

An Oral Organogel - Novel Approach for Controlled Drug Delivery System

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ABSTRACT

Organogels are semi-solid systems in which an organic liquid phase is immobilized by a three-dimensional network of self-assembled, interlaced gelator fibres. In this system, despite having a mostly liquid content, have the appearance in addition to rheological behaviour of solids. The pace of investigation into these systems has only accelerated in the recent few decades. As a result, many pressing problems about organogel systems, for instance the particular molecular requirements for gelation, remain unanswered. Nonetheless, after their findings, numerous organogel systems have been quickly applied to various areas of interest. Unfortunately, the lack of toxicological information on organogelators, as well as the few pharmaceutically acceptable solvents employed in gel systems, limits their application in drug administration.

This article aims to offer a complete review of organogels, with a focus on the relationship between the gelator's structural features and the intermolecular interactions that ensue. The characterisation and uses of organogels as drug delivery platforms for active agent administration via the oral route. Oral Organogel requires a smaller number of excipients, less steps in processing and low cost with controlled release effect. However, *in vivo* studies are limited for oral organogel.

Keywords: Organogel, Control Release Drug Delivery, Oral, Topical, Transdermal

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INTRODUCTION

Oral Route

Oral administration has been the most widely utilized mode of administration for both traditional and new medication delivery mechanisms throughout history. There are several obvious reasons for this, not the least of which is patient acceptability and convenience of administration. Because sterility and possible harm at the administration site are avoided, the types of sustained and controlled-release methods used for oral administration allow for more flexibility in dose formulation. Enhancing concentration at the absorption site is thought to improve absorption rate and, as a result, circulating blood levels, resulting in higher drug concentrations at site-specificity. As a result, therapeutic doses can be increased, although toxicity is a significant problem. These systems typically rely on drug release from various dosage forms, penetration into the biological environment, and absorption into the bloodstream through an epithelial barrier.

Controlled Release Formulation

Control drug delivery system provides a continuous supply of the active ingredient at a zero-order rate by continuously

releasing a quantity of the medication corresponding to the amount removed by the body for a set length of time.

Thus, an ideal Controlled drug delivery system delivers the drugs at a predetermined rate, locally or systematically, for a specific period.^{2,3,7}

Advantages of Controlled Released Drug Delivery System

Drug plasma level fluctuation is reduced, resulting in a stable drug plasma level for a longer time.

Drug plasma levels are kept within a narrow window with no high peaks and an AUC of plasma concentration vs. time curve, which helps to reduce side effects and improve tolerance.²

Patient Convenience and Compliance: Oral medication administration is the most common and convenient for patients and reducing dosage frequency improves compliance.

Reduced Health Care Expenditure: The overall cost of treating the controlled-release medication might be equivalent to or else less than that of the immediate-release treatment, resulting in fewer adverse effects. The expense of disease management as a whole would be lowered as well. As we get closer to the most significant safe dose, the number of adverse effects drops substantially.

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MAIN TEXT

Gel

A gel is a soft, solid, or solid-like material made up of both solid and liquid components. The liquid element is held in place by the gelator, which is a web of aggregates. Organogel is made up of a small percentage (15%) of gelator molecules. Organogel self-assembles into a vast mesh network in the presence of a suitable solvent through physical or chemical interactions, inhibiting solvent stream owing to surface tension.⁵

Following their self-assembly into diverse aggregates such as rods, tubules, fibres, and platelets, the gelator molecules immobilize enormous amounts of liquid.

Types of Gels

1. Organogel

An organogel is a non-crystalline, non-glossy thermoplastic solid that has a liquid organic phase entrapped in a three-dimensional crosslinked network. As a liquid, you can use an organic solvent, mineral oil, or vegetable oil. The combination of polar and non-polar solvents forms a three-dimensional network caused by reverse micelle development. To achieve a jellified structure, the mixture might be heated and then chilled. Because organogel contains both hydrophilic and hydrophobic components, it is possible to include both hydrophilic and hydrophobic medicines.^{4,5}

2. Hydrogel (Aquagel)

A hydrophilic polymer chain network discovered as a colloidal gel within which water serves as the dispersion medium is known as a hydrogel (Aquagel). The polymer eventually dissolves, releasing the drug from the core. Hydrogels are natural or manufactured polymers that absorb much water. Because of its high water content, the hydrogel has a similar degree of elasticity to actual tissue.

3. Xerogels

Xerogel is a solid made from a gel that has shrunk uncontrollably while drying. As a result, xerogels frequently have high porosity (15–50%), a large surface area (150–900 m²/g), and tiny pore diameters (1–10 nm).

Organogels have the following advantages

- They are simple to prepare.
- They have an organic quality and are resistant to microbial infestation.
- Because there are fewer ingredients and a cost-saving.
- Shelf life is extended.
- Stable in terms of thermodynamics
- Organogel is used to incorporate both types of drugs for instance, hydrophilic and hydrophobic.
- Organic solvents originating from natural sources, such as sunflower and soybean oils, are commonly employed.

Limitations of Organogels

1. It should be stored in the specified condition.
2. The organogel has greasy properties.
3. Syneresis occurs when an organogel is left to stand for a while, and part of its liquid is squeezed out.

4. If the impurity is present, however, there will be no gelling.
5. On a big scale, raw materials like lecithin are not available.^{4,5}

Structure of Organogels & Mechanism of Organogelling

Lecithin solutions in organic solvents are inducing by adding a polar solvent, organogelling, or gelating them. A twist-shift in the amphiphile monolayer determines the aggregate modification. As a result, a hydrated molecule has the same form as a cylinder, resulting in packing constraints in spherical micelles that may be overcome by switching to cylindrical micelles with a lower curvature (Figure 1).³

Gelator Self-assembly

The gelator's environment and how gelator molecules self-assemble are determined by the gelator's component groups, which state the forces of contacts involved in gelator self-assembly. Nonionic surfactant sorbitan monostearate molecules, for example, produce bilayers that are then organized into tubules. The formation of fibrillar aggregates by 12-Hydroxyoctadecanoic acid is due to axial solid hydrogen bonding and dipolar interactions.⁶ Aggregation forces include hydrogen bonding, dipole-dipole interactions, -stacking, electron transfer, London dispersion forces, solvophobic effects, and ionic interactions, depending on the chemical structures of the gelators. The gelator molecules in aggregates must not be identical to those in the simple gelator solid. The gelator molecules in aggregates ought to not be the similar as the gelator molecules in the plain gelator solid. Gelator molecules in aggregates must not be the same as the gelator molecules in the plain gelator solid. The clean solid along with the varied packing, including forces of interactions in gelator aggregates, are frequently repeated in the two melting points. The liquid phase of the organogel is essential in the gelation process. It influences the organogel's macroscopic (e.g., opacity) and microscopic (For instance, shape, size, cross-sectional nature, helicity, and gel network characteristics) shape, size, cross-sectional nature, helicity, and gel network

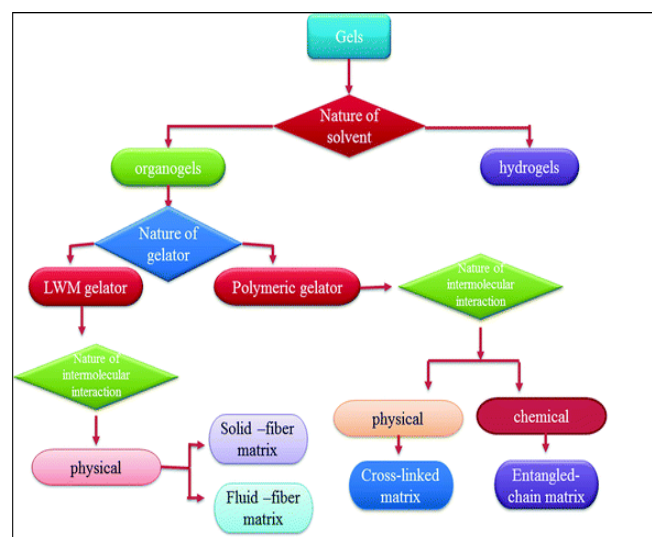


Figure 1: Trends of organogel in drug chemistry

properties. The fluid phase must provide a precise solubility/insolubility balance. The gelator dissolves or disperses at elevated temperatures, although it emerges out of the solution (as aggregates). The gel network can be affected by the size of the container in which the gelation takes place.^{3,4}

Preparation of Organogel

Gelators are created by heating a combination of gelators and organic components to produce an organic solution, and then cooled to form a gel. After cooling, the gelator's solubility in the liquid phase decreases, moreover gelator-solvent interactions decrease, causing molecules to separate from the solution. Gelator-gelator interactions cause tubules, rods, and fibers to self-assemble into well-defined aggregates. The aggregates get entangled and form a three-dimensional network, which gives gel mobility with flexibility. Gel production requires connections between gelators; even if many gelator aggregates exist, the gel state may be lost.

The physical organogels, composed of non-covalent forces, are thermoreversible. Following heating, the gel melts to the sol phase as the gelator aggregates dissolve in the organic liquid, and the hot sol phase cools to produce gelation. The gelation temperature is the temperature at which the gel-to-sol or sol-to-gel transition occurs (T_g). T_g has been measured using a variety of ways. Differential scanning calorimetry, rheological measurements, melting point equipment, hot stage microscopy, and the falling drop method are examples of these techniques. After dissolving surfactant and co-surfactant combinations in an apolar solvent, reverse micelles were produced. With the addition of water, tubular reverse micelles were created. The stretched tubular reverse micelle becomes entangled and forms a 3-dimensional network after being exposed to water, immobilizing the apolar solvent.^{3,6-8}

Solid Fiber Mechanism

Apolar solvent furthermore solid organogelators are heat together to create an apolar organogelators solution. The organogelators precipitates out as fibers that interact physically, forming a three-dimensional network structure that immobilizes apolar solvent and achieves an appropriate degree of subdivision of the gummy particle nature of those particles after cooling at ambient temperature. The gel may be made using the Hydration technique by directly hydrating the inorganic chemical, which results in a dispersed phase of the dispersion. In addition, other substances, such as propylene glycol, propyl gallate, and hydroxyl propyl cellulose, can be employed as water carriers to enhance gel formation.

Organogelators

The upstairs conversation reveals the nature of organogelators when it comes to planning organogels. Organogelators may be classified into two categories depending on their hydrogen bonding capabilities. Anthracene, anthraquinone, and steroidal-based compounds are examples of organogelators that do not create hydrogen-hydrogen bonds, whereas amino acid, amide, urea moieties, and carbohydrates form hydrogen bonds. Discussing the different organogelators before discussing the

different types of organogels as well as their submissions within a controlled delivery would be known.³⁻⁶

4-Tertbutyll-1-Aryl Cyclohexanols is a kind of tertbutyll-1-Aryl cyclohexanol. These gelators are solid at room temperature and apolar solvents such as cyclohexane, benzene, and carbon tetrachloride have limited solubility. The creation of thermo-reversible organogels is aided by aryloxy cyclohexanol derivatives such as 4-tertbutyl-1-aryl cyclohexanols.

Polymer Organogelators

Polymers which are used as organogelators have been demonstrated to achieve equivalent organogelation at small concentrations; also their gelling ability can be adjusted by modifying the chemical structure of the polymer backbone. L-lysine derivatives are utilized as polymeric organogelators in addition to conventional polymers such as polycarbonate, polyesters, and polyurethane (alkaline). Polymeric organogelators generate gels with a lower gel-sol transition temperature and a slight improvement in gel strength than organogels made using low-molecular-weight organogelators.

BOC-ALA(1)-B-ALA(3) -OME Boc-Ala(1)-Aib(2)—Ala (3) Organogelator OME may self-associate and form thermoreversible transparent gels in the presence of various apolar solvents, including as 1, 2-dichlorobenzene, monochlorobenzene, and benzene. The development of thermoreversible translucent organogels.

Organogelators with Low Molecular Weight

This gelator can generate either a solid-fiber matrix or else a fluid-fiber matrix, depending on the activities of the physical intermolecular interactions. A solid-fiber matrix can form on a heated mixture of organogelators in an apolar solvent that is cooled below the organogelators' solubility limit, with the organogelators precipitating as fiber-like structures physically interact to form a gelled structure. In apolar solvents, amphiphaths exist as reverse micelles with little water, creating tubular reverse micellar structures. Solid-fiber matrix

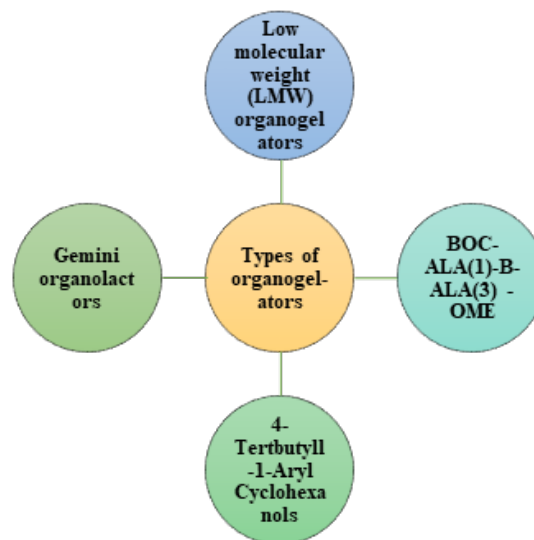


Figure 2: Types of organogelators

organogels outperform fluid-fiber matrix organogels in terms of mechanical properties. This is due to the solid-fiber matrix organogels' well-ordered structures, suited to the fluid fiber matrix organogels' surface chain entanglements. Various amphiphiles that may form self-assembled structures in the presence of apolar solvents have also been attempted, in addition to the organogels described previously.

Organogels in Drug Delivery

In the past, organogels could be used for drug and vaccine supply via different administration routes. At the same time, despite many organogels under investigation, only a few of these formulations have been tested for drug delivery. Most organogels are made up of pharmaceutically ineffective gelators, and organic solvents contribute to this objective. The majority of organogels are studied in chemistry departments, where medication delivery is not always a priority.^{3,6,8} Organogels mainly investigated as following types:

Dermal Formulations

The muscle relaxants in the lecithin-Isopropyl myristate organogel are exposed to provide fast pain relief from bruxism (tooth grinding) and tooth clenching. Antipsoriatic agents and eczema medicines are delivered effectively. The anti-inflammatory composition of phospholipids organogels with anti-inflammatory macromolecules bromelain (15%) and capsaicin (0.025%) is efficient.

Transdermal Formulations

In transdermal formulations, organogel systems have also been used as a matrix for the transdermal transfer of many therapeutic compounds. Solubility of several drugs, such as nifedipine, clonidine, and scopolamine. Furthermore, as compared to drug solubility in IPP alone, broxaterol increased lecithin-IPP solution, suggesting the organogels' solubility boosting potential. Nicardipine, a calcium channel blocker, has been integrated to achieve systemic absorption using topical techniques due to its low dosage, short half-lives, and broad first-pass metabolism.

Parenteral Depot Formulations

L-alanine-based injectable in situ forming organogels could be used to transport labile macromolecular bioactive compounds. The organogels system, when delivered subcutaneously in rats, releases bioactive chemicals (e.g., leuprolide) for 14–25 days after the gelled structure has disintegrated, according to experimental results.

Topical Drug Delivery

Muscle relaxants, steroids, hormones, analgesics, antiemetic, and cardiovascular drugs, among others, have been integrated into the organogel with promising results. It has widely used in the cosmetics and personal care industries. Standard lachrymal turnover-based drug products have a fast clearance of solution in addition suspension dose forms. In addition, it has compensations like virtuous tolerability, forming a defensive film over the cornea, and protection from conjunctival adhesion.

Bioadhesives Gelatins Gels

They make both type of capsules soft gelatin and hard gelatin capsules used to disguise the taste of solids and liquids. Once in contact with the aqueous stomach media, the drug remains soluble in lipophilic domains. The absorption profiles of the hydrophobic organogels were parallel to those of the commercially existing Neroal microemulsion formulation.

Oral and Trans-mucosal Formulations

The gelled structure contained ibuprofen, a non-steroidal anti-inflammatory medication. The release experiments revealed that when the concentration of the organogelator within the organogel increased, the organogels' release rate decreased. Thus, according to in vivo tests in rats, organogels may provide a regulated delivery vehicle for the oral administration of lipophilic compounds. Oral organogel formulations were only found in the literature in the form of sorbitan monostearate (SMS) systems. Cyclosporine A, an immunosuppressant commonly used following organ donation, was combined in organogels ranging from very hydrophobic (SMS in sorbitan monooleate) to highly hydrophilic (SMS in sorbitan monooleate) (SMS in polysorbate 80). When delivered to beagle dogs, the hydrophilic organogels allowed for less drug absorption than the hydrophobic formulations, most likely due to the lack of lipophilic domains in which the drug remains soluble once in contact with the aqueous stomach medium. The absorption patterns of the hydrophobic organogels, on the other hand, were identical to those of the commercially available Neroal formulation of microemulsion.

Characterization of Oral Organogel

Characterization of organogel using various procedures and techniques is critical for confirming its stability and efficiency. During the characterization of organogels, several features such as gelator-co-gelator interactions, gelator-polar/apolar solvent interactions, drug interactions with gel components, and gelator assemblies can be examined.

Pre-formulation Study

Melting Point

The melting point is the temperature at which a pure drug and a solid are in equilibrium. In practice, it will be assumed to be an equilibrium mixture at atmospheric pressure. Therefore, melting point apparatus was used in the present study. The melting point of the drug will determine using the capillary melting point method by placing the minimum amount of drug in a thin-walled capillary tube along with the thermometer suspended in the melting point apparatus and determining the temperature range over which the drug melts.

Solubility

Solubility is an important consideration, and thus solubility of the drug will test in various oils (for example, soyabean oil).³⁴

Identification of Drug by Fourier Transform Infrared Spectroscopy

The compatibility study will be conducted using Fourier

Transform Infrared Spectroscopy (FTIR); It will be done utilizing a KBr press and the pressed pellet method. Potassium bromide should be kept for two hours in a hot air oven to eliminate any moisture. The dried KBr crystals will be combined with the drug powder sample, and the combination will be pressed into pellets using a KBr press. The produced pellet will be placed in the sample holder and kept in the instrument while the IR peaks are recorded. Understanding the optical clarity and isotopic composition of organogel is beneficial. In addition, Fourier-transform infrared spectroscopy has successfully investigated hydrogen bonding (weak bond created by H- molecule) as one of the fundamental driving forces in organic solvents for organogelator molecule self-assembly.⁴⁰

Differential Scanning Calorimetry

The physical, chemical, and biological characteristics of APIs and excipients are used to fabricate the product. The drug and excipients must be compatible with one another to produce a product that should be stable, attractive, easy efficacious, to administer, and safe. For many possible reasons, temperature change on the stability of solid dosage form can be complicated. For example, the drug or one excipient may melt or change its polymorphic form as the temperature increases or contains loosely bound water lost with the temperature change. In addition, the relative humidity changes with the temperature change; hence, precaution should be taken to maintain a constant value. The compatibility study provides the framework for the drug's combination with the excipients in the fabrication of the dosage form.³⁵⁻⁴⁰

Evaluation of Soybean Oil

Iodine value

In a 250 mL conical flask, weigh roughly 0.1 g of fat or oil. Chloroform (10 mL) will be added. 25 mL Hanus solution will be added to this and left in the dark for 60 minutes. Blank will prepare in the same way, excluding the sample. After 60 minutes, add 20 mL of 10% potassium iodide and 100 mL of purified water. Titrate the iodine solution with 0.1 N sodium thiosulfate until a yellow hue appears. After that, add 2–3 drops of starch solution to produce a blue solution, then titrate until the blue hue is gone (volume (ml) of $\text{Na}_2\text{S}_2\text{O}_3$ at endpoint indicates S). The operation will be repeated without using a sample (the volume (ml) of $\text{Na}_2\text{S}_2\text{O}_3$ at the endpoint represents B).^{25,26,36,37} The following equation is used to determine the iodine number:

$$\text{Iodine Value} = (\text{ml blank} - \text{ml sample}) \times \text{N sodium thiosulfate} \times 12.69 \text{ g of sample}$$

Saponification Value

A conical flask transferred a sample weight of such size and weighed to the nearest 1 g. Alcoholic potassium hydroxide solution (25 mL) will add to the sample and to one or more additional flasks to be carried through as blanks. A condenser loop will place inside the neck of each flask and heated on the steam bath for one hour. The solution will cool down, and the

Phenolphthalein indicator will be added and titrate with 0.5 N sulfuric acid (H_2SO_4) or hydrochloric acid (HCl) until the pink color has just disappear.^{25,26,37} Calculate the saponification number as follows:

$$\text{Saponification number} = [(B - A) N \times 56.1]$$

Where,

A = milliliters of H_2SO_4 or HCl required for titration of the sample,

B = milliliters of H_2SO_4 or HCl required for titration of the blank,

N = normality of the H_2SO_4 or HCl, and

W = grams of sample used

56.1 = equivalent weight of potassium hydroxide

Specific Gravity

It is the weight of a volume of a material divided by the weight of an equivalent volume of a reference substance, while apparent specific gravity is the ratio of a substance's density to the density (mass per unit volume) of a reference substance

Rheological Studies

Rheological evaluation is instrumental in relating the physical properties of organogels, such as viscoelasticity, viscosity, also mechanical strength. After applying adequate shear to the organogel, it is critical to deform it for easy spreading and drug absorption augmentation after cutaneous application. When the shear rate increases, the strain within the sample becomes more non-linear at first and then becomes more linear. The shear rate required for complete deformation of the gel may be easily estimated, indicating the gel's strength and storage requirements. The rheological properties of organogel can be explained using dynamic and rheological parameters such as loss or viscous modulus (G''), shear viscosity, elastic or storage modulus (G'), and relaxation time. The moduli correspond to the disappearance of viscous energy and the accumulation of elastic energy, respectively. These values can be used to calculate rheological and linear viscoelastic parameters * and G^* . A gel is a rheological word that refers to a preparation in which the loss and storage moduli are frequency independent, and the phase angle is low at all frequencies. The formula can be used to compute it.^{27-32,38,39}

$$\text{Tan} \delta = G'' - G'$$

Gel Strength Measurement

The formulated Gel will place in a vial. Gel Strength measuring apparatus will place above the Gel. The time requires to penetrate the plunger up to 2 cm through a gel will measure using a Nikansui gel strength tester.³⁹

Gel Transition Temperature

The gel-sol transition temperature is the temperature below which Gel does not show any distinct flow property. It can be determined by the simple tube inversion method. It increases with the rise in the gelator concentration.⁴¹⁻⁴³

Evaluation of Diffusivity of Drug in Organogel

By producing organogel in a plastic syringe (2.5 mL) with the tip removed, the drug's diffusion coefficient in organogel may

be determined. At 37°C, the syringe is fixed vertically and dipped in phosphate-buffered saline (pH 6.8) containing API. The solution will be gently stirred at a rate of 50 revolutions per minute. The syringe will be removed from the solution after twenty-four hours, and the organogel will be recovered from the syringe by pressing the plunger. Next, the oil matrix will be sliced every 1.5 mm, yielding organogel discs. Then, using the following formula, the API concentration in each disc is determined.^{33-37,44-50}

$$\frac{C_i}{C_o} = 1 - \operatorname{erf}\left(\frac{x}{2\sqrt{D_i \cdot t}}\right)$$

C_i = concentration of drug in disc

C_o = concentration of drug at the surface of the organogel phosphate buffer solution border

X = Distance from the organogel phosphate buffer solution border to the center of the disc

t = time

D_i = Diffusion co-efficient

Biocompatibility Study

Most organogels contain a large amount of surfactant and toxic organic solvents such as n-octane, cyclohexane, and kerosene. As a result, they render the organogel ineffective for human use. In conclusion, it is essential to keep an eye on the safety and irritancy of the new formulation. The created formulation's safety and irritancy over time. Hemocompatibility is a factor that is frequently examined while determining biocompatibility. This is accomplished by mixing the test sample with blood and positive control (0.1 N HCl, which lyses blood cells) and negative control (normal saline). The percent of hemolysis in the test sample is estimated using the formula below once the incubation time has passed:

If the percent of hemolysis is less than or equal to 5, the test sample is highly biocompatible; if the percent of hemolysis is greater than 5 but less than or equal to 10, the test sample is not hemocompatible; and if the percent of hemolysis is greater than 10, the test sample is not hemocompatible.

The Inverted Vessel Method: Verifying the Gel Formation

Ternary phase diagrams are the phases and structures created when three or more components are combined in a temperature-dependent manner. For example, the fundamental components of Organogel are an organic solvent and a gelator. Organogels, on the other hand, can sometimes fit a different polar phase into their structure. The crucial gelation concentration is the lowest amount of gelator concentration required to cause gelation at room temperature. If the organogelator concentration is less than the critical gelation concentration, the gelator will not promote gelation and stay in the liquid phase. Gelation may not occur if the aqueous phase concentration is beyond the upper critical limit, creating a biphasic system. A bi-phasic system is one in which there is no additional water in the networked form of the organogel. So, with the addition of a large volume of water, this process of preventing the creation of a gelled structure is known as gel solvation. The inversion (turning upside down) of the vessel/tube containing the gel can be used

to determine its creation.

Characterization of Organogel Filled Capsule

Weight Variation

The equivalent amount of organogel is filled in a capsule with the help of a syringe. Then, randomly selected ten capsules from each batch weigh individually for weight variation.

Erosion of Organogel

The organogel formed in the gelatin capsule will be weighed and incubated at 37°C in a 10 mL test solution. (pH 1.2), Phosphate buffer (pH 6.8), Phosphate buffer (pH 6.8) with 375 U/mL lipase and simulated intestinal solution (PBS (pH 6.8) with 375 U/mL lipases) will be used as test solutions. The test solution shall be gently stirred at 50 rpm during the incubation period. After 1, 2, 3, 4, 6, and 8 hours, the organogel will be withdrawn from the test solution and dried in a vacuum for 12 hours. The weights of organogel will be measured before and after incubation, and the erosion rate constant will be computed using the equation below (k).⁴⁹⁻⁵²

$$W_d/W_i - 1/3 = 1 - kt$$

Where W_d and W_i are the dry weight of organogel after and before incubation, respectively, K is the erosion constant, and t is incubation time.

In-vitro Release Study of Drug

The dissolution test evaluates the release of the drug beginning the formulation. The dissolution test performs for the first 2 hours in simulated gastric fluid and then in simulated intestinal fluid. The paddle will rotate at 50 revolutions per minute, and the amount of the test fluid will be 900 mL.⁵²⁻⁶⁰

Scanning Electron Microscopy (SEM)

The surface morphology of the Gel will be examined using a scanning electron microscope. Photomicrographs were obtained at 467x magnification with a tungsten filament as an electron source and a GSE detector after the sample was placed in the sample holder.⁵²⁻⁶⁰

Transmission Electron Microscopy (TEM)

The microstructure organization and morphology of gel particles are studied using a transmission electron microscope.⁵²⁻⁶⁰

Stability Studies of Organogel

The ICH Guidelines shall be followed for the Accelerated Stability Studies. Stability testing is performed to demonstrate how the quality of a drug substance or drug product changes over time because of various environmental variables such as temperature, humidity, and light, as well as to determine the drug product's shelf life under recommended storage circumstances. According to ICH rules, accelerated stability studies must come to a conclusion. The optimized batch's organogel will be stored at two temperatures: room temperature and 40°C 0.5/75 percent RH. The gels were also tested for in vitro drug release after 30 days of storage. The in vitro drug release values of the Gel will be determined and compared to see if the dissolving profile has changed.^{58,59}

Applications of Organogels

Organogels can attain outstanding semi-solid physicochemical qualities, such as a liquid or else solid surface, entangled fibrous nano/microstructures, and entrapping a wide range of mandate chemicals, depending on their structural features too chemical alignment. Chemical composition's outstanding biocompatible and biodegradable feature may be effectively altered in dynamic human settings, and inadequately interacting surface layers are commonly given and advised near to the ground interfacial energy to block adhesion against unwanted deposits. Organogels have been functionalized based on these inherent advantages and have shown promise in anti-icing, anti-fouling, droplet manipulation, medicine administration, food processing, and other applications. Organogel characteristics, on the other hand, have a significant impact on their diverse applications. The fundamental processes for gelation in physical organogels are intermolecular non-covalent interactions such as hydrogen bonding, stacking, van der Waals forces, electrostatic, coordination contacts, or even solvophobic forces transitory and weak polymer networks. As a result, the mechanical strength and stability of these organogels are compromised. In terms of biodegradability and rheological properties, physical organogels have a low stability, making them a good fit for drug delivery and food processing applications. Some biocompatible molecules/ingredients could be liberated from the gelled matrix in a controlled manner by simply disintegrating the gel network. Chemical organogels, on the other hand, are more stable, and their use in more long-term and demanding applications, such as industrial anti-fouling and anti-icing, is expected to rise. Furthermore, the material's mechanical properties are improved by the strong covalently crosslinked network.⁴³

CONCLUSIONS

This formulation requires a smaller number of excipients, offering to alleviate optimization of the formula and is cost-effective; it involves fewer processing steps, so it is easy to formulate organogel. In addition, oral controlled release organogel solves the problem of repeated dosing and patient compliance. Oxic solvents for pharmaceutical formulations. Organogels are intriguing as drug delivery formulations for a variety of reasons, including their ease of preparation and administration. However, the quick diffusion of low molecular weight drug molecules out of the matrix and/or water infiltration into the latter are currently limiting several organogels. Nonetheless, fine-tuning the organogelator structure and maybe the composition of the organic phase is regarded to be a possibility for optimizing sustained drug release duration.

LIST OF ABBREVIATIONS

m: meter
g: gram
nm: nanometer
T_g: gelation temperature
SMS: Sorbitan monostearate

AUC: Area Under curve

FTIR: Fourier Transform Infrared Spectroscopy

APIs: Active Pharmaceutical Ingredients

ml: milliliter

cm: Centimeter

°C: Celsius

ICH: International Council for Harmonisation

RH: Relative Humidity

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