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Review Article

A Brief Review On Emulgel: Recent Advances

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ABSTRACT

Numerous advantages of gels Delivery of hydrophobic medications is severely limited. In order to overcome this limitation and take advantage of the unique properties of gels, even a hydrophobic medicinal moiety is being treated with an emulsion-based approach. The dosage form produced by mixing gels and emulsions is called an emulgel. Dermatological pharmacology is unique in that it uses the skin as a target organ that is directly accessible for diagnosis and treatment. The interaction of hydrophilic cornified cells with hydrophobic intercellular material blocks both hydrophilic and hydrophobic molecules. Research has shown that the presence of a gelling component in the aqueous phase transforms a conventional emulsion into an emulgel. These emulgels are superior than both novel vesicular systems and traditional systems in a number of respects. Compared to current topical drug delivery technologies, emulgels are preferable because different permeability enhancers can increase the impact. Emulgels are a useful supplement to the methods currently utilized to apply topical medications.

INTRODUCTION

Topical drug administration refers to the localised process of delivering medication via topical routes such as the skin, vagina, rectal, and ocular canals. These apply a variety of dermatological and aesthetic treatments on their skin, whether it is healthy or injured. Based on their physicochemical composition, these formulations can be classified as semisolid or solid. Medication is given topically to either have a systemic effect or a site-specific effect. Drug absorption through the skin is enhanced if the drug ingredient is in solution, if its lipid/water partition coefficient is favourable, and if it is a nonelectrolyte. One of the main advantages of topical administration systems is their ability to prevent first pass metabolism. Topical preparations also eliminate the risks and inconveniences associated with intravenous therapy, as well as the different conditions of absorption, such as pH changes, the presence of enzymes, and the duration of gastric emptying. Substantial amounts of aqueous or hydroalcoholic

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liquid are trapped in a network of colloidal solid particles, a relatively novel type of dosage form. More patient acceptance and usability are provided by these. Gels offer numerous advantages, but one major disadvantage is the hydrophobic drug delivery system. Emulgels are designed and utilized to circumvent this limitation, enabling even a hydrophobic medicinal moiety to take advantage of the special qualities of gels and stay away from the disadvantages associated with intravenous therapy. The presence of enzymes, pH variations, and gastric emptying time are additional advantages of topical treatments. [4–3] A more modern class of dosage forms called gels is created by entangling large amounts of hydroalcoholic or aqueous liquid in a network of colloidal solid particles. These particles could be inorganic (aluminium salts, for example) or organic (natural or artificial) polymers. (5)They have a larger fluid component than the treatment or cream premise, which enables greater medication dissolvability and easy medicate relocation through a vehicle that is essentially liquid.(6).

As was previously indicated, the presence of a gelling component in the aqueous phase transforms an emulsion into an emulgel.(7) Drugs are applied topically using emulsions consisting of both water and oil. Thixotropic, greaseless, easily spreadable, easily removable, emollient, nonstaining, long shelf lives, bio-friendly, clear, and attractive in appearance are just a few of the advantageous qualities of emulgels for use in dermatology. [8] Knowing the factors influencing percutaneous absorption is essential when using topical medicines. In [9] Sweat ducts, sebaceous follicles, and the intact stratum corneum are the three possible entry points for molecules into the skin. The passage through this upper layer is the percutaneous absorption stage that limits the pace. The formation of a concentration gradient, which provides the force for drug transport across the skin, drug release from the vehicle (partition coefficient), and drug diffusion between the layers of skin (diffusion coefficient) are the three fundamental processes in percutaneous absorption. For topical treatments, low molecular mass (600 Da), strong solubility in water and oil, and a high partition coefficient are all desirable characteristics. Water soluble ions and polar molecules cannot pass through intact stratum corneum, with the exception of very minute particles. The barrier function of the skin can be altered via topical application.

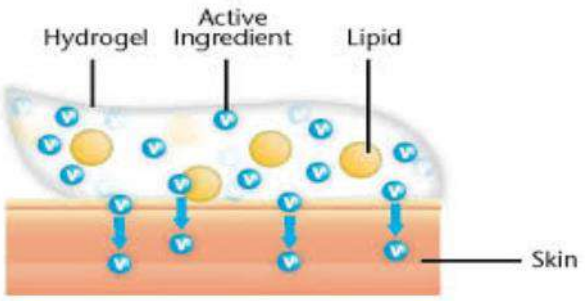

Figure:1-Emulgel structure[27]

Rationale

Despite being widely used, topical treatments, such as ointments, creams, and lotions, have serious side effects. They are very sticky when utilized, and they cause discomfort for the sufferer. They also have a lesser spreading coefficient, therefore they must be applied with rubbing. They exhibit the instability problem as well. All these factors within the main group of semisolid preparations have led to an increase in the use of transparent gels in medicinal and cosmetic preparations. A gel is a colloidal substance that is primarily composed of liquid, with a little amount of a gelating material added to create a network of macromolecular fibres. Hydrophobic medication administration is one major disadvantage. Therefore, an emulsion-based approach is being used to overcome this limitation, enabling the successful integration and administration of even a hydrophobic medicinal component through gels.10]

They also have a powerful ability to penetrate skin. Emulgels offer a number of benefits, as was covered in the earlier introduction.

The emulgel technique is effectively utilized in the manufacturing of herbal drugs.11]

Dermatological delivery of drug

Depending on where on the body it is located, the stratified, keratinized squamous epithelium that makes up the epidermis—the skin's outermost layer—varies in thickness. Dermatological pharmacology is unique in that it uses the skin as a target organ that is directly accessible for diagnosis and treatment. In order to prevent the absorption and loss of electrolytes and water, the skin acts as a two-way barrier. The three primary channels for the absorption of topical medications are transcellular, intercellular, and follicular absorption. Most drugs make the challenging journey through the lipid bilayer and around corneocytes to get to the layers of skin that are viable. The second most common (and maybe less well-known in the clinical context) delivery route is the pilosebaceous route. The barrier is situated in the stratum corneum, the uppermost layer of the epidermis, as demonstrated by almost equal rates of chemical penetration through isolated stratum corneum or entire skin. Antibiotics and medicines have long been given topically to injured body parts using lotions and gels. Topical creams for skin infections, arthritic pain relievers, and gels and creams for vaginal yeast infections are a few of these. It is now possible to absorb other drugs transdermally, or via the skin. Both the troublesome areas of the body and the complete body (like the skin, for example) can be treated with them. (structural)In [12]

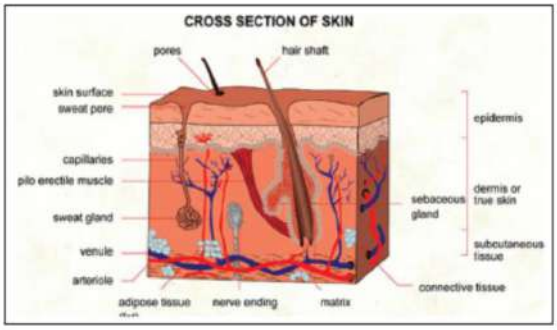

Figure:2-Structure and physiology of the skin [13]

Factors Affecting Topical Absorption of Drug

Physiological Factors

1. Skin thickness.
2. Lipid content.
3. Density of hair follicles
4. Density of sweat glands.
5. Skin pH.
6. Blood flow.
7. Hydration of skin.
8. Inflammation of skin

Physiochemical Factors

1. Partition coefficient.
2. Molecular weight (<400dalton).
3. Degree of ionization (only un ionized drugs gets absorbed well).
4. Effect of vehicles [14-15]

Factors to be Considered When choosing a Topical Preparation

Impact of the vehicle, for instance, an occlusive vehicle increases the active ingredient's penetration and increases effectiveness. The vehicle's own actions could be cooling, drying, emollient, or protecting.

1. Align the preparation kind with the lesions type. For acute weepy dermatitis, for instance, stay away from greasy ointments.
2. Align the preparation method with the location. (Example: gel or lotion for places with hair)
3. Potential for irritation or hypersensitivity. Ointments and creams without alcohol typically cause less irritation than gels. If a preservative or emulsifier allergy is a concern, ointments are free of these ingredients. [20-21]

Method to enhance drug penetration.

1. Chemical enhancement
2. Biochemical enhancement
3. Physical enhancement
4. Super saturation enhancement [22,16]

ADVANTAGES

1. It is easy to include hydrophobic drugs into gels using D/o/w emulsions. Since their solubility acts as a barrier and interferes with drug release, the majority of hydrophobic drugs cannot be put directly to gel bases. It is necessary to introduce hydrophobic medications into the oil phase before forming an oil-water emulsion. Emulgel facilitates this procedure. It is also possible to put this emulsion into a gel base. This may show better drug stability and release than just incorporating drugs into the gel base. Better self-medication and patient compliance
2. Free from problems with first pass metabolism.
3. Site-specificity: These formulations also have the benefit of acting just in the targeted area.
4. Better stability: Other transdermal preparations are comparatively less stable than emulgels. Like powders are hygroscopic, creams show phase inversion or breaking and ointment shows ranciditydueto oilybase.
5. Greater loading capacity: Because other innovative techniques use nanoscale materials like noisome and liposomes, which have vesicular features, they may leak more easily and have lower trapping efficiency. However, gels have a considerably higher loading capacity due to their extensive network.
6. Production feasibility and cheap preparation costs: Emulgel preparation involves only a few straightforward procedures, which boosts production viability. The creation of emulgels does not require any specialist equipment. Additionally, the materials are inexpensive and readily available. reduces the price of making emulgels as a result.
7. Avoid intensive sonication: Vesicular molecules require intense sonication during production, which may cause drug degradation and leakage. However, since emulgel manufacturing does not require sonication, this issue is not present.
8.Controlledrelease:Emulgelscanbeusedtoprolong theeffectofdrugshavingshortert1/2.[17-18,24]

DISADVANTAGES

1. Contact dermatitis causing skin inflammation
2. The potential for allergic responses.
3. Some medications have limited skin absorption.
4. Large-particle drugs are difficult to absorb via the skin.
5. The appearance of a bubble during emulgel production. [18-19,23]

ImportantConstituentsofEmulgelPreparation

1.AqueousMaterial:

Aqueousphaseoftheemulsion is formed by using aqueous material. Water, alcohols are commonly used. [25]

2. Oils: They come together to form the oily phase of the emulsion. Because mineral oils have occlusive and sensory qualities and are widely used as a medicine delivery system, they are often used alone or in conjunction with soft or hard paraffin's in externally applied emulsions. Oils that are commonly used in oral preparations include no biodegradable mineral and castor oils, which have a laxative action on the local level, fish liver oils, and various fixed oils of vegetable origin (such a rachis, cottonseed, and maize oils), which act as nutritional supplements [26–27].

Sr.No.	Chemical	Quantity	Dosage form
a.	Light liquid paraffin	7.5%	Emulsion and Emulgel
b.	Isopropylmyristate	7-7.5%	Emulsion
c.	Propylene glycol	3-5%	Gel

Table1: USE OF OILS [28]

3. Emulsifiers:

For stability purpose as well as to accelerate emulsification. Emulsifying agents are used. E.g.Polyethyleneglycol40[29] stearate,Sorbitanmono-oleate [30] (Span80),Polyoxyethylenesorbitanmonooleate(Tween80)[31],Stearicacid[32],Sodiumstearate.[33]

4.GellingAgent:

Gelling agents are used to create gel bases from which emulsion is added to create emulgel. They are also referred to as thickening agents because they create a gel-like structure and swell in the aqueous phase, increasing the consistency of any dosage form. A system becomes thixotropic when a gelling agent is incorporated into it. [36,37, 34]

Gelling agent	Concentration Used(%w/w)	Pharmaceutical adaptability	API	Ref.
Sodium CMC	3-4 %	Can stand autoclaving and useful for sterile gels	Benzydamine	38
Carbapol-934	1 %	API controlled release achieved	Chlorphenesin	39
Carbapol-940	1 %	API controlled release achieved	Mefenamic acid	40
HPMC	2.5 %	Has good microbial resistance and stability	Chlorphenesin	41
Combination of HPMC and Carbapol	1.2 %	Stability increased	Ketorolac,clotrimazole	42-43
Pluronic ®F127	1-3 %	In cold water better clarity and solubility	Piroxicam	44
Pemulen	0.1-0.4 %	Oily phase released steadily as well as stability increased.	Flurbiprofen	45

Table 2: Gelling Agents Used In Dosage Forms

5. Permeation Enhancers:

These substances interact and partition into skin constituents to cause a transient, reversible increase in skin permeability. Vehicles often include entrance-improving specialists, which incidentally disrupt the deeply desired structure of the stratum corneum skin boundary, fluidize the lipid channels between coenocytes, alter the division of the sedate into skin structures, or otherwise improve conveyance of entering into skin, in order to accelerate advance assimilation of drugs through skin obstruction[46].

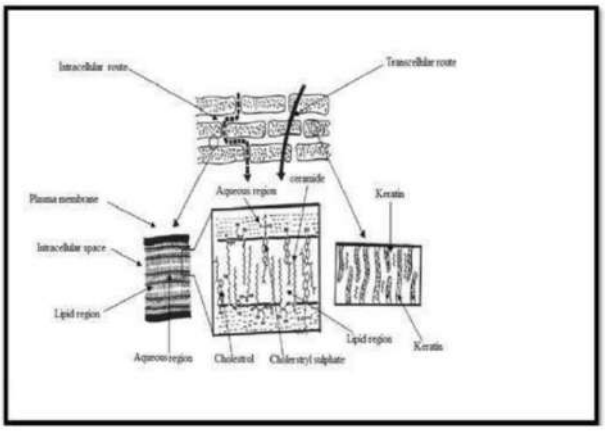

Figure: 3- Mechanism of Penetration into skin.[53]

Sr.No.	Penetration enhancer	Quantity
a.	Clove oil	8%
b.	Menthol	5%
c.	Cinnamon	8%

Table 3: Penetration Enhancers Generally Used For Emulgel [53]

Ideal properties of drug candidate to be formulated as emulgel [47](paper 3)

1. Use a little dose of the drug (10 mg).
2. Molecules should have a 400-Dalton maximum.
3. A 10-hour half-life is ideal.
4. The partition coefficient must range from 0.4 to 0.8.
5. The therapeutic index and oral bioavailability should be low.
6. Drugs should not irritate or should be non-sensitizer.

Emulsion preparation

Step 1: Carbopol 940, a 1% w/w gelling agent, was weighed out and added to warm distilled water while being continuously agitated to create the gel. One to two hours were given to the dispersion to hydrate. After adding more chemicals, like 10% w/w glycerol and 10% w/w propylene glycol, the aqueous dispersion was constantly swirled. The required dosage of medication (1% w/w) was added and dispersed equally. The dispersion was neutralised to pH 6 with triethanolamine, and the final weight was adjusted by adding distilled water. The gel was sonicated for fifteen minutes, and it was then allowed overnight to eliminate air bubbles.

Step 2: Emulsion preparation Depending on whether an emulsion was created using water or oil.

Step 3: Adding the emulsion to the into gel base: At the last emulsion was mixed in gel base to formemulgel. [35,48-49]

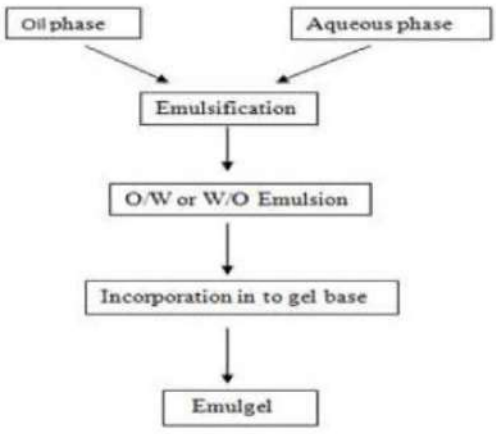

Figure: 4-Preparation steps of Emulgel [28]

CHARACTERIZATIONOFGELLIFIEDEMULSION

Physical appearance: Formulated dosage forms were checked for colour, homogeneity, consistency ,and pH.

pH: Using a pH meter (Digital pH meter DPH 115 pm), the pH values of 1% aqueous solutions of the gellified emulsion were determined.[55]

Spread ability: Equipment specified by Mutimer et al. (1956) and suitably modified for the study's usage is used to measure spread ability. It consists of a wooden block with a pulley attached to one end. The 'Slip' and 'Drag' characteristics of emulgels are utilised in this method to measure **spread ability**. A ground glass slide is fixed to this block. Extra emulgel (about 2 mg) is being investigated on this ground slide. The emulgel is then positioned between this glass slide and another that has the same dimensions as a fixed ground slide and a hook attached to it. Five minutes are spent with a 1 kg weight on top of the two slides to eliminate air and provide a uniform emulgel coating. Extra emulgel is scraped off the edges. The top plate is then subjected to an 80 gramme pull. Measure the time (in seconds) that it takes for the top slide to move 7.5 cm using a thread that is attached to the hook. A shorter period indicates better spread ability. To calculate spreadability, the following formula was used:

S= M.L/T

Where,S=spreadability,

M=Weight tied to upper slide ,L= Length of glass slides

T=Time taken to separate the slides completely from each other

Extrud ability study:

An empirical test is usually performed to find the force required to extrude the material from the tube. The method used to calculate the applied shear in the rheographic region where plug flow occurs due to a yield value exceeding. The amount of emulgel and emulgel extruded from a lacquered aluminium collapsible tube upon application of the weight in grammes required to extrude at least 0.5 cm of emulgel ribbon in 10 seconds is the basis for the extrudability assessment method utilised in the current investigation. More extrusion volume improves extrudability. The extrudability of each formulation is measured three times, with average findings reported. Following that, the extrudability is determined using the followingformula:

Extrudability = Applied weight to extrude emulgelfromtube(ingm)/ Area(incm2)

Globule size and its distribution in emulgel:

The size and dispersion of the globules were measured using the Malvern zetasizer. A sample weighing one gramme was dissolved in filtered water and agitated to attain a uniform dispersion. A sample was placed within the photocell of the zetasizer. It was established what the mean globule diameter and dispersion were.56]

Rheological Analysis

The viscosity of the different emulgel formulations is measured at 25°C using a cone and plate viscometer with spindle 52 (Brookfield Engineering Laboratories) connected to a thermostatically regulated circulating water bath.

Swelling Index:

After measuring the swelling index of one gramme of made topical emulgel on porous aluminium foil, the gel is transferred to a separate 50 ml beaker and mixed with 10 ml of 0.1 N NaOH. Following that, samples were periodically removed from the beakers and allowed to sit on a dry surface before being weighed again. These steps are used to compute swelling index:

Swelling Index (SW) % = [(Wt – Wo) / Wo] × 100.

Where,(SW)%=Equilibriumpercentswelling,

Wo = Original weight of emulgel at zero timeaftertimet,Wt=Weightofswollenemulgel

Ex-vivo Bio adhesive strength measure mentof topical emulgel:

The bio adhesive strength is measured using the modified method (MICE SHAVEN SKIN). The new skin is cleansed with 0.1 N NaOH after it has been cut into pieces. Two pieces of skin were attached to two glass slides separately; one glass slide was attached to a piece of wood, while the other was attached to the right side balance. The right and left pans were balanced by applying additional weight to the left pan. One gramme of topical emulgel is placed between the two slides holding the areas of hairless skin, extra weight from the left pan is taken out, and pressure is applied to eliminate any air pockets.The equilibrium was maintained for five minutes. Once the patch has come away from the skin's surface, weight is gently added to the left-hand pan at a rate of 200 mg/min. The amount of weight (in grams) needed to pull the emulgel away from the skin surface served as a gauge for the bioadhesive strength. Following methods are used to determine the bioadhesive strength:

Bioadhesive Strength = Weight required (in gms) /Area (cm2)

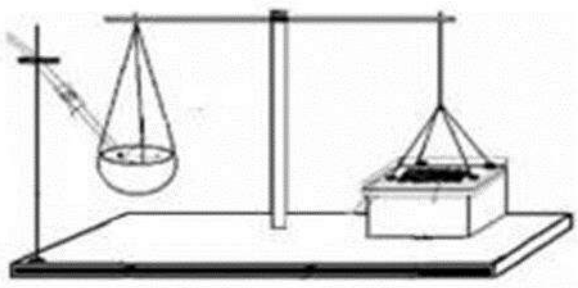

Figure:5 Setup for bio adhesive test [12]

Drug Content Determination:

The medication concentration in the gellified emulsion was measured with a spectrophotometer. The drug concentration of the gelled emulsion was ascertained by sonicating a predetermined amount of the emulsion into methanol, the solvent. The absorbance was measured using a UV/VIS spectrophotometer (UV 1700 CE, Shimadzu Corporation, Japan) following the proper dilution.In [57]

In-Vitro Release Study:

A Franz diffusion cell (15.5 ml cell volume, 3.14 cm2 effective diffusion area) was used for the drug release investigations. The surface of the egg membrane received a consistent 200 mg application of gelatinized emulsion. The egg membrane was clamped between the donor and the receptor chamber of the diffusion cell. A freshly made PBS solution (pH 5.5) was introduced into the receptor chamber in order to solubilize the drug. The receptor chamber was stirred using a magnetic stirrer. The samples (1.0 ml aliquots) were taken at the proper intervals. Using a UV visible spectrophotometer, samples were analysed for drug content following the appropriate dilutions. Cumulative adjustments were made in order to ascertain the total amount of drug release at each time interval. The total amount of drugs released throughout time includes cumul ative amount of drug released across the egg membranewasextractedasafunctionoftime.[58]

Microbiological assay:

The ditch plate method was employed. It is a technique used to assess a compound's fungistatic or bacteriostatic activity. It is mostly used for compositions that are semisolid. Sabouraud's agar dried plates that had been previously prepared were employed. A ditch is cut in the plate, and three grams of the gellified emulsion are added to it. Freshly made culture loops are streaked in a right angle over the agar from the ditch to the plate's edge. The fungal growth was examined after 18 to 24 hours of incubation at 25°C, and the % inhibition was calculated as follows.

%inhibition=L2/L1×100

WhereL1=total length of the streaked culture ,andL2=length of in hibition.

Skin irritation test: The test article was then introduced into each site (two sites per rabbit) under a double layer of gauze to a skin region that was about 1" x 1" (2.54 x 2.54 cm2) in size. On the skin of the rabbit, the gellified emulsion is applied. The creatures were put back in their cages. After being exposed for 24 hours, the gellified emulsion is removed. To get rid of any last bits of test article residue, the test locations were cleaned with tap water.[59]

Kinetic Modelling: Ex-vivo permeation study data were fitted into mathematical models for the evaluation of drug release kinetics, including zero order, first order, Higuchi, and models. The value of R2 was used to predict the model with the best fit. More R2 means that the model fits more perfectly for an optimal fit. Therefore, the model that describes the best order of drug release and has an R2 value that is closest to 1.[50]

Stability studies [53]

The prepared emulgels were placed in aluminum collapsible tubes (5 g), and stability tests were conducted on them for three months at 5°C, 25°C/60 RH, 30°C/65 RH, and 40°C/75% RH. At 15-day intervals, samples were taken out and examined for their physical characteristics, pH, rheological characteristics, drug content, and drug release profiles.

Syneresis measurement test [54]

On rest, gel contracts and a small amount of liquid is squeezed out (syneresis). Using appropriate equipment and centrifuge tubes, this may be measured.

Syneresis (%) = Liquid separated from Emulgel/Total weight of Emulgel before centrifugation × 100

Formulation name	API	Manufacturer	Use
Voltarol 1.16% emulgel	Diclofenac sodium	Novartis	Anti-inflammatory
Diclomax emulgel	Diclofenac sodium	Torrent pharma	Anti-inflammatory
Miconaz-H-emulgel	Miconazole nitrate,Hydrocortisone	Medical union Pharmaceuticals	Topical corticosteroid and antifungal.
Excex gel	Clindamycin, Adapalene	Zee laboratories	Antibiotics
Lupigyl gel	Metronidazole	Lupin pharma	Infections

Table 4 :Various Marketed Emulgel Formulation[51,53]

Fig.:6- An emulgel marketed product [52]

CONCLUSION

The most frequent issues encountered during formulation and development of any new formulation stem from the hydrophobic behavior of pharmaceuticals, which results in poor water solubility and bioavailability issues. Many medications are hydrophobic, making it difficult to distribute them to the biological system. Different forms of topically applied creams, ointments, and lotions have good emollient characteristics yet delay the release of medications due to the presence of oleaginous bases. Gel offers a more rapid medication release than other topical systems because it gives medicines an aqueous environment. Topical medicine delivery will be widely employed in the upcoming years to improve patient compliance. Emulgel is superior to other materials in terms of spreadability, adhesion, viscosity, and extrusion.Additionally, they will serve as a means of adding hydrophobic pharmaceuticals to gel bases that are water soluble.

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