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3.2.2

Number of books and chapters in edited volumes/books published and papers published in national/ international conference proceedings per teacher during the year

3.2 Research Publication and Awards

3.2.2.1. Number of books and chapters in edited volumes/books published and papers published in national/ international conference proceedings per teacher during the year

A- Number of books and chapters in edited volumes/books published

Sr. No.	Name of the teacher	Title of the book/chapters published	National / International	Year of publication	ISBN number of the proceeding	Affiliating Institute at the time of publication	Name of the publisher
1.	Dr. K. S. Jain, **Ms. D. K. Kadam**	Pharmaceutical Chemistry	National	2022-2023	978-93-95039-03-1	K. K. Wagh College of Pharmacy	BSP-Books Pvt. Ltd
2.	**Kajal Baviskar, Anjali Bedse, Shilpa Raut,** Narayana Darapaneni	Artificial Intelligence and Machine Learning-Based Manufacturing and Drug Product Marketing	International	2022-2023	Online ISBN: 9781119865728	K. K. Wagh College of Pharmacy	Scrivener Publishing LLC, Wiley Online Library
3.	Dr. K. S. Jain, **Ms. D. K. Kadam**	Medicinal Chemistry	National	2022-2023	978-93-5451-947-5	K. K. Wagh College of Pharmacy	Nirali Publications
4.	Dr. Hitesh Shahare, Dr. Sunil V. Amrutkar, **Dr.Rakesh D.Amrutkar**, Dr.Manoj R.Kumbhare,	A textbook of Biochemistry	National	2022-2023	978-93-93304-29-2	K.K.Wagh College of Pharmacy	Briliant Publication
5.	**Anjali Bedse**, Deepa Sign, **Shilpa Raut, Kajal Baviskar,** Aarti Wable, Prajwal Pagare, Samrudha Wavikar, and Samiksha Pagar	Organogel: A Propitious Carman in Drug Delivery System	National	2022-2023	978-1-80356-985-7	K.K.Wagh College of Pharmacy	IntechOpen

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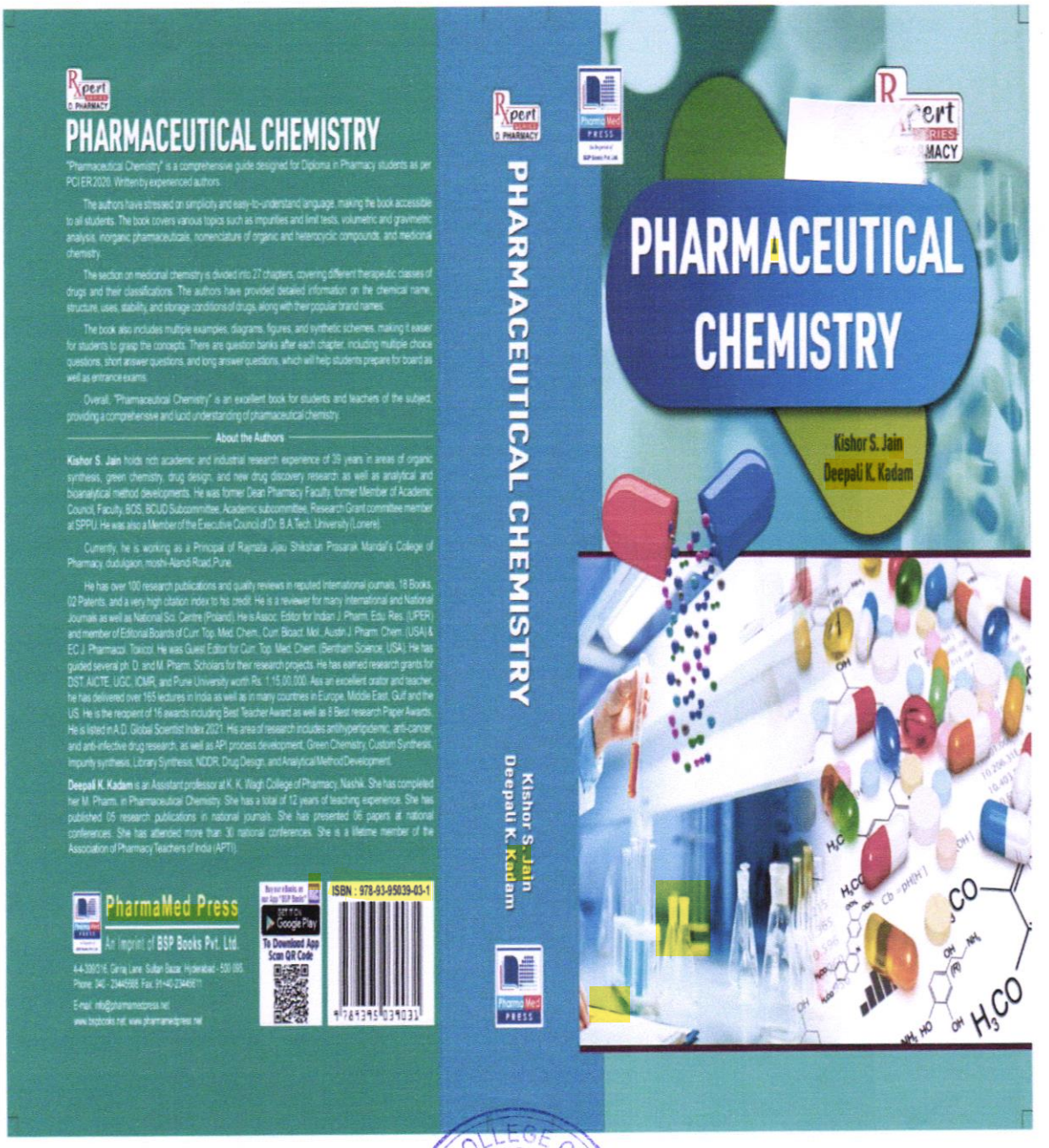

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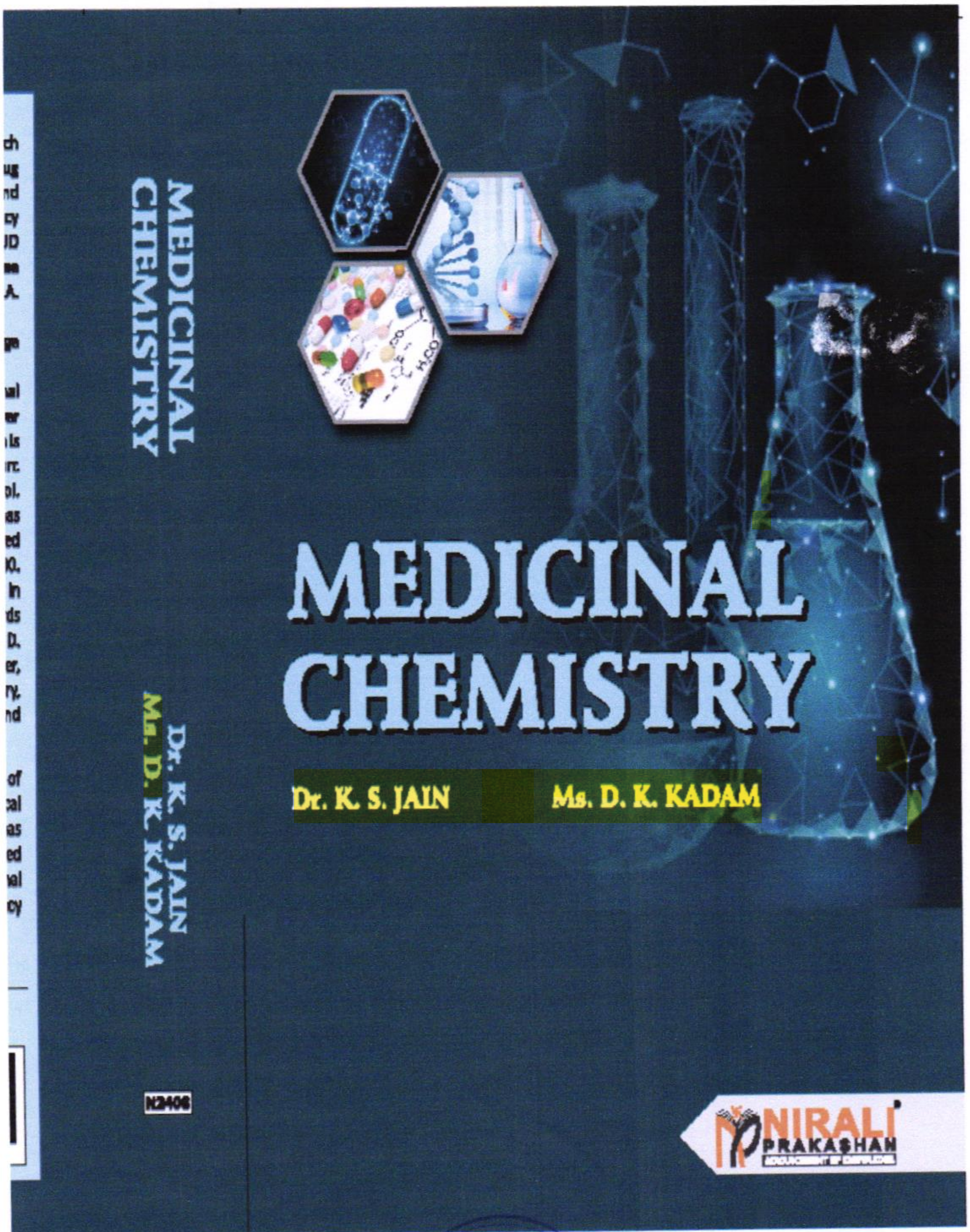

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HISTORY AND DEVELOPMENT OF MEDICINAL CHEMISTRY

♦ LEARNING OBJECTIVES ♦

After completing this chapter, student should be able to understand:

- *Definition and Scope of Medicinal Chemistry.*
- *History and development of Medicinal Chemistry in various phases.*
- *New Drug Discovery and Development.*
- *The importance of various Physicochemical Properties of drug substances in relation to their Biological Action.*
- *The principles and phases of Drug metabolism and its importance.*
- *The Factors affecting Drug Metabolism including Stereochemical aspects and Metabolic Fate of various Drugs with selected examples.*

1.1 INTRODUCTION

1.1.1 Definition and Scope of Medicinal Chemistry

It is the branch of chemistry which deals with the fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs, as well as, the chemical synthesis of important drugs under each class.

Though, most of the infectious diseases like tuberculosis, typhoid, malaria, infective hepatitis, tetanus, cholera, etc., which kill lakhs of people every year in underdeveloped or developing countries, have been completely wiped off from the developed nations, some are still back in resistant forms. Also, disorders and infections like heart disease, diabetes, alzheimer, cancer and HIV infection are now considered the biggest killers.

1.1.2 The Art of Medicinal Chemistry

The science that strives to identify, create or modify molecules for therapeutic application - has enriched greatly from developments in the areas of organic chemistry, biology, biophysical/biochemical methods, and computational tools. While opportunities are enormous, advancing a drug candidate from benchtop (preclinical) to clinic (clinical) is associated with challenges. A good understanding on both these aspects would significantly accelerate drug discovery process. Really, the unprecedented increase in human life expectancy, which has almost doubled in a hundred years, is mainly due to drugs and to those who discovered them.

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1 1.1 Biomolecule

◆ **Content**

1. Introduction

Biochemistry broadly deals with the chemistry of life and living processes. The human body is composed of multiple types of specialized tissues.

Biomolecules are molecules that are involved in the maintenance and metabolic processes of living organisms. These non-living molecules are the actual foot soldiers of the battle of sustenance of life. They range from small molecules such as primary and secondary metabolites and hormones to large macromolecules like proteins, nucleic acids, carbohydrates, lipids etc.

It also includes small molecules like primary and secondary metabolites and natural products. Biomolecules consist mainly of carbon and hydrogen with nitrogen, oxygen, sulphur, and phosphorus.

Biomolecules are very large molecules of many atoms that are covalently bound together which in turn consist of vast cluster of cells differentiated into specialized chemical factories.

◆ **Definition**

"Biomolecules can be defined as molecules that are produced by living organisms and form the structural basis of all living organism."

The organic compounds such as amino acids, nucleotides and monosaccharides serve as the monomeric units or building blocks of complex biomolecules – proteins, nucleic acids (DNA and RNA) and polysaccharides, respectively. The important biomolecules (macromolecules) with their respective building blocks and major functions are given in Table 1.1. As regards lipids, it may be noted that they are not biopolymers in a strict sense, but majority of them contain fatty acids.

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Chapter

Organogel: A Propitious Carman in Drug Delivery System

Anjali Bedse, Deepa Singh, Shilpa Raut, Kajal Baviskar, Aarti Wable, Prajwal Pagare, Samruddha Wavikar and Samiksha Pagar

Abstract

A gel is a semi-solid formulation having an external solvent phase that is either apolar (organogels) or polar (hydrogels) that is immobilized inside the voids contained in a three-dimensional networked structure. Organogels are bi-continuous systems composed of apolar solvents and gelators. When used at a concentration of around 15%, the gelators form self-assembled fibrous structures that become entangled with one another, resulting in the formation of a three-dimensional networked structure. The resulting three-dimensional networked structure blocks the flow of the external apolar phase. Sterol, sorbitan monostearate, lecithin, and cholesteryl anthraquinone derivatives are examples of gelators. The unique characteristics such as thermo-reversibility, viscoelasticity, and versatility impart a longer shelf-life, prolonged drug release, and patient compliance. These characteristics can easily be adjusted by simple formulation modifications, resulting in highly-structured architectures. Organogels are more likely to be used in various types of delivery systems because of their ability to entrap both hydrophilic and hydrophobic molecules inside their structure. Their combination with other materials allows for tailoring their potential as dosage forms. Organogels have potential applicability in numerous ways; hence this article discusses the various aspects of it.

Keywords: organogels, organogelators, drug delivery, lecithin

1. Introduction

Gels are defined as semisolid, cross-linked systems containing condensed solid particles interpenetrated by a liquid [1]. Gels can be referred to as hydrogels or organogels, which can be distinguished on the basis of polarity comprised by the gel, that is, if the liquid phase in the gel is water then it is referred to as a hydrogel, whereas if the liquid phase in the gel is an apolar solvent, then it is referred as an organogel. Organogels are the carriers used for delivering the medicament at its desired site [2]. Organogels are formed by gelators, which are foundational building blocks. Gelators are often certain low-molecular-mass substances (e.g., sorbitan derivatives, lecithin, fatty acid derivatives, bis-urea compounds) [3–5]. The gelators help in the formation of a 3D structure of a mesh network due to the entanglement of

self-assembled fibrous structures, which are formed due to some physical or chemical interactions of gelators when used in the concentration of <15% (approx.) [6, 7]. Gelators are hence responsible for immobilizing the apolar solvent phase. The gels formed by the physical interactions are termed physical gels (held by physical forces such as Van der Waals and hydrogen bonds) whereas the gels formed by chemical bonding are termed chemical gels (held by covalent bonds) [7]. The gelators elevate the surface tension which predominantly prevents the flow of the solvent phase. Gelators immobilize organic solvents by the establishment of non-covalent intermolecular interactions forces (H-bonds, electrostatic interactions, metal coordination, p–p stacking, and London dispersion forces), resulting in the formation of various entangled structures like wrinkles, lamellar, and fibers [8–11]. The thermo-reversible property, non-irritating nature, and biocompatibility of the organogels have generated much interest in their potential application as a drug delivery system. Wide formulations can be developed for the administration of drugs via various routes using organogels as they can incorporate hydrophilic and hydrophobic bioactive agents within their gel structure. The rate-limiting step in the bioavailability of drugs from organogels is its characteristic features, that is, high permeability, and low aqueous solubility, which affect the rate of drug release from drug delivery systems. They have no confined application as they can be used for topical application or for the release of drugs into systemic circulation by cutaneous delivery and percutaneous absorption [7, 12].

2. Types of organogel

2.1 Lecithin organogels (LOs)

Since LOs have the desirable physicochemical characteristics ideal for topical formulations, these are employed most frequently for topical application. These are useful for the delivery of a wide variety of hydrophilic as well as lipophilic drugs through the skin. Lecithin is a constituent of natural origin which can be isolated from various animal and plant sources (except egg yolk) and hence biocompatible, safe and stable [7, 13, 14]. It is a potential vehicle for a number of bioactive agents. Lecithin is chemically a phosphatidylcholine, a constituent of the class phospholipids. It has been observed that lecithin is unable to form a gel if its phosphatidyl content is less than 95% [7, 15]. The concept of designing organogels with lecithin was first mentioned by Luisi and Scartazzini in the year 1988 [16]. Lecithin can only produce gelation if it is used in its pure form (e.g., the hydrogenated form of soya-lecithin failed to induce gelation). The unsaturated fatty acids present in naturally occurring lecithin are hence important [15].

2.2 Pluronic lecithin organogels (PLOs)

High-purity lecithin is costly and difficult to procure in significant quantities. Due to the convenience of synthetic polymers such as pluronics, which serve as co-surfactant and stabilizers, they have been widely studied in combination with lecithin to formulate lecithin micro-emulsion-based organogels [17]. It was prepared in 1990 in the US by a compounding pharmacist to use as a topical carrier system [15]. The primary benefit of employing PLs in organogels is their capacity to self-assemble into micelles at approximate physiological temperatures [11]. Pluronic F-127 is a

copolymer which causes gelation when used in a concentration of 15–30% w/v [18]. It is formed by adding the Pluronic F-127 to the LOs. It is majorly used for transdermal as well as topical drug delivery systems and also for oral and mucosal drug delivery systems to some extent [15]. It forms a non-transparent yellow gel [19]. After topical administration, PLOs rupture the lipid layer of the stratum corneum and deliver the drug into the systemic circulation with minimal irritation to the skin [7, 18]. Additionally, in order to have a synergistic effect, it has also been demonstrated to be a useful transporter for combinations of drugs [20]. It works best when combined with medications whose molecular weight is less than 500 Da [21].

2.3 Limonene GP1/PG organogels

Limonene is a terpenoid with magnificent penetration power and is used in transdermal drug delivery systems as it can enhance the bioavailability of drugs [22]. This organogel is prepared by mixing a suitable amount of GP1 (dibutyllauroylbutamide) amino acid type of organogelator with limonene and PG (propylene glycol), followed by its incubation at 120°C. After cooling down to an appropriate temperature, it forms a gel that appears white in color. It has been observed that the co-existence of limonene with GP1 and PG influences its rheological behavior to some extent, whereas their chemical characteristics are not significantly affected [7, 15, 19, 23]. The GP1/PG organogels tend to have increased gel moduli due to the incorporation of limonene, which gives an indication of increased gel physical stability [24]. Other terpenoids such as cineole and linalool, have also been successfully mixed with GP1 and PG to obtain an effective organogel with improved penetration power [18].

2.4 Micro-emulsion-based organogels (MBG) stabilized by gelatin

Micro-emulsions offer good bioavailability of drugs when introduced via topical or systemic routes of the drug delivery systems. Micro-emulsions are known to deliver a greater amount of drug than other gel systems [15]. The micro-emulsion system can undergo gelation when gelatin is dissolved in the water microphase, and the resultant gel will consist of more than 80% hydrocarbon solvent [25]. The basic mechanism involved in the formation of MBG is that a solution of gelatin in water is added to the parent micro-emulsion after it has been incubated at 50°C in the incubation chamber. In order to obtain an optically transparent single-phase gel, the resulting liquid is forcefully mixed and then allowed to cool to ambient temperature [26]. Gelatin is a protein that has the ability to form gels. It can undergo gelation when its concentrated solution is heated beyond 45°C and is then cooled down below 35°C and increases thermostability. When gelatin is added to w/o micro-emulsions, a transparent gel of the complete micellar solution is obtained [7, 15, 19, 27, 28].

2.5 Sorbitan organogels derived from fatty acids

Sorbitan monopalmitate (span 40) and Sorbitan monostearate (span 60) are the gelators of this class. They are non-ionic, hydrophobic in nature, and possess surfactant properties. They form a solid-fiber matrix when heated with the apolar solvent and then cooled down to a relatively lower temperature. A gel of toroidal reverse micelle is formed due to a drop in the temperature, which is followed by self-assembly leading to its transformation into rod-shaped tubules. The gel so obtained is white,

opaque, semisolid, and thermostable at room temperature. These organogels are used as vehicles for hydrophilic vaccines [29–31].

2.6 Polyethylene organogels

Low molecular-weight polyethylene is solubilized in mineral oil at a high temperature of more than 130°C, yielding a colorless organogel. This causes intermolecular interaction within the polyethylene, which leads to the precipitation of its molecules, which forms a solid-fiber matrix to form a gel [16]. They are generally used as a base for ointment preparations [19]. A study conducted in the 1950s concluded that the patches of polyethylene organogel were found to be non-irritating along with low sensitizing properties [15].

2.7 Eudragit organogels

Eudragit organogels are formed by the mixture of polyhydric alcohols (propylene glycol and glycerol), a high concentration (30–40%) of Eudragit (L or S), and liquid PEG. To prepare a formulated Eudragit organogel, the drug is first dissolved in the PEG, and this solution is then added to the Eudragit powder. This mixture is further triturated with the help of a mortar and pestle for approximately 1 minute. The concentration of Eudragit and the amount of drug are found to directly influence the consistency of the gel. The gel viscosity is enhanced with a high concentration of Eudragit, whereas it decreases with an increasing amount of the drug. In low concentrations of drugs, the gel has high rigidity as well as stability [7, 15].

2.8 Supramolecular organogels

These organogels are made of gelators of low molecular mass. The molecules of different gelators of this class differ immensely in their structural characteristics. Hence, they have offered a scope of interest to develop different gels with technological application. For example, having sensitivity toward external stimuli like light. Remarkable thermoreversibility and mechanical capabilities are displayed by supramolecular organogel systems with controlled self-assembled structures. These organogels can offer controlled drug delivery. They can be used as carriers for multiple purposes [15, 32].

2.9 L-alanine-derived organogels

LAM (N-lauroyl-L-alanine methylester) undergoes gelation with organic solvents such as triglycerides and soya-bean oil. It is not as extensively used as other organogels. At room temperature, it remains in a gel state [7, 15, 18]. In a biphasic mixture of water and apolar solvent, a fatty acid derivative of L-alanine aids the gelling of the solvent-specific portion of the mixture without gelling the aqueous portion [33]. This characteristic makes it considerably more appealing to use in organogel. It can be used as an implant for sustained release system. Currently, it is used as a vehicle for the drugs like leuprolide, rivastigmine [7, 18].

3. Importance of organogels

For the conveyance of medications in the body/target site, numerous procedures and frameworks have been analyzed. Out of the effective applications accessible, organogels are getting greater fame on account of the simplicity of utilization, better

ingestion through the skin layers, etc. Amongst the existing dosage forms, organogels are the easiest to prepare and have also been proven to be cost-effective [7, 34, 35]. They offer a better stability profile than that of other gels. The characteristic features of organogels not only make it easier for the manufacturer to process but also provide an easy handling and utilization method for the consumers, hence making it of commercial importance. The organogels can deliver the drugs more effectively than other dosage forms. This has been validated through a study which was conducted by I.M. Shaikh et al., where it was observed that the penetration efficiency of organogel (LO) was greater than that of hydrogels when applied over skin [35, 36]. As it offers a controlled drug delivery system, many chronic diseases could be cured if the organogels are loaded with appropriate drugs and then implanted at the target site. This characteristic also eliminates the obligation of frequent dosing. They have an extended application as they lend opportunities to incorporate various constituents having wide-ranging characteristics. Organogels can be used as an alternative to UV-treatment methods. Hence, it will eliminate the chances of cancer caused by exposure to UV rays [37, 38]. Organogel can reduce/control the dissemination rate of medication, hence making it liable for designing an appropriate formulation for an appropriate purpose to deliver the drug as required. As it comprises both hydrophilic and lipophilic parts, both lipophilic and hydrophilic bioactive agents could be consolidated within it [15, 38]. Therefore, wide-ranging drugs could be incorporated into them.

4. Advantages of organogels

It is an easy formulation to prepare and has a longer life span. Bioactive agents of distinct characteristics can be incorporated [37, 38]. Their physical form remains unaffected by the factor of time owing to structural cohesion. It is cost-effective as it requires a lower number of components [37–39]. They have simple handling and usage requirements. It also provides improved patient compliance [34]. It has various applications for topical delivery systems. It has thermal stability [38]. A few chemical modifications can lead to the release of drugs in the desired manner and at the desired place [34]. It bypasses first-pass metabolism, ensuring that medicines have the highest possible bioavailability. They are relatively safe as bio-compatible constituents are used. Hence, it can be used to deliver various drugs. It is non-invasive and is better tolerated by the patients. It is a thermodynamically stable system. As it can be used for an extended period of time, the need for dosing is less frequent. It has both hydrophobic and hydrophilic units. Therefore, bioactive agents of either nature can be incorporated into it. There is no risk of microbial contamination as they are insensitive to moisture [34, 38].

5. Limitations

It accounts for low thermostability. It has a greasy texture [2]. For the drugs that are intended to be penetrated through the skin, they must possess an appropriate partition coefficient. It holds good chances for the occurrence of swelling (uptake of liquid resulting in an increase in its volume) or syneresis (natural shrinkage if allowed to be at rest for a period of time) [15, 40]. Organogels intended for topical application might irritate the local skin. Topical organogels cannot comprise bioactive agents with

molecular weights of more than 500 Dalton, since skin can be permeated by drugs with molecular weights under 500 Dalton [18]. The purity of the constituents present is important, or else there might be no gel formation. Few organogelators are not available on a large scale, hence causing expense elevation for formulation, for example, lecithin organogelator. The purity of the constituents present is important, or else there might be no gel formation. Precise control of process variables (pH, temperature, etc.) is mandatory. Skin permeation enhancers and non-polar solvents are added in order to achieve deep penetration through skin, which may produce toxicity. Because of the gelator and the necessary solvent used, it is difficult to determine whether the gelation process will be successful [41].

6. Properties of organogel

A few characteristic attributes that organogels possess include non-invasiveness, non-toxicity, etc. But its substantial physicochemical properties, which frame it as a significant and essential system, are as follows.

6.1 Viscoelasticity

The term "viscoelasticity" is related to the materials that possess the two properties, that is, viscosity and elasticity. The viscoelastic property of organogels has also been authenticated by stress relaxation studies [6, 42]. They act as solids at lower shear stress (elasticity) and as a flowing fluid at escalated shear stress [15, 38]. At low shear rates, there is no pressure acting over them; hence they behave like solids with an intact structure, but at higher shear stress, as the pressure increases, the 3D-mesh network within the structure starts rupturing, permitting it to flow. It is observed that the organogels appear to follow the Maxwell model of viscoelasticity. It is observed that they retain plastic-flow behavior. "Organogels" are similar to other gel systems; the gelling agent creates an ongoing, three-dimensional network in the solvent, obstructing the flow of liquid. The rheological behavior of the gelator solution and its interaction with the solvent can greatly influence the flow property of the organogels [6, 15].

6.2 Thermostability

The nature of the organogels makes them innately thermostable. The capability of the gelators to undergo self-assembly under suitable conditions to produce organogels may be responsible for the stability of the organogels. The overall free energy of the system decreases when the gelators undergo self-assembly, yielding a low-energy thermostable organogel. At elevated temperatures, the molecules within the organogels acquire some kinetic energy to reduce any loss in their structure, and low temperatures, they resume their original structure. This innate property of the organogel is responsible for its longer shelf-life, thereby making it ideal for the delivery of bioactive agents [15, 16, 19].

6.3 Thermoreversibility

The matrix structure of the organogel is distorted when it is heated at a temperature that is extended from its critical temperature and hence it starts flowing. This

added thermal energy causes interaction amongst the molecules of the organogel, causing disruption in the structure. But as the temperature decelerates, the interaction of the molecules also retards, which results in the reverting back of the organogel to its original configuration. This whole phenomenon is called thermoreversibility property of the organogels. For example, PLOs, when heated above 25°C (critical temperature), lost solid-matrix configuration, and after cooling, and returned to a stable configuration. The fluid matrix systems (Fluid matrix organogels) are thermoreversible [7, 16].

6.4 Non-birefringence

Birefringence is the optical property of a material that allows propagation of light when polarized light passes through it. The organogels are non-birefringent, that is, they do not allow the propagation of light when polarized light passes through their matrix. As a result, when organogels are observed under polarized light, these appear as dark matrix. This can be attributed to the isotropic property of the organogels [16, 19, 29, 43].

6.5 Optical clarity

The transparency or opacity of the organogels will depend on the chemical makeup they possess. For example, sorbitan monostearate organogels and PLOs are opaque, whereas the lecithin organogels are transparent in nature [30, 44].

6.6 Chirality effect

It has been observed that the stability and growth of the solid-fiber networks are both impacted by the presence of chirality in LMW (Low-Molecular Weight) gelators. Additionally, the thermoreversibility of the gels produced as a result of the self-assembled solid-fiber network is related to chirality. A competent solid-fiber gelator has been shown to be generally effective in possessing a chiral center, but fluid-fiber gels are unaffected by chirality. The gelators inclusive of chiral centers aid in the production of a tight molecular packing, hence impart kinetic and thermodynamic stability to organogels. The Crown ether phthalocyanine organogel is a good chiral organogel example [7, 45].

6.7 Biocompatibility

Previously, the organogels were formulated by using several non-biocompatible components, which resulted in non-biocompatible organogels. Currently, research on organogels involving different biocompatible constituents such as vegetable oil and cocoa butter has increased their potential for extended use in biomedical field [15, 19, 38, 40].

7. Organogelators

Organogelators are the gelling agents that have the capability to transform a preparation into a semisolid mass, that is, gel. They are used to impart the desired consistency in organogels. Hence, they are an integral component in the formulation of

organogels. The solubility of the organogelator in the solvent generates a few forces, which is the reason for the stability of the thermodynamic and kinetic characteristics of the gel [7]. Organogelators have the property of changing their physical state depending upon the temperature. They remain as a solid matrix at room temperature but transform into liquid at relatively lower temperatures. The structure of organogels mainly depends upon the constructing ability of the organogelator [9]. The degree of cooperative self-assembly in an organogel is also regulated by the gelator structure and solubility [46]. The most manageable type of organogelators are n-alkanes and are useful in gelling the other proportionally short-chained alkanes [2]. It precipitates out as fibers form a 3D-structure. It is mainly responsible for the design/structure of organogels. They produce bond formation within the molecules of organogels, leading to their interaction and bonding amongst each other and an increase in the thickness of the preparation. Depending upon the type of bond they form, organogelators can be regarded as-hydrogen bond forming organogelators, viz., amino acids, amides, carbohydrates, etc., or as non-hydrogen bond forming organogelators, viz., anthraquinone, steroidal moieties, anthracene, etc. [9, 19, 38]. The ongoing research on organogelators has formed a branch for other novel types of gelators, including sugar-based organogelators and green organogelators, etc. [47, 48]. These new types of gelators each have their own concepts that should be studied comprehensively for a better understanding of the widespread availability of organogelators from a variety of sources.

7.1 Types of organogelators

7.1.1 Aryl cyclohexanol derivatives

These are 4-Tertiary Butyl-1-aryl cyclohexanols derivatives. Their characteristic features, which they impart in the gel, may differ depending upon the nature of the apolar solvent involved in the organogel. They possess low solubility in apolar solvents and hence they might appear as a turbid or transparent preparation, depending on the nature of apolar solvent involved. Their physical state is solid at room temperature. They can produce gelation only if the phenyl group in their structure lies in the axial configuration. The derivatives possessing phenyl groups in the equatorial configuration are unable to form the gel. They help in obtaining the organogels with the desired property of thermo-reversibility. A few common examples of this class are CCl4, benzene, cyclohexane, etc.

7.1.2 Polymer organogels

These are long chain-containing gelling agents. These are the gelators that possess a high capability of inducing gelation. They have a molecular size of more than 2 kilo Dalton. They can impart gel formation even if used in very low concentrations. They can appear in different shapes (straight, branched, etc.). Their efficiency of imparting gelation can be modified if their chemical structure is somewhat altered. They can be further divided into physical or chemical organogelators. If they form chemical bonds within the network of organogel, then they are regarded as physical organogelators which result in a cross-linked network, and if they form non-covalent bonds, then they are regarded as chemical organogelators which result in an entangled chain-linked network. The transition temperature for the transformation of the gel state to a sol state is also very low. They have relatively higher gel-strength than other LMOGs. They mostly

include L-lysine derivatives and the other conventional examples are polyethylene, polycarbonate, polymethylmethacrylate, polyester, etc. [18, 19, 34, 38, 40].

7.1.3 Gemini organogelator

"Gemini" means "twins". This word has been derived from Latin language. The first Gemini organogelator of L-lysine was synthesized by Suzuki et al. [49]. It had two chains of L-lysine of different chain lengths, linked together by an amide bond. This chain length is inversely proportional to the gelation ability of the gelator. They possess good gelation properties. They have a high ability to immobilize various kinds of apolar solvents. A good example of this class is Bis (N-lauroyl-L-lysine ethyl ester) oxylamide which can immobilize solvents like ketones, alcohols, etc. [9, 18, 19, 38].

7.1.4 Boc-Ala(1)-Aib(2)-β-Ala(3)-OMe organogelators

It is a synthetic tripeptide gelator of synthetic origin. It is capable of undergoing self-CB (1, 2-dichlorobenzene), 1-chlorobenzene, etc.

7.1.5 Low-molecular-weight organogelators (LMWOs)

These are the gelling agents that possess a small molecular weight (≤3000 Dalton) [9, 50]. Assembly which is the contributor of its gel-formation ability. They form thermoreversible and transparent gels. The apolar solvents, to which they can immobilize include benzene. These are most widely used organogelators. They contain a high capability of immobilizing the aqueous phase, even if used in small concentrations (<2%). The length of the alkyl chain in LMWO directly influences its gelling ability [51]. They mostly form solid-fiber matrices or can form fluid-fiber matrices based on the intermolecular interaction they perform. A solid-fiber matrix can be obtained if the organogelator is cooled down beyond the solubility range of the gelator, which is then followed by a rapid, incomplete precipitation, in the organic solvent, which leads to physical intermolecular interactions. For forming a fluid matrix, a polar solvent should be added to the solution of surfactant, leading to the re-arrangement of molecules to form a clump, hence immobilizing the aqueous phase. This also results in a difference in the kinetic-stability between both the matrices, which can be used as a distinguishing factor. Solid-fiber matrix offers an enhanced mechanical property compared to that of fluid-fiber matrix. This is because a solid-fiber matrix contains a highly arranged molecular structure compared to a fluid-fiber matrix. LMOGs have been further categorized into steroidal organogelators, ALS organogelators, etc., depending on the chemical backbone they possess [7, 19, 34, 38, 52].

8. Mechanism of organogelation

Organogelation is generally induced by the incorporation of a polar solvent into the organogel. If lecithin is present in it, then, it forms reverse spherical micelles at a ~ 0.01 mM concentration. This is induced by the addition of a small quantity of polar additives which bind to the hydrophilic head of the lecithin. This creates linear networks. If the amount of polar additive is further increased, then it leads to the formation of long tubular flexible micelles. After overlapping with each other sufficiently, they entangle themselves and build up a transient 3D network (**Figure 1**).

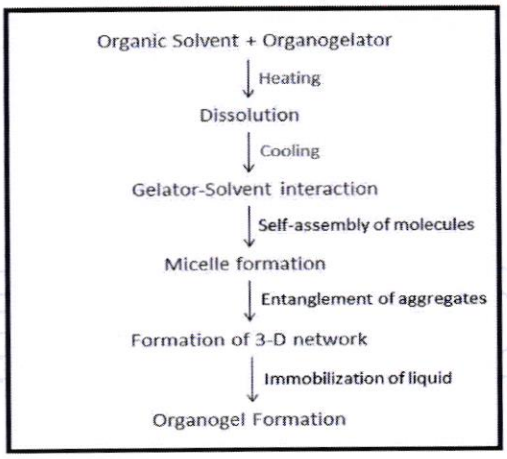

Figure 1.
Mechanism of Organogelation.

In the case of PLOs, the mechanism of gelling and the structural network may be related to the synergistic contribution of both phospholipids and polymeric co-surfactant molecules in their respective hydrated states. In this case, solvent molecules and lecithin phosphate groups can be arranged in such a way that a hydrogen-bonded network will be formed [15, 34, 52].

9. Mechanism of gel permeation into skin

Human skin is made up of different types of tissue layers. The outermost layer, Stratum corneum is the rate limiting barrier for the permeation of gel into the skin [35]. It has been observed that lipid based formulations enhance penetration through the skin; however, they modify the hydration state of the skin, causing dermatitis. Aqueous formulations maintain the skin intact and bioactive, but have less penetration [18]. In the case of Pluronic Lecithin organogels, penetration and permeation are enhanced due to lecithin, which alters the skin structure and transiently opens the skin pores. It is believed that this happens due to the interaction between the lecithin's phospholipid and skin lipids. Hence, there occurs the formation of a cylindrical network which results in an increase in the area of the lecithin polar region, and non-polar solvent acts as a penetration enhancer and then penetration occurs by forming a thin film on the skin surface (**Figure 2**) [16, 18, 35].

10. Method for preparation of organogels

At 60°C, the oil-surfactant mixture is heated to produce a transparent solution that, when cooled, transforms into organogels. Lecithin solutions are made by first dissolving lecithin in organic solvents using a magnetic stirrer, according to the phase diagrams that have been constructed. Organogels are created by adding water with the use of a micropipette syringe. Heat may be used occasionally to completely dissolve drugs. Lecithin and an organic solvent are combined to create the oil phase, which is then let to stand overnight to guarantee full breakdown. When preparing the aqueous (polar) phase, pluronic is added to ice-cold water and stirred to ensure

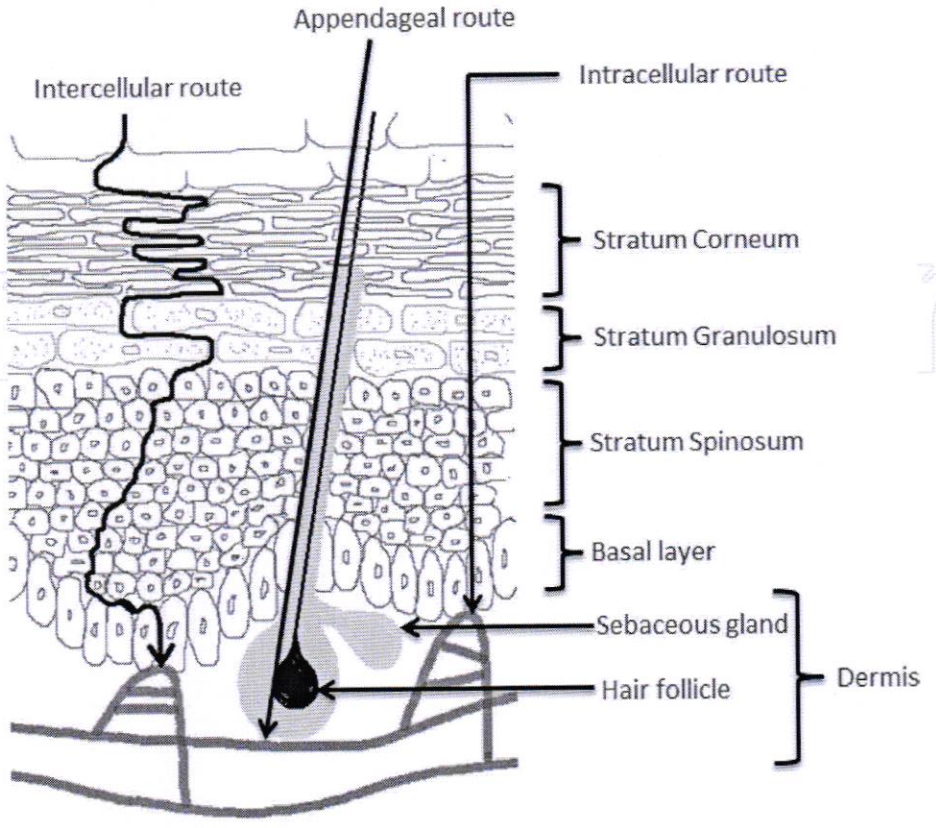

Figure 2.
Pathways for permeation of organogel into skin.

thorough dissolve. The produced PLO is blended with the Pluronic's aqueous phase using a high-shear mixing technique by a magnetic stirrer. Fatty-acid gelators can also be used to create organogels by first dissolving them at a higher temperature in a water-in-oil emulsion, then lowering the temperature. The solubility of the gelator decreases as a result of the drop in temperature, which leads to precipitation and self-assembly of the gelators into a network of tubules that become entangled to create a gelled structure [2, 19].

10.1 Fluid-filled fiber method

It is a well-known technique for making organogels, where in reverse micelles are produced by dissolving surfactants and co-surfactants in an apolar solvent. Reverse micelles are then transformed to tubular reverse micelles after the addition of water. The elongated reverse micelle becomes entangled to create a 3-dimensional network, which immobilizes apolar solvent [53].

10.2 Solid fiber method

In the Solid fiber method, an apolar solvent and solid organogelator are heated together at an apolar solution of the solid organogelator is produced. Then cool it at room temperature, the organogelator precipitates out as fibers that interact physically with one another to form a three-dimensional network structure that immobilizes apolar solvent [15, 38].

Types	Administration Route	Study carried out	Model Drugs	Reference
Sorbitan monostearate	Nasal Oral Subcutaneous & intramuscular	In vitro release In vivo efficacy	Propranolol Cyclosporin A	[55] [56]
Lecithin	Transdermal	Clinical studies Skin permeation and effectiveness in vivo Skin permeation in vitro Skin release in vitro	Metoprolol Aceclofenac Indomethacin Diclofenac Bioactive agents	[57] [13, 58, 59]
Eudragit organogels	Rectal Buccal	In vivo efficacy	Salicylic acid BSA	[44, 60]

Table 1.
Formulations of organogels used in drug delivery.

10.3 Hydration method

In this technique the inorganic chemical is directly hydrated to form the dispersed phase of the dispersion, which is then used to create gel. Other substances such as propylene glycol, propyl gallate, and hydroxypropyl cellulose may be employed in addition to water as a carrier to improve gel formation [53].

10.4 Novel methods

Conventional methods of preparing organogels usually require longer heating times and neutralizing agents. Evren et al. prepared organogels employing a new technique, high-speed homogenization which was followed by microwave heating. Evren et al. prepared Triclosan organogel employing Carbopol 974 NF in PEG 400. Carbopol in varying concentrations (2–4%) was dispersed in PEG 400. The resulting dispersion was homogenized at 24,000 rpm.. The dispersion was heated using two methods. The first involved heating at 80°C, stirring mechanically at 200 rpm. In the second method, the dispersion was subjected to micro-irradiation (1200 W/1 h) for 2 min. The results demonstrated that microwave heating was suitable for preparing carbopol organogels. Owing to significant reduction in time and energy, the method holds good promise for industrial applicability [54] (**Table 1**).

11. Factors affecting organogels

11.1 pH

A pH change stimulates the reversible transition of an organogel from a gel state to a sol state [61]. Hence, pH can influence the physical state of gels.

11.2 Temperature

Organogels are often less stable with increasing temperatures, causing disruption of the 3D mesh-network structure. Temperature also affects viscosity. As the temperature increases, the viscosity decreases [4]. Hence, the temperature range during their storage should be closely controlled [5, 18, 19].

11.3 Organogelator

The type of organogelator used for the preparation has the capability to influence the mechanical and rheological properties of the organogel [40].

11.4 Adjuvants

a. Surfactants: Characteristics of gel can be varied depending upon the surfactant.

b. Salts: The addition of salt to the organogel may result in salting-out (formation of more secondary bonds amongst the molecules) [15, 38].

c. Organic solvent: The structure of an organogel depends upon the nature of the solvent (polar/non-polar).

d. Organogelator: The rate of drug release from the organogel is affected by/depends upon the concentration of the gelator used [62].

e. Skin permeation enhancers: These chemical entities might also possess additional characteristics, which may interact and alter the properties of the organogel.

Terpenes operate as chemical penetration enhancers and also act as rheology modifiers, which may result in any alteration in the flow property and deformation characteristics of an organogel [63].

11.5 Moisture

Organogels swell when exposed to moisture as they absorb water molecules from it This may aid in the instability of the organogels [38].

11.6 Purity

The constituents used in an organogel should be in its pure form. Any impurity in the components may lead to instability in the network of the matrix, for example, lecithin is unable to induce gelation if not used in its pure form [2, 40].

12. Application of organogels

12.1 Pharmaceutical industry

a. Topical drug delivery system.

The skin, being the largest tissue in the body, provides good bioavailability of drugs, as the drugs meant to enter the systemic circulation via permeation through the skin bypass the first-pass metabolism. Pluronic lecithin organogels (PLOs) contain isopropyl myristate/isopropyl palmitate as an apolar organic solvent used as a vector for the release of NSAIDs (ketoprofen, flurbiprofen, diclofenac sodium), used as an analgesic. Reverse micellar MBGs possess soya-lecithin/iso-octane/water as a solvent phase for the delivery of propranolol. Organogels can be regarded as potential matrices for the controlled release of topical antimicrobials. Organogels loaded with Piroxicam are used for the treatment of rheumatoid arthritis. In-situ forming organogel of L-alanine injectable can be used for the release of labile macromolecular drugs. Various studies on formulation of transdermal organogels, such as development of PLO with mometasone furoate for psoriasis and fluconazole-loaded organogels based on olive oil for fungal infections, have exhibited positive results [9, 42, 64].

b. Oral and trans-mucosal drug delivery system.

The drugs can be delivered through oral cavity with the help of implantation of bio-adhesive organogels, that is, the drugs will be administered as implants. The drug can be dissolved within the organic solvent and then mixed with the muco-adhesive polymer. An organogel of 12-HSA-soyabean oil was used for the delivery of ibuprofen [15]. An in-vivo study conducted in rats depicted that the organogels can be employed as a vector for controlled release of lipophilic drugs [38]. Sorbitan monoleate based organogel, incorporated with cyclosporine A is given orally. An oral organogel can be prepared by incorporating an NSAID (ibuprofen) to achieve desired therapeutic results [65].

c. Parenteral drug delivery system.

Parenteral routes are the preferential choice for the administration of drugs, as it avoids first-pass metabolism, provides quicker onset of action, etc. An in-situ forming organogel prepared for sustain delivery of leuprolide (used in prostate cancer) from the L-alanine derivatives in safflower oil and was injected by SC route. It was observed that the gel degraded slowly for drug release over a span of 14–25 days [7, 15]. Sorbitan monostearate organogel preparation have been developed and given by SC and IM route for the release of propranolol/ cyclosporine A/ BSA and HA [7]. A study depicted that, safflower oil-based N-methyl pyrrolidone (NMP) injections were introduced into rats subcutaneously, which was well-tolerated by the surrounding tissues over a period of 8 weeks [66]. The injection of an in-situ organogel forming implant based on SAM (N-stearoyl-L-alanine methyl ester) demonstrated significant promise for safe and suitable delivery method for therapeutic medications that require regulated release [67]. A successful evaluation was conducted for the purpose of using parenteral organogel in schizophrenia therapy [68]. The micro-emulsion based organogels and niosomes containing organogels have been formulated for delivery of vaccines. After administration of these gels via intramuscular route, a depot effect was observed (**Table 2**) [15].

d. Ophthalmic drug delivery system.

Ophthalmic solutions are generally used for administering drugs in the eye, but due to its consistency, frequent dosing is required as the drug may not be properly

Parameters	Description
Gelation Studies	A straightforward visual test to establish whether gelation has been established and includes: inverting the reaction vessel, pouring with organogel; if the sample does not flow, gelation has occurred [40]
Rheological Behavior	An indication of the structural organization of the organogel is obtained by its rheological behavior. The viscosity the usually determined with the help of a Brookfield viscometer [69]
Structural features	Utilizing NMR spectroscopy, the molecular design of organogels has been evaluated, and FTIR spectroscopy has demonstrated hydrogen bonding. Optical microscopy, freeze fracture electron microscopy, transmission electron microscopy and X-ray diffraction have been used to learn about the molecular packing within the organogel network [29, 38]
Phase transition Temperature	It is the determination of the temperature at which the organogel transforms from gel state to sol state. It provides details on the types of the microstructures that make up the cross-linked gelling network. The presence of uniform microstructures within the gel is indicated by a restricted PTT range (3–5°C). Hot stage microscopy (HST) and high sensitivity DCS are employed to determine it. Basically, the organogels are placed in glass tubes which are subjected to incrementing temperature. The transition is analyzed by inverting the tubes and this temperature is then noted [59]
pH	A digital pH meter is used to assess the pH of the formulation. A suitable amount of organogel is dissolved in a solvent. The pH meter electrode is submerged in this mixture, which then display the value of pH [42]
Water Content	Evaporation of water can cause viscosity to drop, which can impair the stability of the gel. The use of NIR spectroscopy (NIR, 1800–2200) to measure water content [59]
Stability study	The stability of organogels can be determined at different temperature and relative humidity conditions as per ICH guidelines. 25°C ± 2°C at 75 ± 5% RH 40°C ± 2°C at 75 ± 5% RH
In vitro studies	Through a dialysis membrane, the formulation is subjected to in vitro diffusion. A Franz diffusion cell can be employed to determine the drug release [2]
In vivo studies	Various animals, such as rats, are employed as models for several evaluation such as skin irritation tests and compatibility tests
Physical examination	It is a preliminary assessment in which, the prepared organogel is evaluated for its color, texture, appearance, odor, etc. [29]

Table 2.
Evaluation of organogels.

absorbed in the target site. Hence thicker preparations like gels are desired to increase the contact time to facilitate the maximum absorption of drugs from the formulation. Methazolamide is incorporated into carbomer and poloxamer gels for the treatment

of glaucoma which was ineffective when formulated as ophthalmic solution [38]. Organogelators are employed with drugs such as Eudragit L and S for ophthalmic preparation for sustained delivery [50].

12.2 Food industry

Organogels are primarily employed in the food industry owing to their ability to reduce oil mobility in food items, particularly those containing multiple ingredients. Organogels can be used as replacer for Trans and saturated fat in processed foods to install a specific texture. Wax-based organogels provide good oxidative stability, and also influence the firmness and spreadability and thus can be used in spreadable food product [18, 64, 70].

12.3 Cosmetics industry

Low molecular weight organogelators (LMOGs) such as DBS and 12-HSA are used for preparation of lipsticks [71]. 12-HSA organogelator is used in sunscreens to block UVB rays [41]. It is possible to improve the properties of organogels developed for cosmetic applications by using organic solvents like Amazonian oils, which already possess moisturizing and nourishing effects [72]. Various dermatological cosmetics such as lip-gels, skin, and hair protectants can be prepared in the form of organogels [18, 38]. Other cosmetic preparations such as shampoo, dentifrices, and perfumes are prepared in the form of organogels [15].

13. Conclusion

Organogels are a visco-elastic substance primarily made by gelling the organic solvent with a bioactive agent. It has captivated a section of curiosity to explore all the aspects of their application, as these can potentially eliminate or replace many components, techniques as well as limitations being faced normally for different types of formulations, due to unique properties. The organogels have a huge area for application, although possess few drawbacks and limitations. Though these can be administered to the body via various drug delivery routes, the major site is topical route considering ease of application and many more reasons. A stable organogel designed with all the bio-compatible components might attract the commercial market in future as they can potentially become the preferential choice of formulators and consumers.

Acronyms and abbreviations

LOs	lecithin organogels
PLs	pluronics
PLOs	pluronic lecithin organogels
GP1	dibutyllauroylbutamide
PG	propylene glycol
MBG	micro-emulsion based organogels
w/o	water in oil
span 40	sorbitan monopalmitate
span 60	sorbitan stearate

PEG	poly ethylene glycol
LAM	N-lauroyl-L-alanine methylester
CCl_4	carbon tetrachloride
LMWO	low-molecular-weight organogelators
3D	3 dimensional
NSAIDs	non-steroidal anti-inflammatory drugs
HST	hot stage microscopy
PTT	phase transition temperature
NIR	near infra-red
NMP	N-methyl pyrrolidone
SC	subcutaneous
IM	intramuscular
SAM	N-stearoyl-L-alanine methyl ester
BSA	bovine serum albumin
HA	hemagglutinin

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3.2.2

B - Papers published in national/ international conference proceedings

3.2 Research Publication and Awards

3.2.2.1 Number of books and chapters in edited volumes/books published and papers published in national/ international conference proceedings per teacher during the year

B- Papers published in national/ international conference proceedings

Sr. No.	Name of the teacher	Title of the paper	Title of the proceedings of the conference	National / International	Year of publication	Affiliating Institute at the time of publication
1.	Dr. Anjali Bedse	In Vivo Pharmacokinetic study of felodipine microparticles loaded rectal dosage form	72nd Indian Pharmaceutical Congress	National	2022-23	K.K.Wagh college of Pharmacy, Nashik
2.	Dr. Rupali A. Patil	Anti-hyperbilirubinemic screening of aqueous extract of mimosa pudica roots in experimental animals	72nd Indian Pharmaceutical Congress	National	2022-23	K.K.Wagh college of Pharmacy, Nashik
3.	Ajaykumar Surana	Phytochemical investigation , thrombolytic and antioxidant activity of clerodenrum thomsoniae balf.f	72nd Indian Pharmaceutical Congress	National	2022-23	K.K.Wagh college of Pharmacy, Nashik
4.	Shilpa Borate	Simultaneous estimation of curcumin and Vitamin E in bulk and pharmaceutical dosage form by UV Spectrophotometry	72nd Indian Pharmaceutical Congress	National	2022-23	K.K.Wagh college of Pharmacy, Nashik
5.	Dr. Rakesh Amrutkar	"Recent Advances in Nanotechnology: Drug Discovery & Therapeutics"	2nd NIRMA e-CONFERENCE	International	2022-23	K.K.Wagh college of Pharmacy, Nashik
6.	Sunanda Malode	Commercialization of natural products	ISFCON-2023	International	2022-23	K.K.Wagh college of Pharmacy, Nashik

72nd INDIAN PHARMACEUTICAL CONGRESS

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72nd Indian Pharmaceutical Congress, Nagpur

January 20-22, 2023

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CERTIFICATE OF PARTICIPATION

DELEGATES

It is our pleasure to certify that **ANJALI BEDSE** of **K. K. WAGH COLLEGE OF PHARMACY, NASHIK** has participated as delegate in the 72nd Indian Pharmaceutical Congress held at Department of Pharmaceutical Sciences, Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur January 20-22, 2023.

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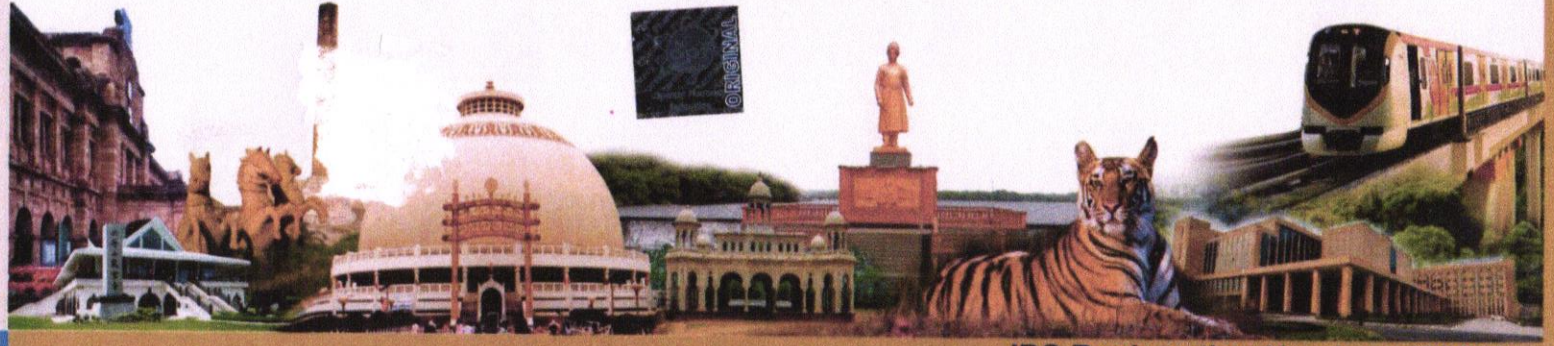
President, IPCA	Chairman,LOC	Organising Secretary,LOC	Organising Secretary,LOC



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SCIENTIFIC ABSTRACTS

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E-1

IN VIVO PHARMACOKINETIC STUDY OF FELODIPINE MICROPARTICLES-LOADED RECTAL DOSAGE FORM

Anjali P. Bedse, Hitendra S. Mahajan
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Felodipine is a long-acting 1, 4-dihydropyridine calcium channel blocker. It acts primarily on vascular smooth muscle cells by stabilizing voltage-gated L-type calcium channels in their inactive conformation. Felodipine is used to treat mild to moderate essential hypertension. Felodipine has poor aqueous solubility and undergo extensive first pass metabolism with 15% bioavailability. The current research deals with preparation and evaluation of felodipine mucoadhesive microparticle-loaded rectal dosage form which may remain adhered in the lower rectum and avoid first pass metabolism. Felodipine alginate tamarind microparticles loaded suppositories were developed for rectal administration to avoid hepatic first pass effect so as to enhance its absorption. The formulated suppositories were evaluated for various parameters like weight variation, disintegration time, in vitro dissolution study, stability study and pharmacokinetic study. The disintegration time and percent cumulative drug release of microparticles loaded suppositories was found to be in the range from 13.69 ± 0.93 min to 20.94 ± 0.63 min and 88.23 ± 0.91 to 96.47 ± 0.02 respectively. During In vivo pharmacokinetic study of rectally administered felodipine microparticles loaded suppository, in male Sprague–Dawley Rats, the relative bioavailability was found 148.15%. The study reveals that rectal administration of felodipine as microparticles loaded suppository was an alternate route of administration.

E-2

SYNTHESIS AND DESIGNING OF MODIFIED CHITOSAN COATED LIPIDIC NANOSHELLS FOR DISRUPTING EGFR SIGNALING CASCADE IN EFFECTIVE MANAGEMENT OF GLIOBLASTOMA MULTIFORME

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Glioblastoma Multiforme (GBM), a highly infiltrative grade IV primary malignant brain tumour is characterized by poor prognosis which ultimately leads to a high mortality rate. Nanotechnology have been seen as an alternative novel therapy for the treatment of GBM. Thymoquinone (TH) is the main active constituent of Black seed (Nigella sativa, family Ranunculaceae) plant oil and possesses potent anticancer activities. This study aims at improving aqueous solubility of TH and enhancing the bioavailability by synthesising Modified Chitosan Coated Thymoquinone loaded Lipidic Nanoshells (CH-TH-NSs) using 32 factorial design-response surface methodology. The formulated Nanoshells were optimised with Particle size (nm) and entrapment efficiency (EE%) as indicators. Modified Chitosan (Cs) showed higher mucoadhesion and solubility in nasal pH. Transmission electron microscopy (TEM) and Scanning electron microscopy images revealed that prepared CH-TH-NSs were nano-spherical and having the ideal nano size and zeta potential. XRD study showed the transformation of TH from crystalline to amorphous and additional confirmed by DSC thermogram indicating TH forming a molecular dispersion with Nanoshells. The pharmacokinetic parameters over 24 hours suggested higher time to maximum concertation of intranasally administered CH-TH-NSs in comparison to intravenous and intranasal TH solution. Cell cytotoxicity and cellular uptake studies was done on Glioma C6 cell lines, microscopic images suggested higher internalization of NSs and enhanced solubility giving improved cytotoxic outcomes, with better IC50 values. Molecular docking study displayed better interaction on binding sites of EGFR and ultimately providing better inhibition and enhanced anti-GBM activity.

E-3

NANOFABRICATION OF STEROIDAL SAPOGENIN WITH ANTHRAQUINONE AND THEIR PHARMACOKINETICS IN RATS

Prasad Sherekar, Sanvidhan G Suke, Shubhada Mangrulkar and Archana Dhok
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Steroidal sapogenin i.e. diosgenin (DG) and anthraquinone i.e. emodin (ED) both are active phyto-constituents having anti-inflammatory and anti-fibrotic activities, which has limited by poor solubility and fast biotransformation. Encapsulating these drug molecules in polylactic-co-glycolic acid (PLGA) nanoparticles can improve their pharmacokinetics and bypass therapeutic obstacles. Present study has thus investigated pharmacokinetics of PI nanoparticles (DG-EDn) encapsulating DG and ED via modified solvent-emulsion diffus evaporation method. Physio-chemical characterizations of DG-EDn were performed confirm functional stability of both drugs within nanoparticles. DG-EDn has recorded m particle size of 163 nm and 0.492 of polydispersity index with 18.73 and 22.25 percen encapsulation efficiency for DG and ED respectively. In continuation, DG-EDn sho -14.63 mV of surface zeta potential and uniform spherical morphology examined u scanning electron microscopy. Moreover, nanoparticle showed in vitro controlled drug rele pattern over 24 hours with ◻ 50% of both drugs depletion. For pharmacokinetics studies, drugs and nanoformulation were orally (10 mg/kg) administrated to twelve rats equ allocated to three groups (DG, ED, and DG-EDn). The drug concentrations were evaluated i blood-plasma withdrawn at different time interval using HPLC. In results, pharmacokinetic DG has significantly enhanced due to nanoencapsulation with ED in PLGA, while improvement was observed for ED. DG-EDn subsidizes increased mean plasma residence and maximizes area under curve with decreased drug clearance rate for both drug molec Consequently, changes in pharmacokinetics of both drugs attributed to size and sur characteristics of nanoparticles. The physio-chemical characteristics and pharmacokin investigations reveal the efficacy of DG-EDn to be suitable drug delivery modality with s pharmacological strength.

E-4

ENALAPRIL MALEATE MUCOADHESIVE BUCCAL FILMS: DESIGN AND EVALUATION

Debashish Mohanty, Archana Pattanaik, Souvik Giri, Nilima Shukla
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Angina pectoris and excessive blood pressure are both treated with enalapril maleate means there was a considerable amount of first-pass hepatic metabolism and bioavailability. The goal of this project was to create mucoadhesive buccal films cont enalapril maleate that would improve patient compliance, therapeutic effectiveness bioavailability.Ten different formulations of mucoadhesive films consisting of en maleate were created in the current study using solvent casting. We used sodium HPMC, and PVP K-90 as mucoadhesive polymers. The produced films' weight, thic surface pH, swelling index, homogeneity of the drug content, in vitro residence time, toughness, in vitro release, and penetration studies have all been examined. Film permeation studies reveal that controlled release may endure for more than six hou films containing 20 mg of the enalapril maleate formulation (F5) were believed to be th candidates for the manufacture of buccal films for effective therapeutic reasons sinc showed acceptable swelling, a sufficient residence time, and supported controlled relea

E-5

DESIGNED AND EVALUATION OF CHITOSAN NANOPARTICLES LOADEI NANOFIBER HYBRID SYSTEM FOR VAGINAL CONTROLLED RELEASED OF A

Souvik Giri, Debashish Mohanty, Archana Pattanaik, Nilima Shukla
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Vaginal drug delivery systems prevent systemic side effects and can provide long-te release in the vaginal area. As a vaginal drug delivery system, nanofibers and nanoparti appropriate for a wide range of applications. A non-steroidal anti-inflammatory and an drug called Benzydamine is used to treat vaginal infections. This study aimed to lyophilized Benzydamine nanoparticle formulations with free Benzydamine formula nanofiber and gel forms to provide prolonged release for protection from vaginal inf The formation of nanoparticles loaded with Benzydamine occurred through the pr ionic gelation. Polyvinylpyrrolidone (PVP) solutions were prepared at 10% concentra combined with nanoparticles to produce nanofiber formulations loaded with benz nanoparticles. For the vaginal gel formulation, 1% of hydroxypropyl methylcellulose was used as a gelling agent. Various evaluation parameter of the nanoparticle were n like zeta potential, polydispersity index etc. For electrospinning, the viscosity, surface and conductivity of the polymer solutions were measured. The mechanical properti fibres, contact angle, and drug loading capacity were determined. Scanning microscopy (SEM), differential scanning calorimetry (DSC), transmission electron mi (TEM), Fourier transform infrared spectroscopy (FT-IR), mucoadhesion, ex vivo per studies, and in vitro release studies were performed for the selected formulations. Th suggest that fibres and gels loaded with Benzydamine and Benzydamine nanoparti be a potential drug delivery system for the treatment of vaginal infections.

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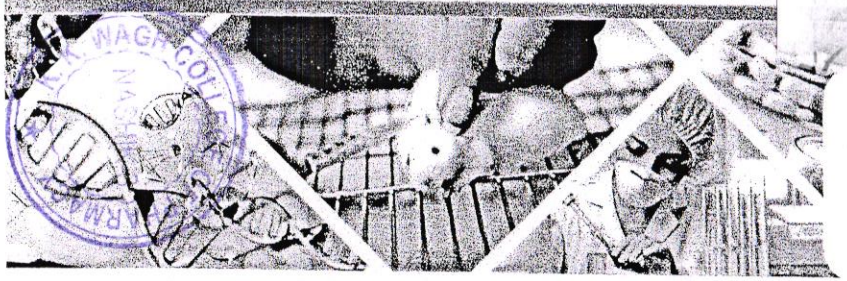
Certificate

POSTER

It is our pleasure to certify that,

RUPALI A. PATIL presented a Poster in Scientific Session entitled **"ANTI-HYPERBILIRUBINEMIC SCREENING OF AQUEOUS EXTRACT OF MIMOSA PUDICA ROOTS IN EXPERIMENTAL ANIMALS"** in the 72nd Indian Pharmaceutical Congress held at Department of Pharmaceutical Sciences, Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur during January 20-22, 2023.

Dr. V. G. Somani	Mr. Atul Mandlekar	Prof. Milind [illegible]ekar	Prof. Prakash Itankar	Prof. Roop K. Khar	Prof. Dadasaheb M. Kokare
President, IPCA	Chairman,LOC	Organising [illegible]y,LOC	Organising Secretary,LOC	Convener, IPCA-SSC	Chairman, Scientific Committee, LOC



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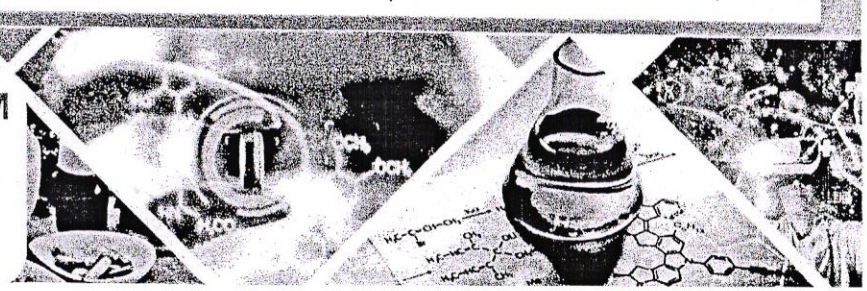

D-2

ANTI-HYPERBILIRUBINEMIC SCREENING OF AQUEOUS EXTRACT OF MIMOSA PUDICA ROOTS IN EXPERIMENTAL ANIMALS

Rupali A. Patil, Pradhnya M. Ghate
. K. Wagh College of Pharmacy, Hirabai Haridas Vidyanagari, Amrutdham, Panchavati, Nashik 422003 Maharashtra, India.
rupaliapatil2020@gmail.com

ct of aqueous extract of Mimosa pudica L. roots (AEMP) was investigated for the cetamol and phenlyhydrazine (PHZ) induced hyperbilirubinemia in Wistar rats. In both els, the common parameters estimated were serum Bilirubin, Hemoglobin (Hb), serum s of liver biomarker enzymes viz., aspartate transaminase (AST), alanine aminotransferase) and alkaline phosphatase (ALP), various in vivo biochemical parameters like superoxide utase (SOD), catalase (CAT), reduced glutathione (GSH) and extent of lipid peroxidation) in the liver. Paracetamol and PHZ exhibited significant increase in the level of bilirubin and while levels of other parameters significantly decreased on 10th day. AEMP exhibited ficant decrease in the levels of bilirubin and LPO and increase in the levels of other neters on 10th day. Present study indicates that aqueous extract of Mimosa pudica root s potential anti-hyperbilirubinemic activity in both the models

D-3

ARMACOLOGICAL SCREENING AND EVALUATIONS OF CARDIO PROTECTIVE CTIVI OF ETHANOLIC EXTRACT OF PTEROLOBIUM HEXAPETALUM ROTH, INST ISOPROTERENOL- INDUCED MYOCARDIAL NECROSIS IN EXPERIMENTAL RATS.

mathi.V, Balaji.V, Mohankumar S, Murugan S, Naveenkumar S, Naveen S. M
/aka Mission's College of Pharmacy, Vinayaka Mission's Research Foundation (Deemed to be University), Salem – 636008, TamilNadu, India
gomicology@gmail.com

tive: To evaluate the cardioprotective effects of ethanolic extract of Pterolobium etalum Roth against Isoproterenol (ISO) induced myocardial necrosis in experimental Methods: Isoproterenol (80 mg/kg) was subcutaneous(s.c.) administered to animals for 24 on two consecutive days to cause myocardial infarction. Rats were given pretreated with (100-200 mg/kg/day, orally) for 30 days prior, to receiving Isoproterenol injected on days nd 32nd days. After 24 hours, blood was collected from cardiac puncture for biochemical eter estimations and histological analyses. Results: In the present study, isoproterenol administrations significantly elevated the levels of cardiac troponin-T, lipoproteins, aminotransferase and aspertate-aminotransferase, cholesterol, and triglyceride, while (100-200mg/kg) oral treatment for 30 days elicited a significant cardioprotective activity oring the level of serum markers enzyme. The P. Hexapetalum had a more noticeable at a dose of 200 mg/kg than at a dose of 100 mg/kg, returning all the parameters to a that was close to normal. The histopathological findings of the ISO-induced myocardium d an infracted zone with inflammatory cells, myocardial fibrosis, and myofibrils, which educed by Pterolobium Hexapetalum Roth pretreatment. The effect of P.Hexapetalum mpared to that of Metoprolol. Conclusion: It can be concluded our data suggest that bium petalum possess cardioprotective activity against Isoproterenol- induced dial n...osis in rats..

D-4

CT OF POLYHERBAL FORMULATION (PHF) AND ITS COMPARATIVE STUDY H OTHER TREATMENT IN DIFFERENT TYPES OF DERMATITIS (ECZEMA) IN EXPERIMENTAL ANIMALS

Kiran Gaikwad and Sandip S. Hurpade
Dr. Rajendra Gode College of Pharmacy, Malkapur, Maharashtra, India 443101
kiranpgaikwad10@gmail.com

dermatitis (AD) and allergic contact dermatitis are skin disorders that are a type of AD is a childhood disorder & allergic contact dermatitis. When the skin touches bacteria, the skin inflammation causes itching and redness. The Poly Herbal tion uses this content: chaulmoogra oil 10%, neem oil 8%, and Karanja oil 30%, then e an ointment. They are using this ointment topically for mice's skin after 30 days of itching, dryness, and inflammation necessary for the basic treatment. This paper a different study of eczema AD & contact allergic dermatitis by using a polyherbal ...

D-5

NEUROPROTECTIVE ACTIVITY OF VALERIANA WACLLICHII VIA MODULATION OF GABA SIGNALLING IN RATS.

Shilpa Vishwakarma, Raja Rahul S, Rohit Goyal, Varun Gupta, Kanaya Lal Dhar
School of Pharmaceutical Sciences, Shoolini University, Solan, HP

Valeriana wallichii, a member of the Caprifoliaceae family, is used for its diuretic, anti-ulcer, anti-spasmodic, anti-epileptic, anti-anxiety, anti-rheumatic, and anti-spasmodic properties. Valpotriates, valeric acid, valerenic acid, valechlorine, valerianine, resins, and alkaloids are said to be present in V.wallichii. The valeric acid present in V.wallichii has a structure that is comparable to that of the neurotransmitter GABA. Another function of valeric acid is as an NMDA-receptor antagonist. The purpose of the current study was to examine the neuroprotective effect of V.wallichii, which contains valeric acid, as well as any potential mechanisms by which it can lessen the neurotoxicity caused by intracerebroventricular streptozotocin in Wistar rats. V.wallichii rhizomes were coarsely ground up and extracted using the percolation method with dichloromethane. Both sexes of Wistar rats (220–250 g) were put into 5 groups of six each. FT-IR was used to separate the valerian acid from plant extract and characterise it. Picrotoxin (2 mg/kg) was used as GABA-Antagonist. Intracerebroventricular streptozotocin administration caused significant ($p < 0.05$) increase in escape latency, retention transfer latency on morris water maze on 17th, 18th, 19thand 20thday and elevated plus maze on 19th and 20th day respectively, as compared to normal untreated rats. In comparison to the intracerebroventricular-streptozotocin group, treatment with V.wallichii extract at doses of 100 and 200 mg/kg and valeric acid at doses of 20 and 40 mg/kg significantly reduced the escape latency and retention transfer latency. Additionally, lipid peroxidation was reduced and glutathione levels were increased in rat brains when plant extract and valeric acid were combined. Administration of picrotoxin effectively reversed the effects caused by plant extract and valeric acid in intracerebroventricular-streptozotocin treated rats. According to the results, valeric acid found in V.wallichii significantly improves experimental dementia by having a GABAergic impact.

D-6

IMPACT OF CULTIVATION METHODOLOGIES ON THE ANTI-DIABETIC, ANTIHYPERLIPIDEMIC, OXIDATIVE STRESS AND PANCREATIC REGENERATION POTENTIAL OF FEW MEDICINAL PLANTS

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Dr. Arun Motghare College of Pharmacy,
Kosra-Kondha, Tah. Pauni, Dist. Bhandara 441 908 (MS) India

With the objective of studying the toxicity and pharmacological activity especially anti-diabetic potential by taking Momordica charantia, Ocimum sanctum, Trigonella foenum graecum and Gymnema sylvester as experimental plants was a challenge. The researchers basically wish to check the different cultivation technologies (non-organic & organic) and its impact on biological efficacy of these plants. The first time ever in the research on organic and non-organic plants, bioluminescent bacterial (Vibrio harveyi) strains were utilized to compare the toxicity levels. Assay was based on the inhibition of bacterial strains as a measure of intoxicant levels and ultimately decrease in luminescence was observed. All non-organic crop shown higher toxicity level and highest decrease in relative light units. STZ and NAD induced type 2 diabetes model was utilized. The sub-chronic anti-diabetic activity was observed in decreasing order of positive control > OMC-200 > OTF-200 > OOS-200 > NMC-200 > NTF-200 > OGS-200 > NOS-200 > NGS-200. Induction of diabetes resulted in significant decrease in body weight of diabetic control mice compared with control group at the end of experiment ($P < 0.01$). Administration of extracts to the diabetic mice improved the body weight of animals at the end of 3 weeks. Hypolipidemic activity was observed in the decreasing order of OTF > OMC > OOS > NTF > NMC > OGS > NOS > NGS. All the extracts at all the doses, lowered serum SGPT and SGOT levels also but the higher level of significance was at 200 mg/Kg compared with normal control ($P < 0.01$). The organic Trigonella foenum graecum extract gave the highest decrease in the SGOT & SGPT level to 77 and 47.5 units/L respectively. The role of extracts in the management of free radicals were determined in the erythrocyte lysate, pancreas and liver. As similar as above, the organic crop showed the pronounced increase in SOD, CAT and GSH levels and significantly inhibited the increase in LPO level in E. lysate, pancreas and liver. Histopathological studies proved the normal architecture of islet, pancreatic tissue and cellular populations in the normal control group, however, infiltration, necrosis of islet and degeneration in pancreatic tissue was observed in diabetic control. All organic extracts represented enlarged islet and well-structured neo islets with normal pancreatic tissue that have confirmed their maximum anti-diabetic potential. Though, no significant differences in the acute anti-diabetic activity and effect on body weight of experimental animals was noted between organic and non-organic crops under study, it has clearly shown evidences of damage by non-organic crops on bioluminescent bacteria during

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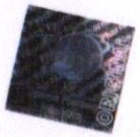
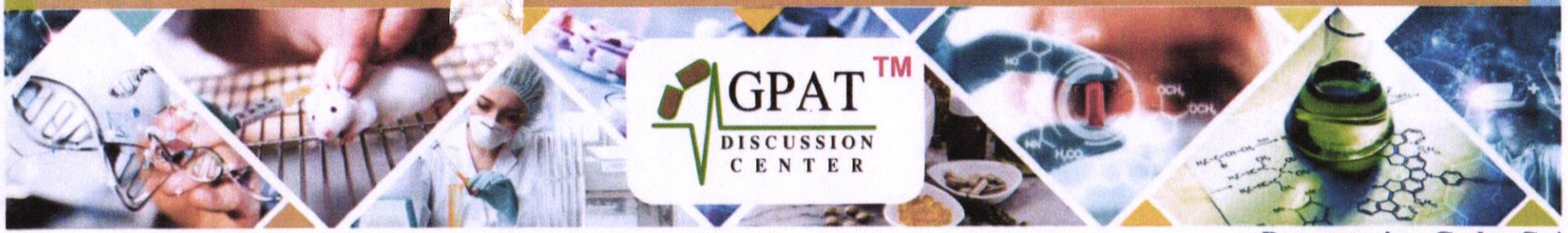


It is our pleasure to certify that,

AJAYKUMAR RIKHABCHAND SURANA presented a Poster in Scientific Session entitled **"PHYTOCHEMICAL INVESTIGATION, THROMBOLYTIC AND ANTIOXIDANT ACTIVITY OF CLERODENDRUM THOMSONIAE BALF.F"** in the 72nd Indian Pharmaceutical Congress held at Department of Pharmaceutical Sciences, Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur during January 20-22, 2023.

POSTER

Dr. V. G. Somani	Mr. Atul Mandlekar	Prof. Milind Umekar	Prof. Prakash Itankar	Prof. Roop K. Khar	Prof. Dadasaheb M. Kokare
President, IPCA	Chairman,LOC	Organising Secretary,LOC	Organising Secretary,LOC	Convener, IPCA-SSC	Chairman, Scientific Committee, LOC



Presentation Code: C-4

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AJAYKUMAR SURANA of **K. K. WAGH COLLEGE OF PHARMACY, NASHIK** has participated as delegate in the 72nd Indian Pharmaceutical Congress held at Department of Pharmaceutical Sciences, Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur January 20-22, 2023.

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C-1

EXTRACTION, IDENTIFICATION AND EVALUATION OF TARO STARCH FROM COLOCASIA ESCULENTA

Atar Sumayya Kasim
BN University, Udaipur 313001 Rajasthan India.

In the present work, extraction of starch from corm of Colocasia esculenta is done by simple extraction method and evaluated for the phytochemical analysis along with anti-ulcerogenic activity. Colocasia esculenta is a tropical plant mostly cultivated in high rainfall areas. It is commonly known as taro. The phytochemical analysis of above extract shows the presence of protein and glycoside. The anti-ulcerogenic studies were carried out against the standard drug omeprazole using fundic mucosa of sheep. Three group control standards (omeprazole) and tests having concentrations 10,30 and 100 μg/ml. The inorganic phosphate released is observed at 420 nm. In this shows the H+ K+ ATPase level is decreased due to standard drug but in test compound its level is increased as compare to standard hence, the test compound indicates moderate activity.

C-2

STANDARDIZATION, QUANTIFICATION & STABILITY OF PROTODIOSCIN BY HPTLC

Y. B. Bawne, S. I. Deore, B. K. Shrikhande, S. Dhurde
Institute of Pharmacy Maregaon
Wani, Maharashtra. principalbawnesir@gmail.com

This research project includes standardization, development, evaluation, quantification, and stability studies of a Protodioscin drug. A standard Protodioscin chromatogram was used to compare Tribulus terrestris extract and product extract. In the overlain spectrum of standard Protodioscin with Tribulus terrestris extract and capsule product, there is an exact match. Find out the quantitative estimation of Protodioscin in aphrodisiac products followed by recovery studies for Protodioscin and Protodioscin (By HPTLC) was found to be 0.70%. Work achieved a close result after precision (inter and intraday) for Protodioscin, ruggedness and robustness, and repeatability for Protodioscin. These are identified as the linearity of Protodioscin as y = 11.7712x + 37.736 and R2 = 0.9989. After an accelerated stability study in three-month intervals up to six months, the concentration of the drug decreased negligibly. The result of the microbiological test was not affected by the accelerated stability study. These results were confirmed with the chromatograms of HPTLC fingerprinting.

C-3

EVALUATION OF PHYTOCHEMICAL AND ANTIDEPRESSANT ACTIVITY OF CROSSANDRA INFUNDIBULIFORMIS (L) NEES AERIAL PART EXTRACT

Prashanti Chitrapu, Renuka Pothu and Reenu Yadav
Faculty of Pharmacy, Mansarovar Global University, Billkisganj, Sehore,
Madhya Pradesh-466001. prashantichitrapu@yahoo.com

The aim of the present study is to evaluate the extract of aerial parts of Crossandra infundibuliformis (L) Nees, (Acanthaceae) for its phytochemical constituents and antidepressant activity. This plant is found abundantly in tropical areas. Acanthaceae, a family which is well known for its medicinal values due to the presence of valuable and range of phytochemical compounds. Nowadays, the scientific community is exploring the effective alternatives of allopathic medicine by gaining more knowledge on pharmacologically important properties of medicinal plants as a safer yet efficacious option. Phytochemical analysis was performed on extracts of water, ethyl acetate, acetone, chloroform and propane on C. infundibuliformis and results were tabulated. Depression is an extremely common psychiatric condition about which a variety of neurochemical theories exist and for which a corresponding variety of drugs are used in treatment. Here, we discuss the antidepressant activity of plant species using forced swim test. The results reported in the present work shows evidence that the aerial parts of C.infundibuliformis (L) Nees possess antidepressant activity.

C-4

PHYTOCHEMICAL INVESTIGATION, THROMBOLYTIC AND ANTIOXIDA ACTIVITY OF CLERODENDRUM THOMSONIAE BALF.F

Ajaykumar Surana, Ankita Jadhav, Prathamesh Patil
K.K. Wagh College of Pharmacy, Panchavati, Nashik, M.S, India-422003,
ajaysurana01@rediffmail.com

Clerodendrum thomsoniae Balf.f. (FamilyLamiaceae) is a twining, rambling, vine li commonly known as bleeding glory bower, bleeding-heart vine and glory tree. Obje present research to perform preliminary phytochemical investigation, antioxid fibrinolytic activity of leaves of C. thomsoniae. The total phenolic content was deter Folin-Ciocalteu method.Thrombolytic activitywas evaluated by clot-lysis method. An activity was evaluated by in vitro assay involving H2O2 scavenging, DPPH radical sca All extracts showed concentration dependent free radical scavenging activity. The pre phytochemical investigation of extracts of C. thomsoniae leaves shows the pres sterols, triterpenes, alkaloids, flavonoids, tannins, glycosides, proteins and carboh The total phenolic content of the Petroleum ether, Chloroform and alcoholic extract w to be 19.083, 30.58 and 99.25mg tannic acid equivalent/g of extract respectivel when treated with sterile distilled water (negative control) showed only negligible (7.89%). Blood Clots when treated with petroleum ether, chloroform extract and extract showed 34.52 %, 14.67% and 11.19 % clot lysis respectively. Alcoholic extr found to be good scavenger of H2O2 and DPPH radical than other extracts of C.thom The Petroleum ether extract of C. thomsoniae leaves had shown good clot lysis activity basis of the findings of the present study, it is observed that C. thomsoniae shows rem thrombolytic activity and antioxidant activity. Further study required to confirm in v lysis properties and phytoconstituents responsible for it.

C-5

ATTENUATION OF STZ INDUCED DIABETIC NEPHROPATHY USING HORDI VULGARE LINN. EXTRACT

Renuka Mahajan, Narendra Dighade, Prakash Itankar, Satyendra Pras
Department of Pharmaceutical Sciences, Rashtrasant Tukadoji
Maharaj Nagpur University, Nagpur- 440033, Maharashtra, India.
pathak.renuka@gmail.com

Objective: The present investigation was undertaken to scientifically justify the tra use of Hordeum vulgareLinn. for the management of Diabetic nephropathy (DN), a chro of kidney function occurring in those suffering from diabetes mellitus. Methods:Th involved phytochemical evaluation, chromatographic analysis, antioxidant activity DPPH, Nitric oxide radical scavenging and reducing power methods, pharmac screening of hydroalcoholic extract using STZ induced Sprague Dawley rat mod development of phytoformulation. Result and Discussion: The phytochemical evalua hydroalcoholic extract of H. vulgare revealed presence of alkaloids, saponins, t flavonoids and glycosides. The chromatographic analysis revealed band at Rf 0.59 and Retention time 2.454 min which complement with the marker compound Epicatechi STZ induced Sprague Dawley male rats at the end of 3rd week represented abnormal le serum creatinine, albumin, BUN, total cholesterol, triglycerides and urine albumin as creatinine which were observed normal after 8 weeks' treatment of hydroalcoholic ext H. vulgare. Oral granules encapsulated in capsule shells for ease of patient were pr using methods mentioned in Ayurvedic pharmacopoeia. Conclusion: The epicatechin ha previously studied for its effect on blood glucose level and was found efficien hydroalcoholic extract of H. vulgare evidenced potential against DN. This effect attributed to the presence of phytoconstituents present. The approach will be use translating the traditional knowledge of medicinal plant into modern dosage for confirming the safety values.

C-6

ISOLATED POTENTIAL TRITERPENOIDS FROM AERVA LANATA LINN FO EVALUATION OF PARACETAMOL INDUCED HEPATOTOXICITY.

Hemalatha. K and Sumalatha. CH.
Acharya & BM Reddy College of Pharmacy, Bengaluru- 560 107, Karnataka.
hemalathak@acharya.ac.in

To evaluate the hepatoprotective activity of isolated triterpenoids from aerial parts of Lanata extract paracetamol induced hepatotoxicity. The ethanolic extract was obtain continuous soxhlet extraction with ethanol (70 %). The extract was concentrated, dried

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SHILPA RAGHUNATH BORATE presented a Poster in Scientific Session entitled **"SIMULTANEOUS ESTIMATION OF CURCUMIN AND VITAMIN E IN BULK AND PHARMACEUTICAL DOSAGE FORM BY UV SPECTROPHOTOMETRY"** in the 72nd Indian Pharmaceutical Congress held at Department of Pharmaceutical Sciences, Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur during January 20-22, 2023.

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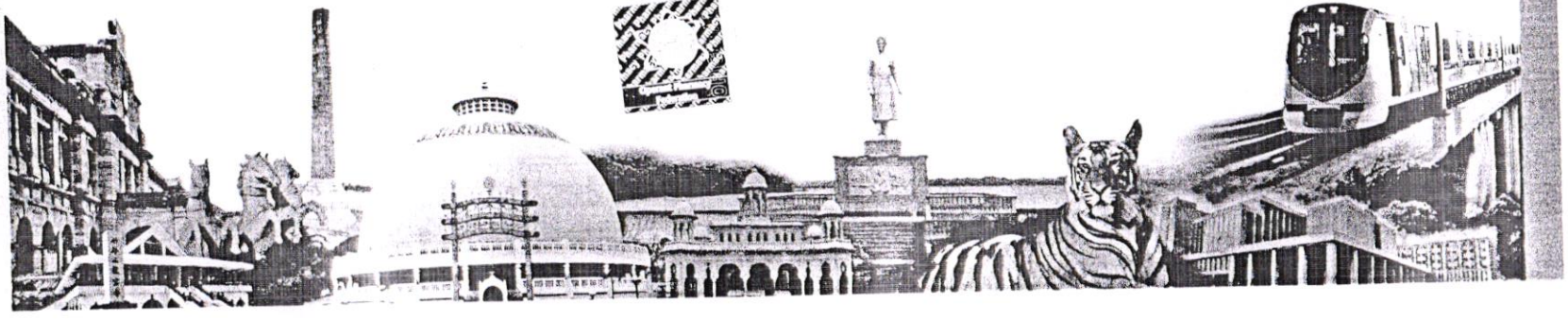

F-1

DETERMINATION OF AMOUNT OF RETINYL PALMITATE AND ASCORBIC ACID OF EXTRACT GEL OF SWEET CORN FIBRE BY UV AND HPTLC METHOD

N. Sunitha, R. Ramesh, Sk Umera Azmi, B. Venkata Krishna Reddy
SIMS College of Pharmacy, Guntur, Andhra Pradesh, Pin 522002

Sweet corn fibres of about 15 gm were extracted with methanol for 5 hours in heating mantle at 40oC and filtered and allowed to dry. The dried gel was further analyzed for estimation of Retinyl palmitate by spectrophotometrically by laboratory method and found to be 140 mg/kg. The dried extract gel was further estimated for ascorbic acid both by UV and HPTLC and found to be linear in the range of 1-5 ug/ml and 5-10ug/ml , correlation coefficient was found to be 0.997 and 0.998 and the amount of ascorbic acid was found to be 338 ng/ml and 9.9 ng/ml by UV and HPTLC respectively. The method was found to be linear.

F-2

A VALIDATED HPTLC METHOD FOR THE ESTIMATION OF AMITRIPTYLINE HCL IN BULK AND ITS TABLET DOSAGE FORM

Deepak Pokharkar, Raghavdeep Sharma, Shreelekha Neetin Desai
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A simple, rapid, reliable and accurate HPTLC method has been developed for the quantitative determination of Amitriptyline HCL in bulk and tablets. Various aliquots of the sample solution were spotted automatically by means of camag ATS 4 applicator on precoated silica gel 60 F254 on aluminium sheet as stationary phase pre washed with methanol using Toluene: Methanol: Acetone: Ammonia (5:3:2:0.2)v/v/v/v as mobile phase. The spots were scanned at 254 nm. The Rf value of AMITRIPTYLINE HCL was 0.66 ± 0.02. Calibration curves were linear in the range of 67.5 - 472.5 ng/band. The limit of detection and limit of quantification were found to be 9.37 ng/band and 2.80 ng/band respectively. The suitability of this method for the quantitative determination of compound was proved by validation in accordance with requirements of pharmaceutical regulatory standards.

F-3

STRESS STABILITY STUDY SHOWING EFFECT OF ACID, BASE, H□□ AND DRY HEAT ON CYCLOBENZAPRINE HCl AND AMITRIPTYLINE HCl BY HPTLC METHOD

Deepak Pokharkar, Rohit Shikhare, Anjali Sunilkumar
NCRD's Sterling Institute Of Pharmacy, Near Seawoods Railway Station,, Plot No. 93/ 93A, Sector - 19, Nerul (E, Seawoods, Navi Mumbai, Maharashtra 400706.
deepak.pokharkar@ncrdsip.com

Forced degradation studies include degradation of drug substances and drug products at conditions more severe than accelerated conditions. These studies illustrate the chemical stability of molecule which further facilitates the development of stable formulation with suitable storage conditions. Cyclobenzaprine is a part of a group of medications referred to as cyclical antidepressants. Cyclobenzaprine is a tricyclic amine salt that works in the central nervous system (CNS) as a depressant that reduces muscle hyperactivity and Amitriptyline HCl belongs to a class of medications called tricyclic antidepressants. It works by affecting the balance of certain natural chemicals in the brain. It prevents the reuptake and hence the inactivation of neurotransmitters called noradrenaline and serotonin, that are present at the nerve terminals in our brain. Degradation products of Cyclobenzaprine HCl and Amitriptyline HCl formed under different forced conditions have been characterized through (High Performance Thin Layer Liquid Chromatography) HPTLC studies. The method was developed using TLC silica gel 60 F254 aluminum backed plate as the stationary phase for Cyclobenzaprine HCl by developing the Mobile phase as n-Hexane: Ethyl Acetate: Methanol: Glacial Acetic Acid taking absorbance at 292nm (Rf value within 0.10 ± 0.02) and for Amitriptyline HCl developing the Mobile phase as Toluene: Methanol: Acetone: Ammonia taking absorbance at 250nm (Rf value within 0.66 ± 0.02). The forced degradation study was carried out in accordance with the (International Council for Harmonization) ICH guidelines Q1A (R2) under oxidative condition 6% Hydrogen peroxide for 3 hours, in acidic condition 0.1M HCl at 80°C for 60 Minutes, in basic condition 0.1M NaOH at 80°C for 60min and in thermal condition 60°C for 3 hours. Degradation products were well separated by proposed method.

F-4

FORCED DEGRADATION STUDY OF MELATONIN: ISOLATION AND CHARACTERIZATION OF DEGRADATION PRODUCTS

Shubhangi Sutar, Sachinkumar Patil
Ashokrao Mane College of Pharmacy, Peth-Vadgaon, Maharashtra, India.416112
shubhangi.sutar28@gmail.com

Melatonin is a hormone mainly released by the pineal gland at nighttime, and have long been allied with manage of the sleep–wake cycle. While a dietary supplement, it is frequently used for the short-term treatment of insomnia, for example from jet lag or shift work, and is typically taken by mouth. To continue safe for additional processing or human consumption, study of stressed degradation for the identification of probable degradants is required. The stability indicating high performance thin layer chromatographic method was developed for Melatonin with Camag HPTLC system. Silica C60F254 precoated TLC plates were used as stationary phase for separation of degraded products. Mobile phase composed with toluene: methanol: formic acid (7:3:.0.1) at 290 nm. From the mass particulars along with IR, NMR interpretation, the plausible structure of acidic and alkaline degradation product of melatonin could be 2-(5-methoxy-1H-indol-3-yl) ethanamine. Furthermore In silico toxicity studies of the degradation products were performed to assess the toxicity profiles of the products with ProTox online sever. This analytical method can be measured as a substitute practical and cheap method for simple, accurate and efficient quantitative detection of melatonin in the presence of its degraded products.

F-5

REVERSE PHASE-LIQUID CHROMATOGRAPHY ASSISTED PROTOCOL FOR DETERMINATION OF MOLNUPIRAVIR USED TO CONTROL SARS-COV-2 INFECTIONS: AN INVESTIGATIVE APPROACH

Jaya P. Ambhore and Vaibhav S Adhao
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In recent years as a result of the SARS-CoV-2 infection antiviral drugs have received more attention and many potential drug molecules are currently under investigation to end the epidemic. Molnupiravir, a prodrug is one of the assuring candidates for SARS-CoV-2. Therefore, the current research work aimed to investigate the easy, defined, sensitive, and robust avenue as a liquid chromatography for estimation of molnupiravir from the pure blend and its dosage form. The reversed-phase chromatographic appropriate and efficient separation for molnupiravir has been attained with Hypersil BDS C18 column along with Water: acetonitrile (70: 30 % v/v) solvent system. The determination was carried out at 30 oC at a 1 mL/min rate for the flow of the solvent system through the column. The eluents of the column were monitored using a Photodiode Array detector (PDA) at 235 nm. The investigated reversed-phase chromatographic appropriate and efficient separation for molnupiravir revealed admirable retention time i.e., 4.009 min. The developed investigation of molnupiravir was show a linear response in the concentration range of 10-50 μg/mL with better coefficients of determination above (r2 0.999). The estimable liquid chromatography was successfully validated by ICH guidelines and all method validation parameters of estimable in compliance with ICH guidelines (Technical Requirements for Pharmaceuticals for Human use standards). The developed liquid chromatographic avenues were easy, defined, sensitive, robust, and rugged .They have admirable potential to estimate molnupiravir from the pure blend and its dosage form. Thus, the projected reversed-phase chromatographic method has a high prospect of adoption in the pharmaceutical industry.

F-6

SIMULTANEOUS ESTIMATION OF CURCUMIN AND VITAMIN E IN BULK AND PHARMACEUTICAL DOSAGE FORM BY UV SPECTROPHOTOMETRY

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A simple, accurate, precise and reproducible method has been developed and validated for the simultaneous estimation of Curcumin and Vitamin E in bulk and pharmaceutical dosage form. As there is no reported UV analytical method for the simultaneous estimation of Curcumin and Vitamin E in combined pharmaceutical dosage form, a new method is needed to analyze the drugs simultaneously. The estimation was done by the Q absorption method at wavelengths

of 231nm and 285nm. Curcumin and Vitamin E follow Beer-Lambert's law at the selected wavelengths in the concentration ranges of 8 - 12 μg/ml and of 16 - 24 μg/ml respectively. The recovery studies confirmed the accuracy, precision and ruggedness of the method according to ICH guidelines. The proposed method can be successfully applied for the determination of Curcumin and Vitamin E in a combined pharmaceutical dosage form.

F-7

UV SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF ETODOLAC IN BIOLOGICAL MATRIX

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In the current research, a new UV Spectrophotometric method was developed for the determination of Etodolac in spiked human plasma. The objective behind the research was to develop and validate a simple, rapid, precise and accurate method using UV Spectroscopy for determination of Etodolac in spiked human plasma. All the parameters for analysis were chosen according to ICH [Q2(R1)] guideline and validated. Etodolac was extracted from spiked human plasma by single step extraction. Quantitation was achieved through ultra violet detection at 250 nm. The concentration ranges from 2-20 μg/ml for Etodolac. The limit of detection (LOD) and limit of quantification (LOQ) were found to be 0.0669 and 0.0203 μg/ml respectively. The % RSD for both inter-day and intra-day precision was found to be $< 2\%$, demonstrating that the developed technique was precise. Furthermore, the rate of recovery at 3 levels i.e.,50%, 100%, 150% was close to 100%, confirming the method's accuracy. The ruggedness result showed that during different analyst conditions, % RSD of the test solution was not affected and was within the limits. The % assay was found to be 97.39% w/w. % Recovery of analyte does not need to be 100 % but the extent of recovery should be consistent. % Recovery was found to be 81.32%. All validation parameters were within the acceptable range. Thus, it can be concluded that this study can be beneficial for the quantitative analysis of Etodolac in biological samples and could be used in routine analysis for most of bio analytical purposes.

F-8

DEVELOPMENT AND VALIDATION OF HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ANTIHYPERTENSIVE DRUG IN PHARMACEUTICAL DOSAGE FORM

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Chromatography is a technique by which the components in a sample, carried by the liquid or gaseous phase, are resolved by sorption-desorption steps on the stationary phase.High Performance Liquid Chromatography (HPLC) is one mode of chromatography; the most widely used analytical technique. HPLC utilizes a liquid mobile phase to separate the components of a mixture. A method involving an UV/Visible detector was developed and proven for measuring antihypertensive(Methyldopa, Hydrochlorothiazide) drug in pharmaceutical dose form. Chromatographic analysis was carried out using a Waters 600 HPLC system, and a Intersil BDS C8, 250 X 4.6 mm, 5μm analytical column was used for separation (250 4.6 mm id, 5 m). It was discovered that the mobile phase containing mixture of Phosphate (buffer pH 5.3): ACN in the ratio of (50:50)v/v. A flow rate of 1.0 ml/min yielded adequate retention time of about 10 min with sharp symmetrical peak at 287 nm. The strategy was shown to be precise (%RSD), linear ($R2 > 0.999$), and targeted

F-9

A VALIDATED STABILITY INDICATING RP-HPLC METHOD FOR ESTIMATION OF MOLNUPIRAVIR CAPSULES IN PHARMACEUTICAL DOSAGE FORM

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A simple reverse phase HPLC method was developed and validated for determination of Molnupiravir present in pharmaceutical dosage form. A reverse phase chromatography has been used on the C18 column (250 x 150 mm,5μ) with a mobile phase composition of methanol and water in the ratio of 80:20%, v/v with retention time 3.6 ± 0.020 min. The correlation coefficient was found to be 0.9993, for the linearity plots. This method was validated for linearity, precision, accuracy, limit of quantitation, ruggedness, robustness. The linearity range for the estimation is between 100-400 μg/ml Limit of detection and limit of quantitation of molnupiravir capsules was found to be 41.4 μg/ml and 125.3μg/ml respectively. Proposed method was successfully applied for the quantitative determination of molnupiravir capsules in pharmaceutical dosage form.

F-10

GREEN METHOD: UTILITY OF HYDROTROPES FOR SOLUBILITY ENHANCEMENT OF DRUGS.

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In the present research, applicability of hydrotropic solvent instead of organic solvent for solubilization of poorly water soluble or insoluble drugs is justified. It is an approach for eco friendly development of technique. The enhanced solubility of drug was measured using double beam UV-VIS spectrophotometer. The selected hydrotropes were sodium acetate, sodium citrate, urea and sodium chloride and the conc range of hydrotrope solvent was 1% to 6 % w/v. The BCS class II drugs rosuvastatin calcium, valsartan and nebivolol were the drugs utilized for experimentation. These drugs solution were prepared in various conc of hydrotropic solvent and solutions absorption was measured. No shift in the absorption maxima of drug or nature of curve was found shown stability of drug in the hydrotropic solvent. The appropriate conc of the increased solubility was known with the graph plotted between absorption and conc. It was found that sodium citrate solution was the appropriate hydrotropic solvent for rosuvastatin, sodium acetate for valsartan and urea for nebivolol. Development of analytical technique by using the hydrotropic solvent is the extensive research of this method.The solvent like methanol, chloroform, carbon tetra chloride or ether makes environmental polluted no doubt these solvents are effective for solubilization. Hence hydrotropic solvent may be practiced in various techniques as green practices.

F-11

IMPURITY PROFILING – AN EMERGING TREND IN PHARMACEUTICAL S

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Concerns about impurities in active pharmaceutical ingredients (APIs) are steadily increasing. Today, not only purity profiles but also impurity profiles are regulated by various regulatory agencies. In the pharmaceutical world, impurities are considered inorganic or organic substances or residual solvents, with the exception of unwanted chemical residues or drug substances, syntheses or APIs.Impurity profiling includes identification, structure elucidation and quantification of impurities and degradation products in drug substances and drug products. The control of impurities in formulated products and APIs is regulated by regulatory agencies such as ICH, USFDA, Canadian Drug and Health Agency. Impurity profiling is very important in modern pharmaceutical analysis. This is because unidentified potential toxic impurities are health hazards and must be identified and determined using selective methods in order to increase the safety of drug therapy. Various pharmacopoeias today require knowledge of impurities in active ingredients and finished drug products.

F-12

DEVELOPMENT AND VALIDATION OF CHROMATOGRAPHIC METHODS FOR SIMULTANEOUS ESTIMATION OF ASPIRIN AND PANTOPRAZOLE SODIUM IN PURE AND MIXTURE FORM

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SSR College of Pharmacy

Validated HPLC and HPTLC methods for simultaneous quantification of Aspirin (ASP) and Pantoprazole sodium (PNT) in pure powder form and formulation has been developed. Disodium Hydrogen Phosphate: Methanol (40:60 % v/v) as the mobile phase for HPTLC on C18 column (250 mm x 4.6 mm, 5μm) at a flow rate of 1.0 mL/min was used. On a layer of silica gel 60F254 with an aluminium backing, the HPTLC separation was carried out using ethyl acetate and methanol (8: 1.5 v/v) as the mobile phase. With a mean recovery of 99.55% for ASP and PNT, respectively, quantification was accomplished using the method with UV detection at 286 nm over the concentration range of 0.1-0.8 g/ml for PNT and 0.4-2.4 g/ml for ASP. With a mean recovery of 99.44 % and 99.01 % for ASP and PNT, respectively, quantification was achieved using the HPTLC method with UV detection at 286 nm over the concentration range of 400 - 2400 ng/spot for ASP and 100 - 600 ng/spot for PNT, respectively. The methods can be used for the simultaneous determination of ASP and PNT in pure powder form and formulations as they are simple, accurate, and sensitive

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Prof./Dr./Mr./Ms. Rakesh Amrutkar *has participated as a* ***Delegate*** *and Presented a* ***Paper (Oral)*** *in the* ***2nd Nirma e-Conference for International Connect (NCIC) – 2023*** *on* ***"Recent Advances in Nanotechnology: Drug Discovery & Therapeutics"*** *organized by* ***Institute of Pharmacy, Nirma University*** *during January 24-25, 2023.*

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PC010

ADMET Profiling and Molecular Docking Studies of some Hydroxyquinoline

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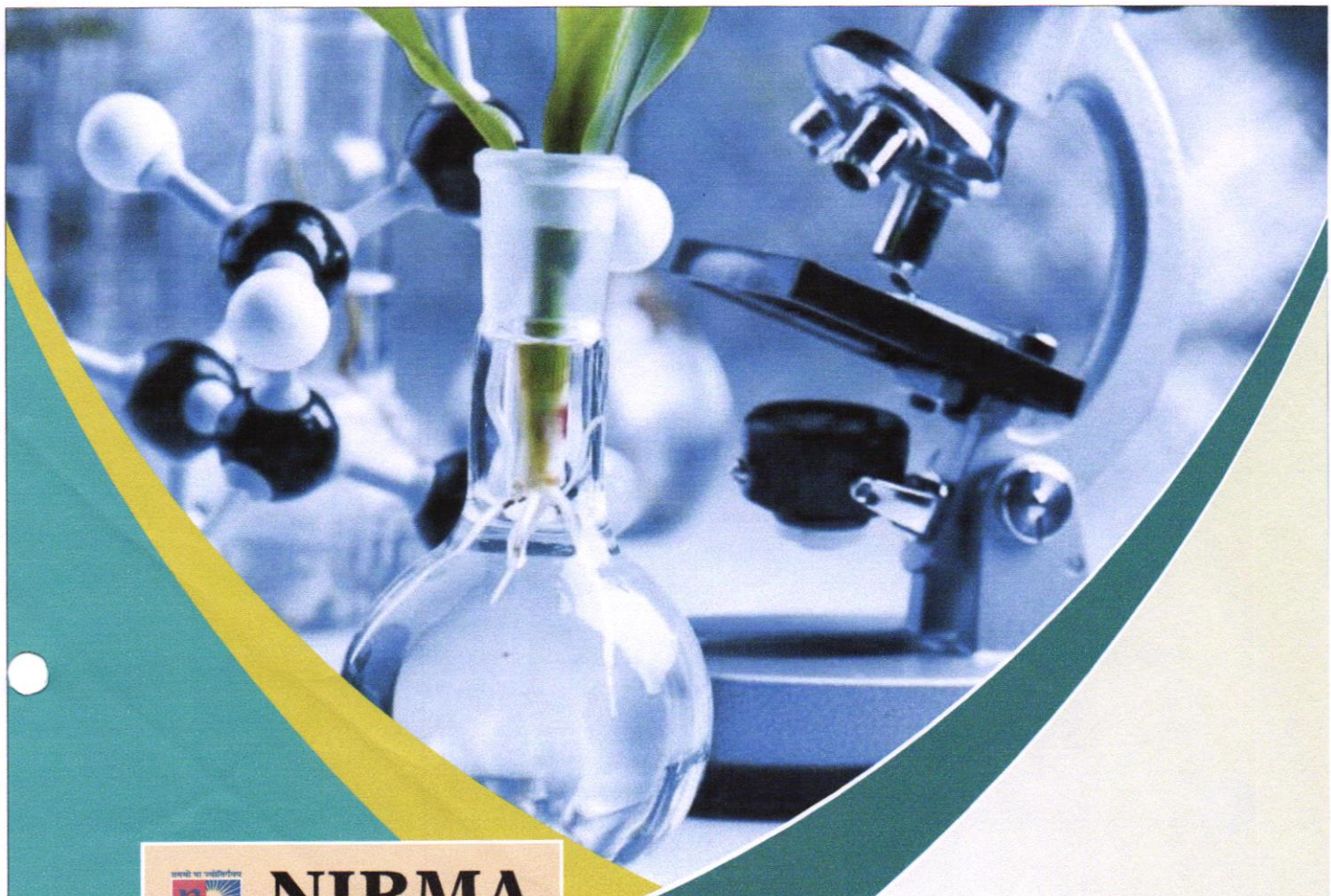
Percentage of compounds failing in clinical trials is considerably decreased due to early absorption, distribution, metabolism and excretion (ADME) screening has been reported in the literature with this preclinical ADME studies eliminate weak drug candidates in the drug development process. Molecular docking is the important process is to understand drug molecular interactions with the preferred binding site of the target specific region of the DNA/Protein (receptor). In this regards we predicted the In-silico ADMET properties and docking studies of some hydroxyquinoline analogues. We confirmed that all compound GI absorption and some Compound have good BBB permeability some analogues inhibit CYPIA2 inhibitors and some analogues showed hepatotoxicity carcinogenicity, immunotoxicity, and mutagenicity. The drug-likeness predication was also showed by using lipnski rule and bioavailability score the results are obtained by computational tool complete the toxicity test to improve predictive toxicity and safety assessment of hydroyquinoline analogues. The docking studies are carried out by using Swiss-Docking Software and hydrogen bonds formed with the surrounding amino acids of receptor are used to predict their binding modes, their binding affinities and scoring functions and reported.



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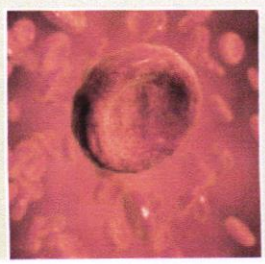
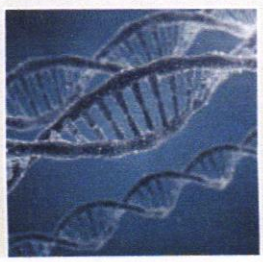
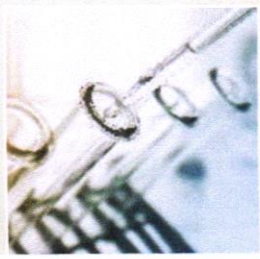
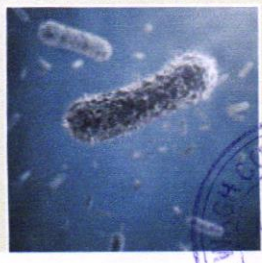

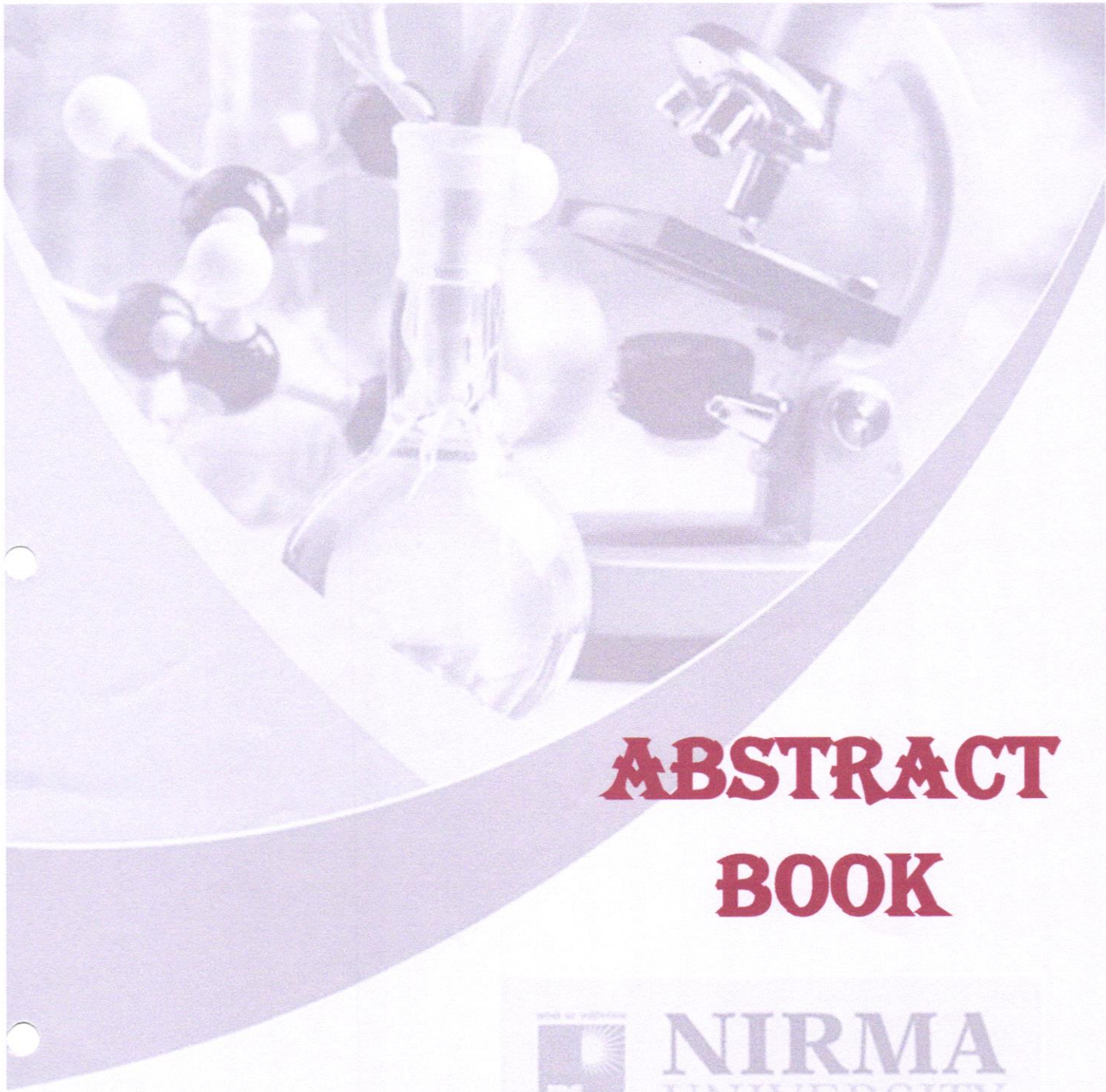

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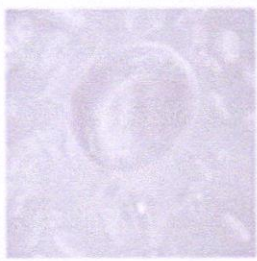


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