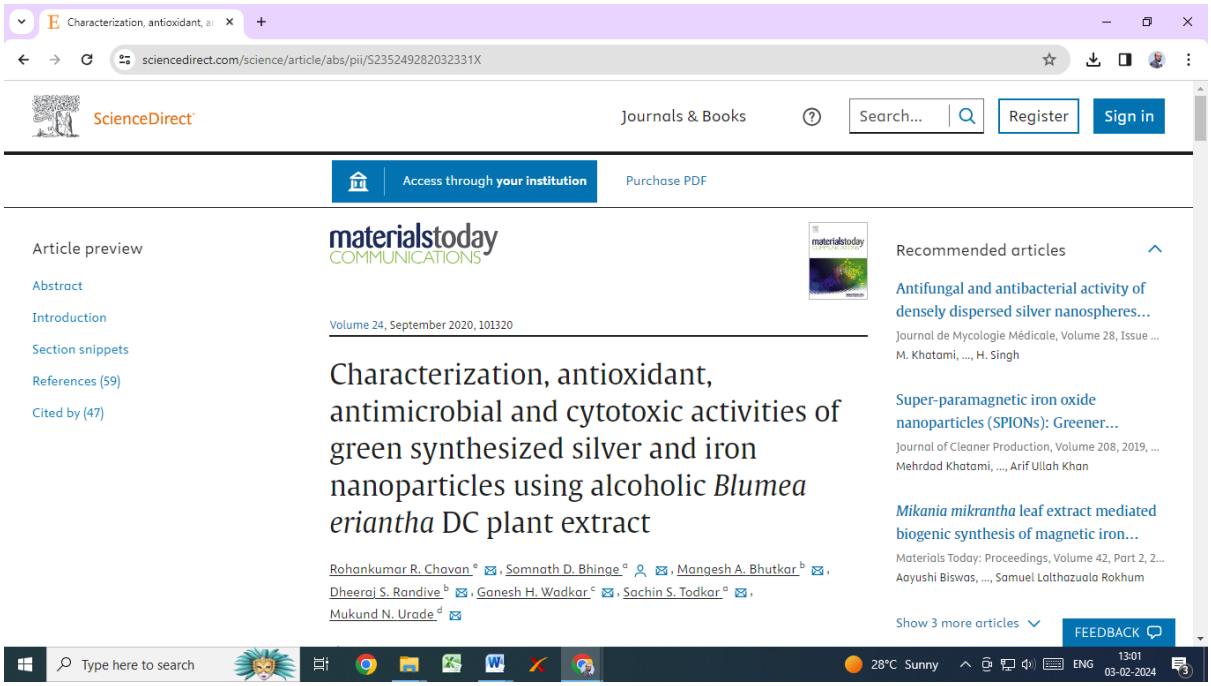

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Review Article

Microemulsion Based Hydrogel Formulation for Topical Drug Delivery - A Concise Review

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ABSTRACT

A hydrogel is a network of water-insoluble polymer chains that can also be found as a colloidal gel with water as the dispersion medium. Hydrogels are natural or manufactured polymers that are superabsorbent (they can hold over 99 percent water). Topical medicines are utilized for localized effects at the application site due to medication penetration into the deeper layers of the skin or mucous membranes. Microemulsions are thermodynamically stable, fluid, transparent (or translucent) colloidal dispersions made up of an oil phase, aqueous phase, surfactant, and co-surfactant in appropriate ratios that form a single optically isotropic solution with droplet diameters typically ranging from 10 to 100 nanometers. Transparency, low viscosity, and, most importantly, thermodynamic stability and capacity to form spontaneously separate micro-emulsions from conventional emulsions. As a topical medication delivery system, micro-emulsions provide a number of advantages over standard creams, gels, and solutions. The Hydrogel technology based on microemulsion will be able to sustain therapeutic concentration at the site of action while also increasing bioavailability. This review focuses on the method of preparation, characterization, evaluation, and stability investigations of microemulsion-based hydrogel.

INTRODUCTION

Pharmaceutical research nowadays is focused on finding appropriate drug delivery systems to meet the therapeutic demands of patients. The discovery of new chemical entities should coincide with the development of novel drug delivery systems, as the majority of compounds identified were hydrophobic in nature. Microemulsion has gained significance in the effective delivery of hydrophobic medications as part of the push to create innovative delivery strategies [1]. In recent years, the creation of so-called "intelligent" or "smart" hydrogels has gotten a lot of attention in soft matter research. Hydrogels having a high water content that can undergo reversible phase transitions in response to changes in temperature, pH, magnetic field, light, solvent, and ionic strength are known as "intelligent" hydrogels.

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Hydrogels made of N-isopropyl acrylamide (NiPAAm) are known to change volume and transparency when heated above 32°C, the gel's lower critical solution temperature (LCST) [2]. Microemulsion is a transparent emulsion that is frequently referred to as O/W or W/O emulsion.

Product with droplet sizes ranging from 10 to 100 nm and little tendency to agglomerate. It is made up of a proper ratio of oil phase, surfactant, co-surfactant, and aqueous phase. Transparency, optical isotropy, low viscosity, and thermodynamic stability are among microemulsion's physicochemical features. Topical drug administration appears to be a viable route of drug administration. Several mechanisms have been postulated to explain the benefits of microemulsions for drug administration in the topical and dermal areas. First, due to the huge amount of a drug integrated in the formulation, the thermodynamics towards the skin are boosted. Second, the drug's higher thermodynamic activity could help it partition into the skin. Third, by serving as permeation enhancers, the microemulsion components may diminish the

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Research paper

Effect of polymers and process parameters in augmenting the compactability and dissolution behaviour of oxcarbazepine spherical agglomerates

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ABSTRACT

The hypothesis for the present work is proposed to explore the spherical crystallization technique for improving the micromeritics, compactability, and solubility characteristics of oxcarbazepine (OXZ), an anticonvulsant drug. Agglomerates containing different polymers (PEG 6000 and PVP K30) and process parameters were investigated for the enhancement of overall physicochemical performance and dissolution. Water, dichloromethane, and chloroform were used as a poor solvent, good solvent, and bridging liquid, respectively. Pure OXZ and spherical agglomerates were characterized for several properties including Fourier transformation-infrared spectroscopy, Differential scanning calorimetry, Scanning electronic microscopy, X-ray powder diffraction analysis, micromeritics, solubility studies, and *in-vitro* drug release kinetics. From the results, a considerable improvement in drug solubility and micromeritics of agglomerates than pure OXZ was observed. Compressibility parameters assessed from the Heckel plot showed agglomerates with a polymer having a higher value of slope (k) and less MyP is accountable for plastic deformation in agglomerates. Prepared spherical agglomerates showed an enhancement in solubility and rate of dissolution, which might improve their bioavailability.

1. Introduction

The recent trend in the pharmaceutical industry is focused to deliver quality medicines developed through a pharmacoeconomic approach. Tablet is well accepted solid dosage form by the patients for the oral administration of the drugs. Drugs with poor flowability and mechanical properties of crystal-like compressibility are unsuitable for direct compression process; and require wet granulation which is uneconomical, laborious, and tedious. Techniques used to improve flow properties of compression mixture comprised of extrusion-spheronization, melt solidification, melt granulation, melt extrusion, and spherical crystallization [1]. Spherical agglomeration (Crystallo-co-agglomeration) is a recent alternative technique wherein in-situ formation and agglomeration of crystals is carried out to prepare directly compressible agglomerates [2–4]. This technique allows simultaneous crystallization and agglomeration in a single step, to transform the fine spherical crystals produced, directly into the more compactable and directly compressible form [5,6]. Apart from modifications in the primary and secondary properties of the particles, the Crystallo-co-agglomeration technique not only reduces the number of unit operations and processing costs but also improves the dissolution rate and bioavailability of the actives [7,8]. Moreover, during processing, modification of crystal habit with improved physicochemical (solubility, dissolution rate, and stability) and micromeritic properties (flowability, and compactability) [9] has emerged as a potential area of research in pharmaceutical manufacturing. Consequently, the directly compressible spherical agglomerates formed by this technique exhibited a considerable impact on the formulation of dosage forms [6,10].

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Research Article

Formulation and Characterization of Rapidly Dissolving Buccal Films of Montelukast Sodium

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Rapidly Dissolving Film, Montelukast Sodium, Solvent Casting Method, Buccal Film.

ABSTRACT

In the event of chronic illnesses, fast-dissolving drug delivery systems have been created as an alternative to traditional dosage forms as an oral mode of drug delivery. Fast dissolving films are now favoured over traditional tablets and capsules for disguising the taste of bitter medications and increasing patient compliance. In this study, montelukast sodium-loaded fast dissolving oral films were made using HPMC K-100 and the solvent casting method. Disintegration time, thickness, tensile strength, percent elongation, folding endurance, moisture content, surface pH, content uniformity, swelling index, FTIR Spectroscopy, Differential Scanning Calorimetry, and an *in-vitro* dissolution investigation were all used to describe the prepared films. The chemical structure of montelukast sodium was preserved in the formulation, according to FTIR analysis. At the end of 5 minutes, the drug release was found to be between 90.75 and 99.14 percent.

INTRODUCTION

In the late 1970s, rapid-dissolving drug-delivery systems were developed as an alternative to tablets, capsules, and syrups for juvenile, geriatric, bedridden, nauseated, or noncompliant patients who had difficulty ingesting typical oral solid-dosage forms. The technique, which was based on the technology of transdermal patches, is also known as oral thin films, fast dissolving films, mouth dissolving films, oro-dispersible films, quick disintegrating films, and melt in mouth dosage form [1, 2]. Drug administration via rapidly dissolving buccal films has developed as a cutting-edge alternative to the usual pills, capsules, and liquids commonly used in prescription and over-the-counter drugs. Thin film strips are primarily designed for oral administration, with the user placing the strip on or under the tongue or along the inside of the cheek, and are similar in size, shape, and thickness to a postage stamp. When a film is placed on the tongue or buccal cavity, it dissolves quickly, sending the medication to the systemic circulation via breakdown [3, 4]. Montelukast sodium is an anti-asthmatic medicine that works as a leukotriene receptor antagonist, highlighting the importance, optimal qualities, and many aspects of mouth dissolving film formulation as a superior dosage form for treating asthma and improving patient compliance [5].

The primary goal of this study is to develop a fast dissolving film of montelukast sodium, an anti-asthmatic medicine, which will aid in the rapid beginning of action and increase the performance of the active pharmaceutical ingredient.

MATERIALS AND METHODS

Materials

Aarti Pharma in Mumbai provided the Montelukast Sodium. Loba Chemie, Mumbai, provided HPMC K100, PEG 600, and sodium lauryl sulhate. All of the other chemicals, excipients, and solvents utilized were obtained from reputable sources and are of laboratory and analytical quality.

Formulation of Fast Dissolving Films of Montelukast Sodium

Solvent casting was used to make the quickly dissolving films, with HPMC K-100 as the film former. With constant stirring on a magnetic stirrer, the calculated amount of polymer, HPMC K-100, was dissolved in one fourth amount of distilled water. The montelukast sodium was adequately dissolved in a suitable amount of ethanol and then added to the polymeric solution

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Formulation and characterization of rapidly dissolving buccal films of montelukast sodium

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Abstract:

In the event of chronic illnesses, fast-dissolving drug delivery systems have been created as an alternative to traditional dosage forms as an oral mode of drug delivery. Fast dissolving films are now favoured over traditional tablets and capsules for disguising the taste of bitter medications and increasing patient compliance. In this study, montelukast sodium-loaded fast dissolving oral films were made using HPMC K-100 and the solvent casting method. Disintegration time, thickness, tensile strength, percent elongation, folding

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REVIEW ARTICLE

Ecopharmacovigilance: Perspectives, concepts, applications, and relationships in modern context

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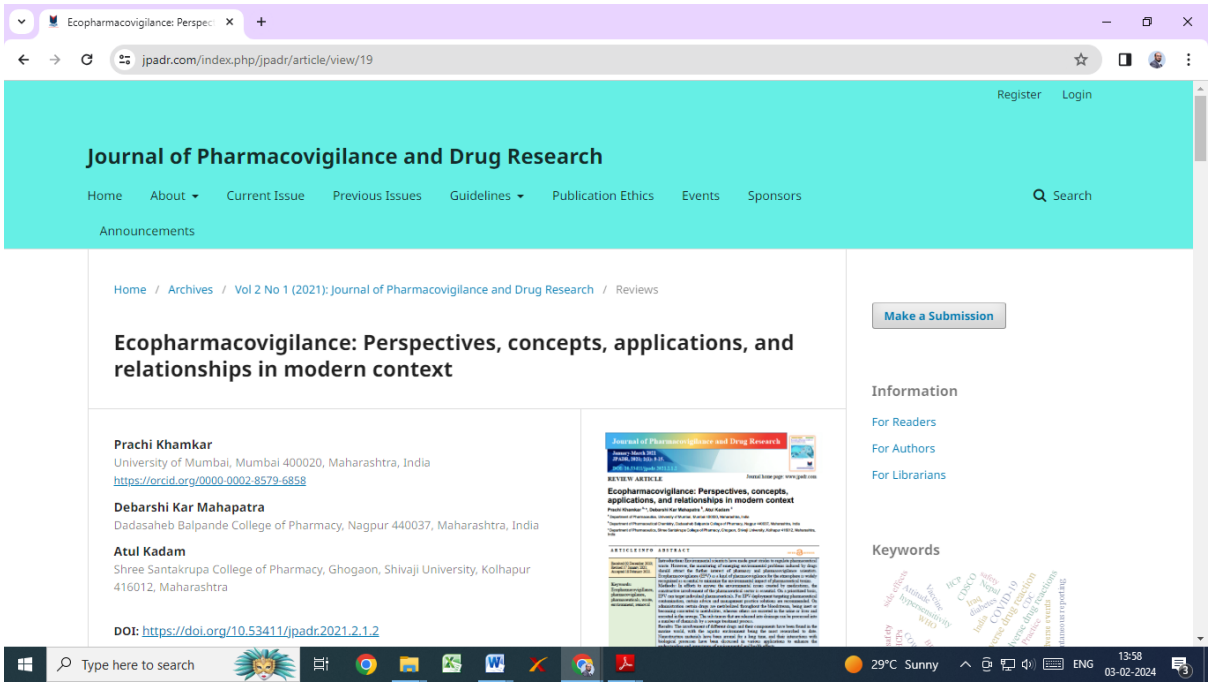
Abstract

Environmental scientists have made great strides to regulate pharmaceutical waste. However, the monitoring of emerged environmental problems induced by drugs should attract further interest of pharmacy and pharmacovigilance scientists. Ecopharmacovigilance (EPV) as a kind of pharmacovigilance for the atmosphere is widely recognized as essential to minimize the environmental impact of pharmaceutical toxins. In efforts to answer the environmental issues created by medications, the constructive involvement of the pharmaceutical sector is essential. In a prioritized basis, EPV can target individual pharmaceuticals. For EPV deployment targeting pharmaceutical contamination, certain advice and management practice solutions are recommended. On administration certain drugs are metabolized throughout the bloodstream, being inert or becoming converted to metabolites, whereas others are excreted in the urine or liver and excreted in the sewage. The substances that are released into drainage can be processed into a number of chemicals by a sewage treatment process. The involvement of different drugs and their components has been found in the marine world, with the aquatic environment being the most researched to-date. Nanostructure materials have been around for a long time, and its interactions with biological processes have been discussed in various applications to enhance the understanding and importance of environmental and health effects. In order to regulate pharmaceutical residues in effluents, Technologies for sewage water management should be applied. In particular, the presence of pharmacy including pharmacovigilance professionals is also important for enhancing multidisciplinary collaboration.

Introduction

The research of "Ecopharmacovigilance" (EPV) has become a recent subject of concern in the sense of the rise of pharmaceutical contamination. For the last 30 years, multinational institutions and the pharmaceutical industry have come to recognize that pharmaceutical drugs have a negative global effect on the climate. Although it is a global issue, like other environmental issues, pharmaceutical pollution more directly and seriously affects those living near production plants whose water and food sources are contaminated with waste pharmaceutical products (**Figure 1**) (Wang and Hu, 2014). With the continued rapid development of the global pharmaceutical industry, increasing attention has been given to environmental issues caused by pharmaceutical pollutants. This is an increase in the consumption, occurrence, and persistence of pharmaceutical products in the environment with their diverse biological effects (Coetsier *et al*., 2007). While not entirely, although to a great degree, medicines were a blessing for mankind in curbing the diseases (Medhi and Sewal, 2012). In the developed world, pharmacovigilance was well accepted and practiced, but decades were absorbed by emerging areas of the globe. India is also currently starting a national initiative to track the adverse effects of medications (Gupta, 2010). These environmental pharmaceutical pollutants include excretion of pharmaceuticals after human and veterinary therapeutic use. This dominates the global input of pharmaceuticals into the environment and are a much more difficult source to control; adding to the direct release into the wastewater



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Regulatory challenges and myths in pharmaceutical 3D printing

Although three-dimensional (3D) printing has been around for some time, many people still underestimate its capabilities. This article addresses the regulatory challenges faced by the pharmaceutical sector and aims to correct some of the most common myths surrounding the technology.

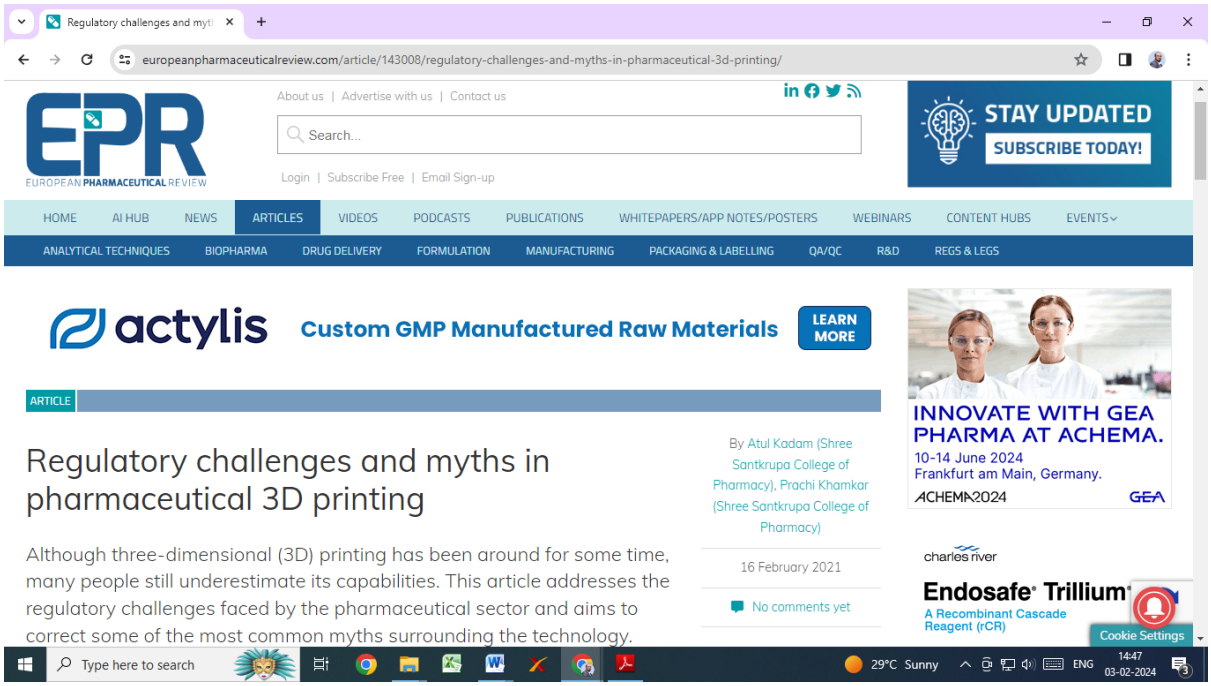
IMAGINE A FUTURE where patients with multiple disease conditions no longer have to take several tablets, numerous times per day. Instead, they can take one tablet containing all their required medications, once daily, thanks to 3D printing.

The process of 3D printing begins with a computer-aided format of a digital prototype of the product. The format is then sliced into horizontal layers that will form the shape of the digital file before being transfered into a 3D printer. Various excipients and drug combinations are then used to print the product with the aid of layering, transforming two-dimensional (2D) layers into a 3D product. Although the pharmaceutical industry is a laggard in this area, it is now waking up to the possibilities of 3D printing and we have witnessed various developments whereby specific tailor-made medicines can be manufactured according to a patient's need.

Where are we now?

The four most frequently used 3D printing machines in the pharmaceutical industry are:

1. Stereolithography (SLA)
2. Fused deposition modelling (FDM)
3. Selective laser sintering (SLS)
4. Binder jetting (BJ).



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FORMULATION AND PROCESS VALIDATION OF CLARITHROMYCIN LOADED IMMEDIATE RELEASE TABLETS

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ABSTRACT

The main aim of the present research work was to study concurrent process validation of immediate release tablet. If each step of production process is validated we can assure that the final product is of the best quality. Validation is best viewed as an impartment and integral part of cGMP. Validation is therefore one element of quality assurance programs associated with a particular process. Quality cannot be assured only by doing finished product testing and in-process monitoring but it should be built into the manufacturing process. So building of quality require a special attention to a few factors like selection of material, process design, control variables, in process control and finished product testing. In this study three initial batch of clarithromycin tablet with same size, method, equipment and validation criteria were taken. The critical parameters involved in dry mixing, preparation of granulating agent, wet mixing, wet milling, drying, lubrication, and compression stages were identified and evaluated. Results obtained with this process validation data provides high degree of assurance that manufacturing process produces product meeting its predetermined specifications and quality attributes. It also provides documented evidence for the operation sequence of manufacturing process and to determine the critical parameters and variables in the process of manufacturing of the tablets. The output of process validation can be used to increase productivity, its consistent quality and decreasing the need for processing or market complaints.

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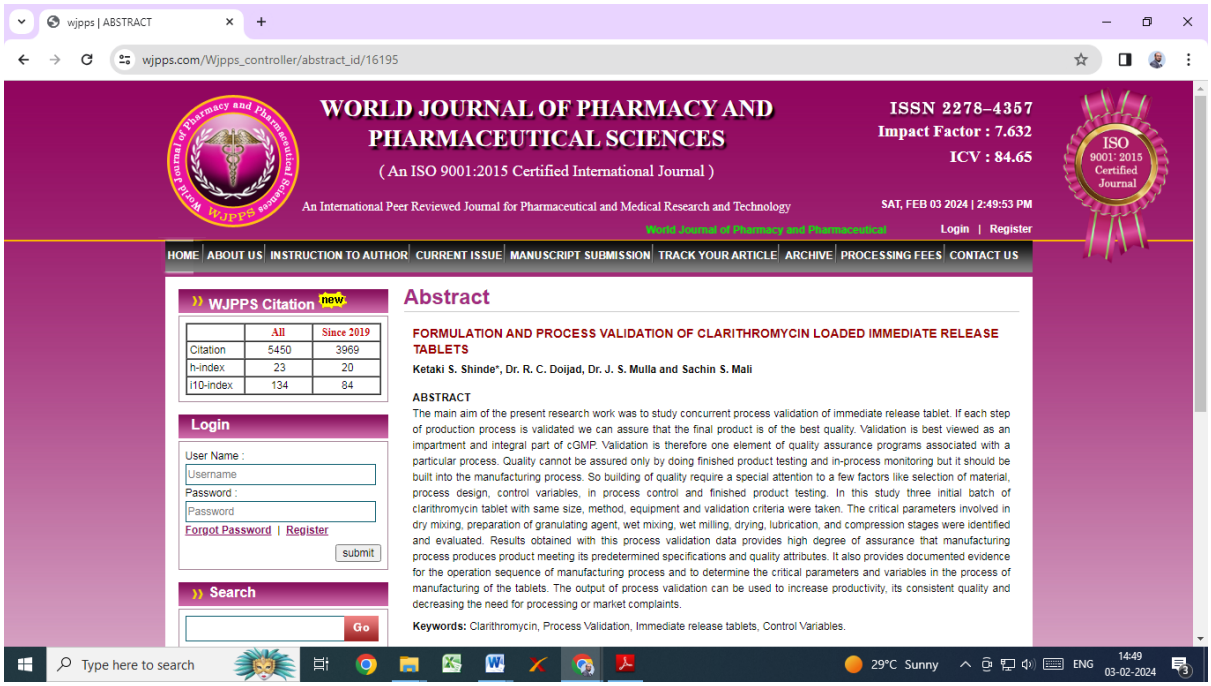

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Review Article

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EJPMR

BASIC ASPECTS OF PHARMACEUTICAL PROCESS VALIDATION OF SOLID DOSAGE FORMS: QUALITY ASSURANCE POINT OF VIEW

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ABSTRACT

The purpose and interest of this overview on pharmaceutical process validation of immediate release tablets, is to highlight the critical process parameters to be validate during the activity of validation of solid dosage form. It is the most common dosage form for orally administration of drug. The Process validation should confirm that the control strategy is sufficient to support the process design and the quality of the product. This validation review covers the solid dosage form of process validation. The process is developed in such a way that the required parameters are achieved and it ensures that the output of the process will consistently meet the required parameters during routine production, the process is validated. A manufacturer can assure through careful design of the device, processes, process controls and process variable that all manufactured units will meet specifications and have uniform quality. This review provides information on objectives and benefits of process validation, types of process validation, major phases in validation and regulatory aspects. Guidelines and strategy for process validation of solid dosage formvalidation and regulatory aspects. Guidelines and strategy for process validation of solid dosage form are also discussed.

KEYWORDS: Pharmaceutical Process Validation, Process Validation Stages, Validation Acceptance Criteria.

INTRODUCTION

Validation is an integral part of quality assurance; it involves the systematic study of systems, facilities and processes aimed at determining whether they perform their intended functions adequately and consistently as specified. A validated process is one which has been demonstrated to provide a high degree of assurance that uniform batches will be produced that meet the required specifications and has therefore been formally approved. Validation in itself does not improve processes but confirms that the processes have been properly developed and are under control.[1] The objective of the design and manufacture of the immediate release tablet is to deliver orally the correct amount of drug in the proper form, over a period of time and in the desired location, and to have its chemical integrity protected to that point. Numerous features are required to ensure product quality and the validation is one of them. It is through careful design and validation of both the process and process controls that a manufacturer can establish a high degree of confidence that all manufactured units from successive lots will be acceptable. Successful validation of a process may reduce the dependence upon intensive in-process and finished product testing. In most cases, end-product testing plays a major role in assuring that quality assurance goals are meet. A validated process is one which has been demonstrated to provide a high degree of assurance that uniform batches will be produced that meet the required specifications and has therefore been formally approved. Validation in itself does not improve processes but confirms that the processes have been properly developed and are under control.[2]

Process Validation Definition[3]

According to US FDA

In 1978

"A validation manufacturing process is one which has been proved to do what it purports or is represented to do. The proof of validation is obtained through the collection and evaluation of data, preferably, beginning from the process development phase and continuing the production phase. Validation necessarily includes process qualification (the qualification of materials, equipment, system, building, personnel), but it also includes the control on the entire process for repeated batches or runs''

In 1987

"Process validation is establishing documented evidence which provides a high degree of assurance that a specific process (such as the manufacture of pharmaceutical dosage forms) will consistently produce a product

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Review Article

Floating Microspheres: A Novel Drug Delivery System

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Buoyancy.

ABSTRACT

The motivation behind composing this audit on Floating microspheres is to gather the ongoing writing with unique spotlight on the essential system of buoyancy to accomplish gastric maintenance. Floating microsphere pledges to be a potential philosophy for gastric retention. The floating microspheres have been created trying to discharge the medication gradually into the GIT and keep up a compelling medication fixation in the serum for longer timeframe. From the system and technological factor of view, the floating drug delivery system is comparatively clean and logical approach. In this review, the current status of floating microspheres including hollow microspheres (micro balloons) and their characterization, advantages disadvantages, application, mechanism and method of preparation for gastric retention of drug are discussed. This review additionally summarizes the *in vitro* and *in vivo* studies to evaluate the overall performance and programs of floating microspheres.

INTRODUCTION

The layout of oral managed drug delivery device have to in the main be geared toward achieving extra predictable and multiplied bioavailability of drug [1]. Thus the purpose of drug delivery gadget is to offer a therapeutic quantity of drug to the proper site within the frame to achieve promptly & then preserve the favored drug concentration. Drug which can be without difficulty absorbed from the GIT and having a brief half-life are eliminated fast from the blood circulation.To avoid these issues oral managed drug delivery structure were advanced as they releases the drug slowly into the GIT and maintain a regular drug concentration in the serum for longer duration of time [2]. It has been often determined that the drug that are easily absorbed form GI tract have a short half live and are eliminated quick from the systemic flow which result in incomplete of drug from upper a part of small intestine [3]. Recent clinical and patent literature has shown increased interest in novel dosage bureaucracy that can be retained in the stomach for a extended and predictable duration of time. GRDF are designed on the idea of one of the several procedures like formulating low density dosage shape that stay buoyant above the gastric fluid (FDDS) or excessive density dosage shape that is retained at the bottom of the belly, imparting bio-adhesion to the stomach mucosa, reducing motility of the GIT by means of concomitant administration of medicine or pharmaceutical excipients, expanding the dosage shape via swelling or unfolding to a huge size which limits the emptying of the dosage form via the polymeric sphincter, making use of ion-alternate resin which adheres to mucosa, or using a modified shape system [4, 5].

Physiology Consideration:

The belly is situated in the left upper part of abdominal cavity immediately under the diaphragm. Its size fluctuates in understanding to the measure of distension: as much as 1500 ml following a dinner; after nourishment has purged a fallen nation is gotten with resting amount of 25-50 mL. Anatomically the belly is split into three regions: fundus, frame and antrum (pylorus) [4, 6]. The proximal part manufactured from fundus and frame acts as a reservoir for undigested material, the antrum is

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Periplaneta americana L. a potential source of traditional medicine: chemometric analysis, *in vitro* and *in silico* study

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ABSTRACT

'Mayurbhanj is the ethnic dominant tribal population district in Odisha, India. The triabl's of Mayurbhanj depends on traditional medicines since time immemorial for health-related issues. Due to the imperative ethnic claim of traditional healers, the financial stringency of the patient community and the necessity to produce a better therapeutic effect has led to investigate ethno zoological sources and to find out the biochemical moiety responsible for the healing process. Considering the ethnic communities' acceptability of the zoological source as traditional medicine, the current evidence-based research study is conducted to investigate the biochemical moiety present in *Periplaneta americana,* responsible for therapeutic activity. The whole powdered *Periplaneta americana* was extracted using maceration techniques with n-hexane and methanol as solvent. The obtained extracts were subjected to GC-MS analysis to identify the biochemical moiety. To check the potential biological activity, an *in-vitro* antimicrobial test was carried out in both turbidimetry and a viable count method against *E. coli*. Moreover, the obtained biochemical molecules were exposed to *in silico* studies for their binding modes and their affinity using Discovery studio software. The major compounds were found to be hexadecanoic acid, methyl ester, n-hexadecanoic acid, oleic acid, octadecanoic acid along with other minor constituents. The maximum inhibitory activity of n-hexane and methanol extract against *S. aureus* at a concentration of 400 µg/mL was found to be 89 and 87%, respectively. The binding models of almost all identified compounds confer very good binding affinities with some key and strong non-covalent interactions with various amino acid residues of receptor active site pocket, which predict the compounds to be potent inhibitors of various infectious bacteria. These findings suggested that the hexane extract of *P. americana* could be exploited as a potential natural source.

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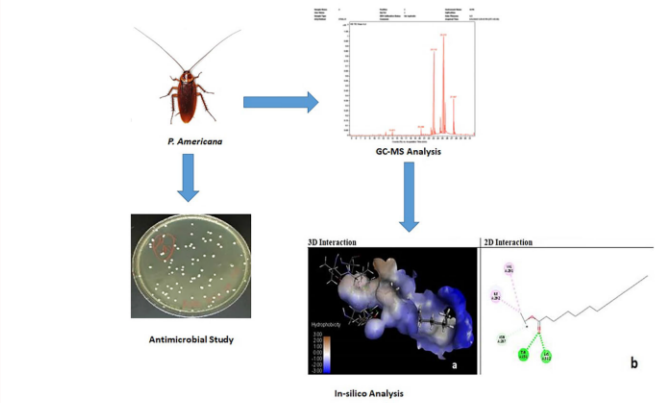

Abbreviations: ANOVA: Analysis of variance; BBB: Blood-brain barrier; CFU: Colony-forming Unit; GC-MS: Gas chromatography-mass spectrometry; MSRA: methicillin-resistant *Staphylococcus aureus*; NIST: National institute of science and technology

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Review Article

Non-Ionic Surfactant Vesicle (Niosome): A Novel Drug Delivery System

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ABSTRACT

Niosomes are vesicles that are created by hydrating a mixture of lipids that are biodegradable, non-ionic surfactant, and cholesterol. In comparison to a drug's traditional dosing form, niosomes boost the drug's action. Drugs that are amphiphilic or lipophilic can be transported via niosomes. The problems associated with pharmaceutical instability, rapid disintegration, insolubility, and low bioavailability may be resolved by niosomes. The manner of formulation determines whether niosomes are multilamellar or unilamellar in structure. For the site-specific administration of anti-cancer, anti-infective drugs, etc., niosomes have a very effective drug delivery capability. In comparison to other drug formulations, niosomes are stable and inexpensive carriers. Niosomes are also used in innovative drug delivery systems, topical drug delivery systems, oral drug delivery systems, and parental drug delivery systems. This review provides an extensive summary of niosomal studies to date, as well as a detailed look at formulation aspects, niosome types, physical characterization methods, and recent pharmaceutical applications like transmucosal, oral, ocular, topical, and pulmonary drug delivery as well as cosmetic applications.

INTRODUCTION

"A good drug delivery system delivers drug to the T-site for use throughout treatment. Targeted delivery is a strategy for delivering drugs to tissues while reducing the concentration of the drug in surrounding tissue. Niosomes are thin lamellar vesicles that are not toxic to organisms. They are formed by mixing cholesterol with a non-toxic alkyl class surfactant or dialkylpolyglycerol ether, followed by hydration in water [1]. Niosomes are versatile and can be combined to deliver several forms of drugs to the intended site. A niosome is a vesicle that can be unilamellar or multilamellar and is formed of non-ionic surfactant, cholesterol, and ionic surfactant. Its purpose is to reduce structural bonds. Drugs that are hydrophilic, lipophilic, or amphiphilic can be incorporated into the niosome's bilayer structural vesicle. Niosome shows more stability than liposome because the liposome can be degraded and oxidized due to its particular lipophilic nature.

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Because niosomal formulations have a non-ionic surfactant, they remain in the bloodstream for a longer period of time, enhancing their target action [2, 3].

Structure of Niosomes

Niosomes are microscopic, spherical, lamellar (unilamellar or multilamellar) structures. The bilayer is produced by combining charge-inducing agent with nonionic surfactants, either with or without cholesterol. Niosomes are formed by combining various surfactant types in different combinations and molar ratios. Alkyl glyceryl ethers, Alkyl ethers, polyoxyethylene fatty acid esters and sorbitan fatty acid esters are a few examples of surfactants [2, 4]. Cholesterol addition keeps the bilayer firm, resulting in fewer leaky niosomes [5]. Charge inducers, but on the other hand, give the vesicles a charge and expand their size, improving drug entrapment effectiveness. The vesicles are stabilised by positive charge inducers such stearylamine and cetylpyridinium chloride as well as negative charge inducers like dihexadecyl phosphate, dicetyl phosphate, and lipoamino acid [6]. Nonionic surfactants in niosomes have a tendency to have hydrophobic ends that face

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