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ORGANOGEL A PROMISING DRUG DELIVERY SYSTEM: FROM THEIR COMPONENTS TO THEIR APPLICATIONS IN DRUG DELIVERY

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ABSTRACT

A three-dimensional network of interlaced, self-assembled gelator fibres immobilises an organic liquid phase in organogels, which are semi-solid systems. These systems appear solid-like and have rheological behaviour despite being primarily liquid in composition. With active ingredients given via transdermal, oral, and parenteral routes, they are used as medication and vaccine delivery systems in pharmacology. The hazardous properties of the chosen organic solvents, however, have historically prevented their use as drug delivery systems. The recent synthesis of more biocompatible organogels has facilitated the development of several biological and pharmacological applications. The purpose of this article is to present a thorough overview of organogels, with a focus on the kinds, characterisation, preparation, and usage of organogels as drug delivery platforms for active agent administration through various such as transdermal, oral, and parenteral is then discussed.

KEYWORDS: Organogels, Colloidal Drug Delivery, Gel, Drug Delivery.

INTRODUCTION

ORGANOGELS

A gel may be defined as a semi-solid formulation having an external solvent phase, apolar (organogels) or polar (hydrogel), immobilized within the spaces available of a three dimensional networked structure. The organogels may be regarded as bi-continuous systems consisting of gelators and apolar solvent, which may or may not contain water molecules

entrapped within the self-assembled structures of the gelator. The gelators when used in concentration < 15% (approx.) may undergo physical or chemical interactions so as to form self-assembled fibrous structures which get entangled with each other resulting in the formation of a three dimensional structure, hence formed, prevents the flow of external apolar phase. Some common examples of gelators include sterol, sorbiton monosterate, and lecithin and cholesteryl anthraquinone derivatives. The thermo reversible property of the organogels has generated much interest for the potential use of the organogels as drug delivery system. The thermodynamic stable nature of the organogels has been attributed to the spontaneous formation on fibrous structure by virtue of which the organogel resides in a low energy state. The occurrence of the gel-to-sol transition above room temperature indicates that external energy has to be supplied to the organogels so as to disrupt the threedimensional structure and subsequent transformation of the gelled state to the sol state. Apart from the temperature sensitivity, organogels are also sensitive to the presence of moisture which has also been explored to develop controlled delivery systems.

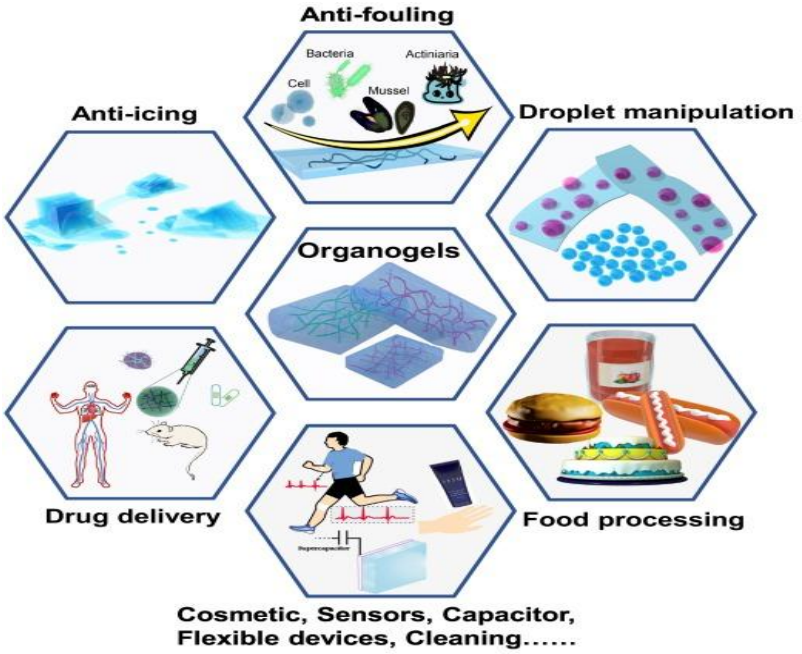

Fig 1: Applications of Organogels.

ORGANOGELATORS

The role of organogeletores in designing organogels is evident from the above discussion. The organogelators may be categorized into two groups based on their capability to form hydrogen bonding. The examples of organogelators which do not form hydrogen bonding include anthracene, anthraquinone and steroid based molecules where as the hydrogen bond

forming organogelators include amino acids, amide and urea moieties and carbohydrates. It would be wise to have a discussion on the different organogelators, before we discuss about the different types of organogels and their applications in controlled delivery.

1)4-terbutyl-1-aryl cyclohexanols derivative organogelatores

4-terbutyl-1-aryl cyclohexanols, categorized under arylcyclohexanol derivatives, helps in designing thermo reversible organogels These gelators are solid at room-temperature having low solubility in apolar solvents viz. cyclohexane, benzene and carbon tetrachloride.

2) Polymer organogelators

Various polymeric structures have been used as an organogelators. Some common examples of polymeric organogelators include L-lysine derivatives apart from the conventional polymers like poly (ethylene glycol), polycarbonate, polyesters, and poly (alkylene).

3) Gemini organogelators

The word Gemini is the Latin word meaning twins. L-lysine based Gemini organogelators was first synthesized by Suzuki et al. (2003). The authers synthesized the Gemini organogelators which had two L-lysine derivatives connected with alkylene spacer chains, of varying chain lengths, by amide bonds.

4) Boc-Ala(1)-Aib(2)-B-Ala(3)-OMe organogelator

Boc-Ala(1)-Aib(2)-B-Ala(3)-OMe is a synthetic tripeptide which has the capability to undergo self-association so as to form thermoreversible transparent gels in the presence of various apolar solvents viz. 1,2-dichlorobenzene (DCB), monochlorobenzene and benzene.

5) Low Moleculer weight (LMW) organogelators

As the name suggest, LMW organogelators are low moleculer weight compounds, viz. fatty acids and n-alkanes, which have the ability to immobilize apolar solvents, even when used in small concentrations(<2%).

Apart from the above-mentioned organogels, various amphiphiles having the ability to form selfasswembled structures in the presence of apolar solvents have also been tried. These organogelators may be categorized as the derivatives and organometallic compounds.[1-3]

NEED OF ORGANOGEL

The organogel do not form semisolids on standing. Because an organogel may consists of macromolecules existing as twisted matted strands. The units are of bound together by strong types of Vander Waal forces so as to form crystalline amorphous regions throughout the entire system. The organogels have lower hydrations, the drug dissolving polymer and is transported between the chains. Cross linking increases hydrophilicity of gels & diminishes the diffusion rate of drug.[4]

ADVANTAGES

Fig 2: Advantages of Organogel.

DISADVANTAGES

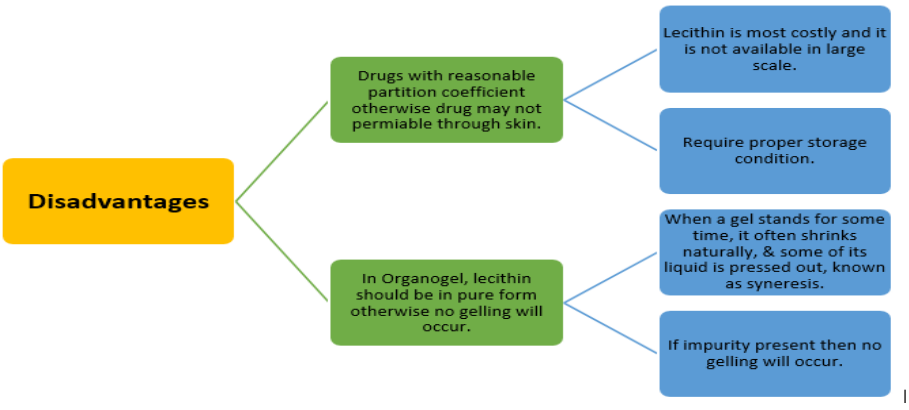

Fig 3: Disadvantages of Organogel.

CLASSIFICATION OF ORGANOGEL

Organogels are generally categorized based on the type of organogelator. In this study, we suggest a unique organogel categorization based on solvent applied, organogelator features, and production methods utilized, depending on the kind of intermolecular interactions(chemical, physical).[5]

Physical crosslinking

Numerous organogels are formed via non-covalent interactions between physical crosslinking molecules or organogelator molecules, resulting in the formation of crosslinking junction sites. Conformational alterations in the organogelator design or the inclusion of crosslinking agents induce the molecules to adhere at the atomic level.[6] These interconnections are created by rather strong physical non-covalent attractions like as □-□ stacking, solvophobic forces, weak van der Waals contacts, or even hydrogen bonding.[7] Low molecular weights organogelators are the most common type of organogelator utilized to create physical organogels. The ability of low molecular weights organogelators to self-assemble via non-covalent contacts allows gelation reversibility and imparts extraordinary thixotropic properties to such gels.[8]

Chemical Crosslinking

Chemical organogels are generated in an organic solvent by chemical crosslinked organogelators in a swelled condition. Through covalent bonding, the 3-D network is irreversibly solidified. Temperature adjustments or simple dilution will not transform the resultant organogels into the liquid phase. Additionally, due to helical polymer analogs, they produce more strong and impervious matrices.[9] Crosslinkers like Cu(I)-catalyzed azide-alkyne compounds, which cause cycloadditions, are used to create supramolecular chemical crosslinking connections.[10] Furthermore, orthogonal couplings are induced by chemical group activations such as covalent bonding and dative, which cause gel formation.[11] Covalent crosslink junctions are divided into two groups by Fox et al., i) dynamic covalent crosslink connections and ii) supramolecular connections by combining physical non-covalent and covalent crosslinks, resulting in a material with great flexibility and creep resistance.[12] Higaki et al., presented a new alkoxyamine polymer-based covalent crosslinked thermodynamic system. The radical exchange reactions were followed by this kinetically based system.[13] Yang et al., have designed a chemical organogel depending on crosslinker tetraethylammonium tetrafluoroborate-acetonitrile and poly (vinylidene

fluoride-co-hexafluoropropylene) electrolytes that function as a potential supercapacitor device with high ionic electro-conductivity.[14]

Bigels

Bigels were initially described by Almeida et al., as a combination of different polyacrylic acid hydrogels scattered in organogels forming a bi-continuous matrix.[15] Bigels can be characterized as an emollient and semi-solid formulation that generates heterogeneous colloidal systems that are categorized into three types viz: i) bi-continuous matrix, ii) organogel dispersed into hydrogel system (O/W), and iii) hydrogel dispersed into organogel system (W/O).[16] In reality, they were employed to regulate the distribution of both hydrophilic and lipophilic drugs; due to the synergetic effects of both gels, those systems followed Higuchi release kinetics.[17] Lupi et al., produced bigel cosmetic formulations and found matrix-in-matrix bigels, which were generated by phase inversion and consisted of disorganized oil droplets scattered in a bicontinuous matrix gelled network.[18]

PROPERTIES OF ORGANOGEL

Table 1: Properties of Organogel.[19-21]

SR NO	PROPERTIES	EFFECT
1	Viscoelaticity	Which is associated with the materials having both viscous and elastic properties4. The organogels seems to follow Maxwell model of viscoelasticity. The organogels behaves like a solid at lower shear rates and hence shows an elastic property. As the shear stress is increased, the physical interacting points amongst the fiber structures start getting weakened until the shear stress is high enough to disrupt the interactions amongst the fiber structures, when the organogels starts flowing. This behavior may be best explained with the plastic flow behavior.
2	Non-birefringence	The organogels when viewed under polarized light appears as a dark matrix. So the isotropic nature of the organogels which does not allow the polarized light to pass through the matrix. This property of the organogels of is regarded as non-birefringent.
3	Thermo reversibility	As the organogels are heated up above a critical temperature, the organogels loses its solid matrix- like structure and starts flowing. This has been attributed to the disruption in the physical interactions amongst the gelator molecules due to the increase in the thermal energy within the organogels. But as the heated organogels systems are subsequently cooled down, the physical interaction amongst the organogelators prevail and the organogels revert back to the more stable configurations.
4	Thermo stability	Self assemble nature of organogel important point of view concern with thermo stability under suitable condition. As the gelators undergo self-assembly; it results in the decrease in the total free energy of the system and renders the organogels as low-energy thermo stable system. So organogel an important vehicle for bioactive agents and for cosmetic

		applications where a longer shelf-life is desirable.
5	Optical clarity	Depending on the composition of the organogels, the organogels may be transparent or opaque in nature. Example-Lecithin organogels are transparent in nature while the sorbitan monostearate organogels are opaque in nature.
6	Chirality effects	LMW gelators have been found to affect the growth and the stability of the solid-fiber networks. The presence of chiral centers within the gelators helps in the formation of a compact molecular packing, which provides a thermodynamic and kinetic stability to the organogels system. Example-Crown ether phthalocyanine organogels are the chiral organogels.
7	Biocompatibility	Initially, organogels were developed using various nonbiocompatible and biocompatible constituents has opened up new dimensions for the use of the same in various biomedical applications.

TYPES OF ORGANOGELS

1. Lecithin organogels

Lecithin organogels have emerged as one of the most potential carrier systems. The organogel matrix mainly consists of a surfactant (lecithin) as gelator molecules, a nonpolar organic solvent as external or continuous phase, and a polar agent, usually water. A lecithin organogel is formed when small amounts of water orother polar substances, such as glycerol, ethylene glycol or formamide, are added to a non-aqueous solution of lecithin. The transfer into jelly-like state has been demonstrated only for nonaqueous solutions of naturally occurs in saturated lecithins. The latter are mainly separated from soy bean and egg yolk.

2. Sorbitan monosterate organogels

Made up of combination of Sorbitan monostearate (Span 60) and sorbitan monopalmitate (Span 40) have been found to gel a number of organic solvents at low concentrations. Span 60 gels were found to be more stable than Span 40 gels and were investigated in greater depth. The thermoreversible gels are prepared by heating the gelator/liquid mixture in a water bath at 60°C (which results in dispersion of the gelator in the liquid medium) and cooling of the resulting suspension, following which the latter sets to an opaque, white, semisolid gel.

3. Micro/Nano-emulsion based organogels

Microemulsions is defined as thermodynamically stable transparent, single optically isotropic liquid system of water, oil and surfactants frequently in combination with suitable cosurfactants. Microemulsions are known to enhance the bioavailability of drugs via topical and systemic routes. Microemulsion appears to have the ability of deliver larger amount of topically applied agents into the mucosa than the traditional gel &creams. Nanoemulsions are thermodynamically stable transparent (translucent) dispersions of oil and water stabilized by

an interfacial film of surfactant and cosurfactant molecules having a droplet size of less than 100 nm.

4. Organogels based on other LMW gelators

Scientists have investigated the transdermal delivery of piroxicam from organogels composed of glyceryl fatty acid ester gelators in pharmaceutical oils.

5. Poly (ethylene) organogels

The only two such systems have been widely tested for drug delivery applications are poly (ethylene) and P (MAAco- MMA) organogels.[22-23]

6. Supramolecular organogels

In the recent past, molecules of a great structural diversity, for instance from the simplest alkanes to the complex phthalocyanines, have been discovered to be gelators. Recently immense interest has been generated in studying gels derived from low molecular mass gelators (supramolecular or simply molecular gels).

7. Eudragit organogels

Eudragit organogels are really mixtures of Eudragit (L or S) and polyhydric alcohols, such as glycerol, propylene glycol and liquid polyethylene glycol, containing high concentrations (30 or 40% w/w) of Eudragit. Drug-containing gels were prepared by dissolving the drug (salicylic acid, sodium salicylate, procain or ketoprofen) in propylene glycol, pouring the resulting solution into Eudragit powder (contained in a mortar), and immediately mixing with a pestle for 1min.

8. In situ forming organogel of L-alanine derivative

Nlauroyl- L-alanine methyl ester (LAM) was found to gel the pharmaceutically acceptable organic solvents, soybean oil and medium-chain triglycerides. Normally the systemexists in the gel state at room temperature. However, the addition of ethanol to a gelator/solvent solution inhibits gelation because the ethanol disrupts the formation of hydrogen bonds (essential for gelator self-assembly into aggregates) between the gelator molecules. This means that a solution of LAM in an organic solvent can remain in the sol phase at room temperature when some ethanol is added to the mixture. When such a sol phase (20% LAM +14% ethanol in soybean oil) was placed in phosphate buffered saline at 37°C it turned into a

opaque gel within 2min as the hydrophilic ethanol diffused away into the aqueous buffer, and as gelator–gelator hydrogen bonds were formed.

9. Pluronic lecithin organogels (PLO)

PLO was developed by a compounding pharmacist in the US in the early 1990s as a topical vehicle. Pluronic lecithin organogels are opaque, yellow gel, PLO is composed of isopropylpalmitate, soy lecithin, water and the hydrophilic polymer, Pluronic F127. The difference between PLO and its precursor, lecithin gels, is the presence of Pluronic F127 (a hydrophilic polymer that gels water) and the greater amount of water compared with the oil. Thus, PLO is not really an organogel but it may be thought of as an _organogel‘ due to its name. Pluronic F127 was added to the original lecithin organogel in order to stabilize the gelformulation. Example- PLOs are mainly used as a topical or transdermal drug carrier, for haloperidol, prochlorperazine, secretin and in some hormones. PLOs have also been investigated/proposed as a vehicle to the oral cavity and mucosa.

10. Premium lecithin organogels (PrLO)

The PrLO is a second general lecithin organogel. The use of PrLO as a carrier for drug delivery has indicated that the gel higher thermostability apart from its non-greasy and non-tacky help in achieving improved bioavailability in the tissues by improving nature, which provides a cosmetically pleasing acceptability. The penetration of the bioactive agents. This gel do not have pluronic derivative.

11. Limonene GP1/PG organogel

The GP1 (dibutyl lauroyl glutamide) / PG (propylene glycol) Limonene, a terpene, has been found to be an excellent penetration organogels can be prepared by mixing the appropriate amounts of enhancer and hence has been incorporated within various transdermal GP1, limonene and PG with the subsequent incubation of the formulations for the improving the penetration of the bioactive agent same at 120o C. When the mixture is cooled down, it forms a across the transdermal layer, thereby improving the bioavailability of the white gel.[24-25]

METHOD OF FORMATION OF ORGANOGEL

1. Fluid-filled fiber mechanism

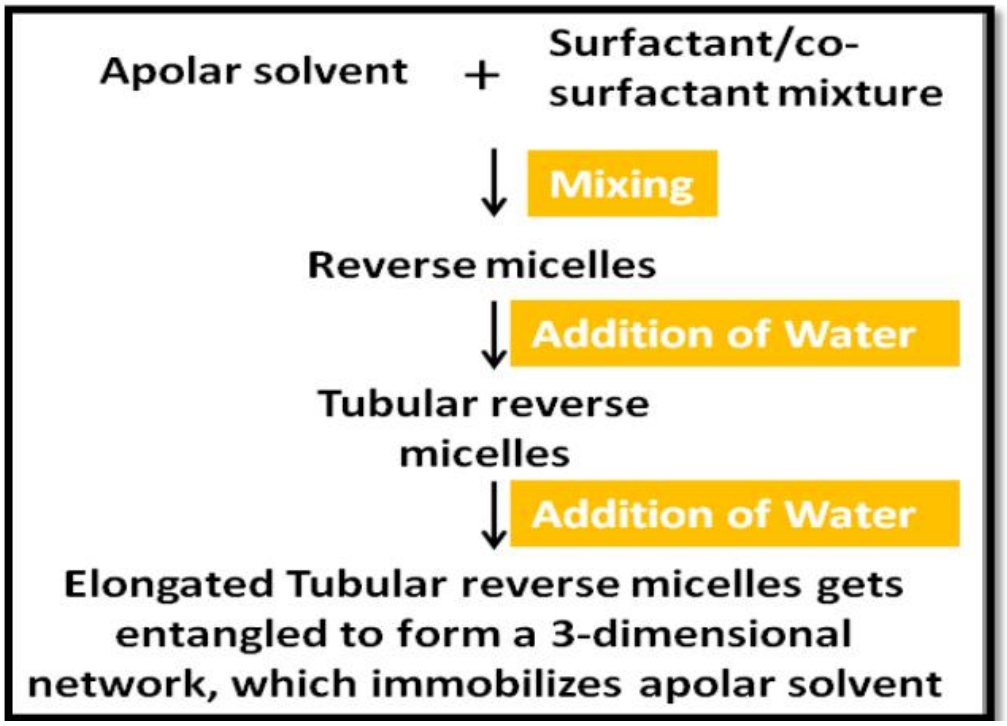

Fig. 4: Method of formation of organogels by fluid fiber mechanism.

2. Solid fiber mechanism

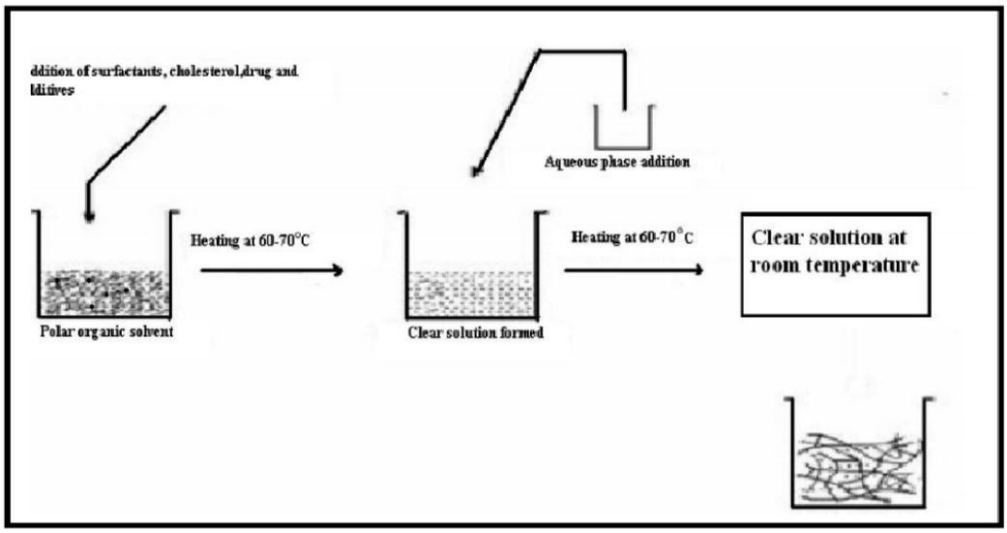

Fig. 5: Method of formation of organogels by solid fiber mechanism.

3. Hydration Method: Gel may be prepared by directly hydrating the inorganic chemical, which produces dispersed phase of the dispersion. In addition of water vehicle, other agents as propylene glycol, propyl gallate and hydroxyl propyl cellulose may be used to enhance gel formation.

4. Novel method

1. Homogenization

2. Micro irradiation

CHARACTERIZATION OF ORGANOGELS

1. Physiochemical properties

Physiochemical properties of the organ gel are due to its structural features. An efficient characterization methodology for any organ gel system begins with its structural elucidation. The isotopic nature and optical clarity organ gel study is feasible by various spectroscopic techniques, namely NMR and FTIR spectroscopy. FTIR spectroscopy has been found to be successful in establishing the hydrogen bonding as one of the major driving force for the self assembly of organogelator molecules in organic solvent. The knowledge of molecular packing within the organogel network has been obtained using scanning and transmission electron microscopies, dynamic and static light scattering (elastic or quasi elastic light scattering technique.) small angle neutron scattering {SANS}.

2. Rheological behavior

The critical parameter such as spread ability, adhesiveness, cohesiveness and gel consistency need to be modified.

3. Viscoelasticity

Organogels have been studied extensively for their rheological attributes and have been determined to be viscoelastic in nature. Scartazzini and Luisi performed the dynamic shear viscosity prepared using different types of organ gel solvent (e.g. linear and cyclic alkenes, amines). The higher values obtained using linear alkenes were related to the higher state of structural organization organogels. Similarly, Schurtenberger E T found that increasing the gelator concentration leads to an increase in the viscosity and in turn the gel strength.

4. Swelling

Gels can swell by absorbing liquid with an increase in volumes. Solvent penetrates the gel matrix, so that gel-gel interaction is replaced by gel solvent interaction. Limited swelling is usually the result of some degree of cross linking gel matrix that prevents total dissolution. solto-gel, TSG, or gel-to-sol, TGS) gives an insight into the nature of microstructures that form the gelling crosslinked network. The phase transition temperatures also help in optimizing the organogel composition.

5. Water Content

Water content of organ gel system is critical, as the water loss by evaporation can lead to consequent decrease in viscosity thus affecting the gel stability. Near infra red spectroscopy studies on lecithin/IPP/water organogel system by measuring the water absorption in the NIR region (1800-2200nm). In this region, water shows a strong absorption peaks at 918nm due to HO-H stretching overtones, which are easily detectable and quantifiable.

6. Phase transition temperature

The phase behavior of organogel varies on changing temperature condition. The phase transition temperature (PTT) (i.e. sol to gel or gel to sol) gives an insight into the nature of micro structure that form gelling cross linked network. For the determination, hot stage microscopy and high sensitivity differential scanning calorimetry have been reported to be useful as accurate and sensitive techniques. PTT also reveals the micro structural homogeneity of the prepared organogel system. For example, a narrow PTT range (i.e. 3) is indicative of homogenous microstructures within the gel.

7. Gelation kinetics

Determined by using method like inverse method and turbidimetry method.

8. Viscoelaticity

Viscoelasticity is associated with the materials having both viscous and elastic properties. The organogels seems to follow Maxwell model of viscoelasticity. Organogelatore the threedimensional structures which are formed due to the physical interactions amongst the gelator molecules. The organogels behaves like a solid at lower shear rates and hence shows an elastic property. As the shear stress is increased, the physical interacting points amongst the fiber structures start getting weakened until the shear stress is high enough to disrupt the interactions amongst the fiber structures, when the organogels starts flowing. This behavior may be best explained with the plastic flow behavior.

9. Optical Clarity

Depending on the composition of the organogels, the organogels may be transparent or opaque in nature. The lecithin organogels are transparent in nature while the sorbitan monostearate organogels are opaque in nature.

10. Thermo Reversibility

Organogels are heated up above a critical temperature, they loses its solid matrix like structure and starts flowing. This has been attributed to the disruption in the physical interactions amongst the gelator molecules due to the increase in the thermal energy within the organogels. But on cooling, the physical interaction amongst the organogelators prevails and the organogels revert back to the more stable configuration.

11. In Vitro Drug Release

The permeation apparatus designed as described by Chowder et.al. was employed to study the release profile of drug from semisolid formulation. The media used as receptor fluid. The release of drug from gel through various membranes was determined using Franz diffusion cell.

12. Safety and Skin Compatibility Study

Organogel systems i.e., gels are composed of pharmaceutically approved (non-immunogenic and biocompatible excipients. However, the level of surfactant and organic solvents in organogels is fairly high. Therefore, it is important to consider the safety and irritancy of the formulation on prolonged use. The irritation potential of organogels has been assessed by Dreher et al, by carrying out human skin irritation study. Results indicated a very low cumulative skin irritation potential of organogels that supports the suitability of organogels as a topical vehicle for longterm applications.[26-28]

USES OF ORGANOGELS

1. For Rheumatoid Arthritis

Rheumatoid arthritis is a chronic disorder for which there is no known cure. Fortunately in the last few years, a shift in strategy toward the earlier institution of disease modifying drugs and the availability of new classes of medications have greatly improved the outcomes that can be expected by most patients.

2. For Osteoarthritis

Eighty percent of individuals older than 65 have radiographic signs of osteoarthritis (OA), and a large percentage have symptoms. Given the chronic nature of the disease and the high incidence of medication side effects in the elderly, an understanding of the risks and benefits of NSAIDs in treating OA is crucial.

3. Inflammatory arthropathies. (E.g. ankylosing spondylitis, psoriatic arthritis, Reiter's syndrome)

4. Dysmenorrhoea (menstrual pain).

5. Postoperative pain, Metastatic bone pain.

6. It are also given to neonate infants whose ductus arteriosus is not closed within 24 hours of birth Headache and migraine.

7. Mild-to-moderate pain due to inflammation and tissue injury.

8. For Acute gout treatment.

9. For Pyraxia: Antipyretics (pertaining to fever) are drugs or herbs that reduce fever.

10. For Muscle injuries.

11. Clinicians faced many problems with conventional dosage form for local delivery of drug so to avoid the risk with topical preparations.

12. Topical preparations are made for the localized effects at the site of their application by virtue of drug penetration into the underlying layers of skin or mucous membrane with low concentrations of potent active drugs in the bloodstream likewise minimize side effects.

13. Helps in achievement of more constant blood levels with lower dosage of drug by continuous drug input. It is very commonly used dosage form and avoided various side effects which may be shown in other dosage form.

14. The main advantage of topical delivery is to bypass first pass metabolism and Avoidance of the risks and inconveniences of intravenous therapy and of the varied conditions of absorption, like pH changes, presence of enzymes, gastric emptying time, reduces frequency of drug dosing are other advantage of topicalpreparations.

15. In the treatment of skin aging Skin aging is an unavoidable aspect of human life. Premature skin aging can result from poor care, environmental pollutants, and ultraviolet radiation exposure. Some indicators of skin aging like wrinkles, lines, spots, uneven skin tone, and pigmentation. One cannot avoid aging but cosmetics and pharmaceutical approaches play an important role in that. Lecithin organogel (LO) is an effective vehicle for topical delivery of many bioactive agents used in aging treatment. Lecithin is cell component isolated from soya beans or eggs and purified to show excellent gelation in non-polar solvents when combined with water. LO can form a heat-stable, resistant to microbial growth, visco-elastic in nature, optically transparent, and non-birefringent, micellar system. Lecithin organogel act as a penetration enhancer. so its ability to dissolve in hydrophilic as well as in lipophilic drugs makes it a dynamic vehicle, which can be explored as a carrier for anti-aging agents.[29-33]

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