Microemulgel: A Novel Approach for Topical Drug Delivery

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How to Cite this Article:

Shendre, K. V., Dhankani, M. A. & Dhankani, A. R. (2026). Microemulgel: A Novel Approach for Topical Drug Delivery. International Journal of Creative and Open Research in Engineering and Management, 02(6). https://doi.org/10.55041/ijcope.v2i4.563

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https://doi.org/10.55041/ijcope.v2i4.563

Abstract:

Topical drug delivery systems are designed to apply medicines directly to specific parts of the body, such as the skin, vaginal, or rectal areas. This method mainly aims to produce a local effect exactly where the drug is needed, while also avoiding first-pass metabolism.

Microemulgel is an advanced dosage form that combines the benefits of both microemulsions and gels. It has several useful properties like easy spreadability, smooth texture, transparency, good compatibility with the skin, and a pleasant feel during application. One of its biggest advantages is its dual release system, which makes it suitable for delivering both water-soluble (hydrophilic) and fat-soluble (hydrophobic) drugs[1].

It is prepared by mixing a microemulsion into a gel base and then evaluated using different parameters such as pH, spreadability, viscosity, swelling ability, and drug release behavior. Because of its very small particle size, microemulgel can penetrate the outer layer of the skin (stratum corneum) more effectively.

Overall, microemulgels are a promising option for topical drug delivery. Their improved penetration and controlled drug release make them especially useful for future applications in skincare and dermatological treatments.

Microemulgel is topical drug delivery system that incorporates the properties of both gel and microemulsion and shows dual release control system.

Keywords: Microemulgel, Microemulsion, Method of Preparation, Topical drug delivery, Gel**,**

1.Introduction:

Microemulgels are an exciting and promising approach in modern drug delivery systems because they combine the advantages of both emulsions and gels. To develop a microemulgel, it's important to carefully select the oil, surfactant, and co-surfactant based on how well the drug (API) dissolves in them. The oil component helps dissolve drugs that are not easily soluble in water, which can improve their absorption in the body. At the same time, the gel base makes the formulation more stable, easy to apply, and helps the drug stay longer at the site where it's needed. Together, these features enhance the drug's ability to penetrate the skin and improve its overall effectiveness[(1)]

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Topical formulations are designed to act directly at the site where they are applied, helping the drug reach deeper layers of the skin or mucous membranes. Gels are widely used because they are easy to apply and feel comfortable on the skin, but they often struggle to deliver drugs that do not dissolve well in water (hydrophobic drugs). This limitation can be overcome by using a microemulsion-based approach. By incorporating the drug into a microemulsion within the gel, hydrophobic drugs can be delivered more effectively while still benefiting from the smooth texture and convenience of gels [(2)]

The skin plays an important role in protecting the body from external factors and maintaining overall health. For treating skin infections, topical drug delivery systems are often preferred because they act directly at the site of application. They also help avoid issues like first-pass metabolism, breakdown of drugs in the gastrointestinal tract, and the discomfort that can come with oral medications.
Microemulgels are a promising advancement in this area. They are formed by converting a liquid microemulsion into a semi-solid gel, combining the benefits of both systems. This dual nature allows them to deliver drugs more effectively, making them an innovative and efficient option in modern drug delivery technologies[(2,3)]

When microemulsions and gels are combined into a single dosage form, the resulting formulation is known as a microemulgel. These systems bring together the benefits of both emulgels and microemulsions. They are capable of incorporating both water-loving (hydrophilic) and oil-loving (hydrophobic) drugs, while also offering a large surface area for better drug absorption. Additionally, the oil phase in microemulgels helps improve drug permeability through the skin and enhances overall bioavailability[(1)]

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When micro-emulsion as well as gels is used in combination to form microemulgel, they exhibit characteristics of both. Microemulgel helps to deliver the hydrophobic drugs by formulating oil in water microemulsion and this microemulsion can be incorporated into the gel base. They provide a larger area for absorption of drug and lipid portion intensify the bioavailability by better penetrability of drugs. Also, the gel base provides the better stability to micro-emulsion. In comparison to micro-emulsions, microemulgel have a firm degree of elegance and they are easily washable if required[(5)]

The concept of microemulsion was introduced by Hoar and Schulman during the 1940's. Microemulsion contains water, oil, and amphiphilic which are an optically isotropic and thermodynamically stable liquid micro-dispersion. Micro emulsion is the vehicle which improves the delivery, efficacy, and bioavailability of many drugs. "Microemulsion" refers to a thermodynamically stable and clear dispersion of two immiscible liquids; contain oil and water which is stabilized by surfactant molecules by forming interfacial film. A microemulsion is considered as a kinetically stable liquid dispersion of a lipid phase and an aqueous phase, with a surfactant. The dispersed particles having a size range of 5-200 nm, and have tiny oil/water interfacial surface tension [(3)]

Microbial infections are increasingly a big concern for society. Because of the ease of transmission from person to person, the number of people suffering from bacterial, viral, and fungal infections disorders rises each year. A few hazardous germs, such as less than 1% of bacteria, can enter human body (the host) and cause illness. Infectious diseases caused by microbes include the flu and measles. There is also compelling evidence that bacteria play a role in many non-infectious chronic diseases, including several types of cancer and coronary heart disease. Microorganisms of many sorts cause various diseases. Pathogens are microbes that cause disease.

Topical preparations produce localized effects at the site of their application into the underlying layers of skin or mucous membranes virtue of penetration. It provides flexibility to deliver drugs more effectively to a selective site. It provides utilization of drugs with a short biological half-life, narrow therapeutic window to increase the duration of action.[4]

2. Advantages and Disadvantages of Microemulgel

2.1. Advantages of Microemulgel[3]. :

- Hydrophobic drugs can be easily incorporated into gels using o/w microemulsion
- Better loading capacity.
- Production feasibility and low preparation cost.
- No intensive sonication.
- Controlled release.
- Ability to deliver drug more selectively to a specific site.
- Avoidance of gastro-intestinal incompatibility.
- Enhanced drug solubility for hydrophobic and poorly water-soluble drugs
- Improved skin penetration due to surfactants and co-surfactants
- Controlled and sustained drug release
- Non-greasy and patient-friendly texture
- Ease of scale-up and manufacturing

2.2. Disadvantages of Microemulgel :

- The larger particle size drugs not easy to absorb through the skin.
- Poor permeability of some drugs through the skin
- Can be used only for drugs which require very small plasma concentration for action

. 3. Ideal Properties of Microemulsion Based Gel[7]. :

- Should be inert, compatible with other additives
- Should be free from microbial contamination
- Should be non-toxic
- Should be economical
- Should be maintained all rheological properties of the gel
- Should be washed with water and free from staining nature
- Should be convenient in handling and its application
- Should be stable at storage condition

4. Factors Affecting Topical Absorption of Drug[1].:

4.1 Physiological Factors:

- Thickness of the skin
- Content of lipids.
- Hair follicle density is the number of hair follicles in a given area.
- Sweat gland density is a measure of how dense sweat glands are.
- The pH of your skin.
- The flow of blood.
- Skin hydration is important.
- The skin is inflamed.
- Lipid content

4.2 Physiochemical Factors:

- Partition coefficient
- Molecular weight of drug
- Degree of ionization
- Effect of vehicles

5. Formulation Consideration :

5.1 **Selection of oil phase**[1].**:** In microemulsion-based gel formulations, the choice of oil mainly depends on how well the lipophilic drug dissolves in it. Usually, low molecular weight oils like triglycerides are preferred because they can easily move into the interfacial layer and help form the right structure. Another advantage of microemulsions is that they are naturally stable systems, so there's no need to add special agents to prevent issues like Ostwald ripening. The oil that shows excess solubility of drug is selected as an oil phase for formulating microemulsion based gel. The consistency of these lipids may range from mobile liquid to high solids. The lipid phase sometime acts as penetration enhancer therefore there is no need to add penetration enhancer in microemulsion delivery system [9]. Researcher shows that the soyabean oil in a system composed of water, essential oils (EOs) and Tween 80. Soybean oil was able to improve the dilutability of EOs-based microemulsions and it had a great impact on the formation of the system, expanding the regimes of microemulsions and reducing the droplet size. It contributed to reduce the EOs volatility as well [10].

5.2 **Selection of aqueous solvents**[1].**:** Water and alcohols are commonly used as the aqueous phase in emulsion formulations.

5.3 **Selection of emulsifiers**[2].**:** Emulsifying agents like polyethylene glycol 40 stearate, sorbitan monooleate (Span 80), polyoxyethylene sorbitan monooleate (Tween 80), stearic acid, and sodium stearate are added to keep the formulation stable. They help maintain consistency and prevent separation, ensuring the product remains effective throughout its shelf life.

5.4 **Selection of surfactants**[1].**:** Surfactants are essential for reducing the interfacial tension between the oil and aqueous phases, thereby stabilizing the microemulsion . Non-ionic surfactants are preferred due to their low toxicity and high skin compatibility. Common examples include: Tween 80 (Polysorbate 80) Span 20 (Sorbitan monolaurate). The second criteria for the choice of surfactants were supported their ability to make microemulsion with designated lipid having the very best solubility for drug. Surfactants are unit active molecules that have each a hydrophilic and a lipotropic domain in their molecular structure. Because of their amphiphilic nature, surfactants enable the dispersion of two incompatible phases lowering the surface tension up to get enough versatile film ready to deform round the droplets with the best curvature. Throughout the emulsification method, they are quickly absorbed within the interface and stop the droplets' aggregation. The non-ionic, zwitterionic, cationic, or anionic surfactants are used to stabilize such systems. Ionic and non-ionic surfactant is effective to the extent of the microemulsion region. Example of non-ionic embodies polyoxyethylene surfactants like Brij 35, tween20/80, or sugar esters like sorbitan monooleate (Span 80).

5.5 **Selection of co-surfactants:** Short- and medium-chain alcohols, like ethanol, isopropanol, isopropyl myristate, and propylene glycol, are often used as co-surfactants in microemulsion formulations. They help lower the surface tension between oil and water, making it easier to form tiny, stable droplets. The cosurfactants with surfactant are used to decrease the interfacial tension to transient negative value. At this negative value, fine droplets are formed due to the interface expansion and more surfactant/cosurfactant get adsorbed on the surface until the bulk condition is depleted enough to make the interfacial tension positive again. Cosurfactant of short-medium chain length alcohols also ensures that the interfacial film is flexible enough to deform readily around droplets, as the interaction between primary surfactant molecules decreases both the polar head group interaction and hydrocarbon chain interaction.

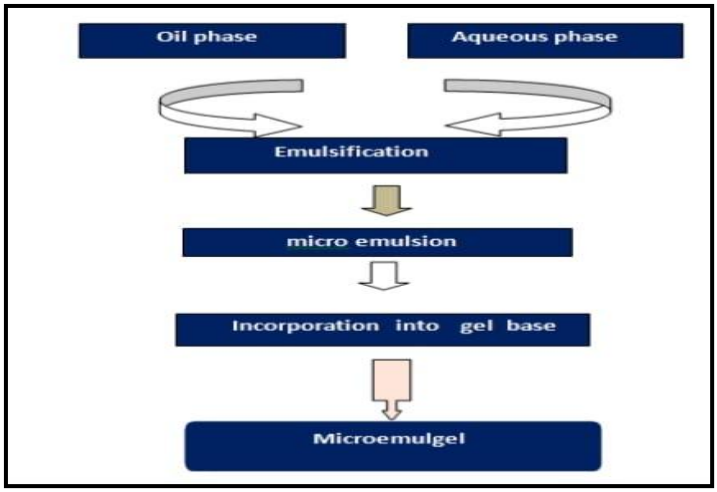
5.6 **Selection of gelling agents:** Gelling agents are added to give the formulation its gel-like structure and can be either natural or synthetic. They also provide thixotropic properties, meaning the gel becomes easier to spread under pressure but retains its structure at rest. Thickeners are often used in oil-in-water microemulsions and nanoemulsions to balance the density of the oil phase with the surrounding liquid, preventing settling or separation. Texture modifiers may also be included to improve feel and consistency. Preservatives are commonly added to water-based systems to prevent microbial growth, though essential oils (EOs) can act as natural antimicrobials, reducing the need for additional preservatives in EO-based formulations. Overall, carefully choosing these components is key to ensuring stability, solubility, and controlled drug release, making the microemulgel effective for topical delivery.

.6. Method of Preparation of Microemulgel:

1.Phase inversion method: Phase inversion in microemulsions can happen in two main ways—either by adding more of the dispersed phase, known as phase inversion concentration, or by changing the temperature, called phase inversion temperature. This process causes major physical changes in the system, especially in particle size. In the PIT method, interfacial tension plays a very important role. When the system is cooled, the interfacial tension decreases, and the system passes through a phase inversion region where it changes from a water-in-oil (W/O) microemulsion to an oil-in-water (O/W) microemulsion. Because the interfacial tension is very low at this stage, tiny droplets form spontaneously, creating a finely dispersed, bluish-looking O/W microemulsion. This method mainly works with nonionic ethoxylated surfactant, as their hydrophobic nature increases significantly with temperature.

On the other hand, in the PIC method, phase inversion occurs by changing the amount of water in the system. Initially, when water is gradually added to oil, small water droplets form within the oil phase, creating a W/O microemulsion. As more water is added, the natural curvature of the surfactant changes, and at a certain point, the system inverts into an O/W microemulsion. This happens at a specific water concentration, which is why it is called phase inversion concentration.

At the inversion point, a special structure called a bicontinuous microemulsion can form, where both oil and water phases are continuous. This is possible because the surfactant layer at the interface is flexible, especially when short-chain surfactants are used.

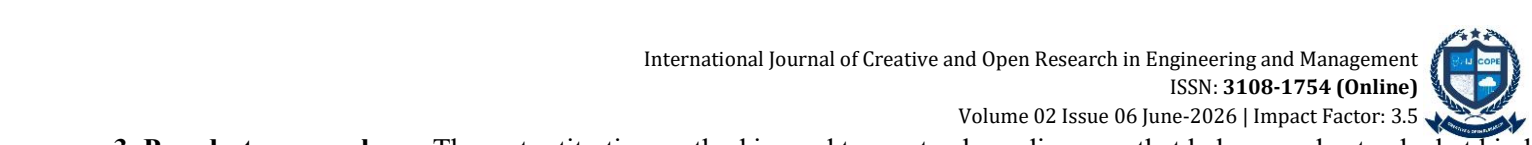


. Figure 1: Schematic diagram for preparation of microemulgel

2. Phase titration method: Microemulsions are formed using a simple method called spontaneous emulsification, where different components are gradually mixed together. To understand how these mixtures behave, scientists use phase diagrams, which act like maps showing what kind of structure will form at different combinations of ingredients. Depending on the type and amount of each component, the system can organize itself into various forms such as emulsions, micelles, gels, or more structured phases like lamellar or cubic arrangements.

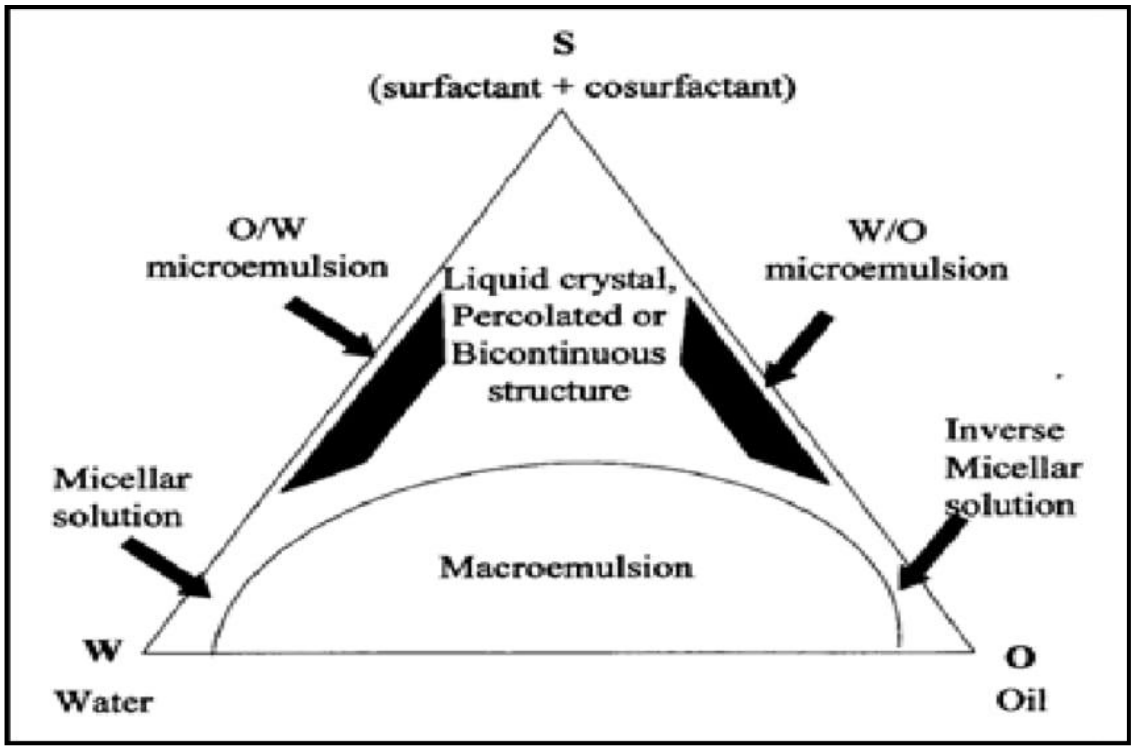
Studying how these phases exist and where they change (phase boundaries) is very important. Although systems with four components can be represented using quaternary phase diagrams, these are often complicated and time-consuming to analyze. For this reason, pseudo-ternary phase diagrams are commonly used, where each corner represents 100% of a particular component or group of components. These diagrams make it easier to identify different regions, especially where microemulsions form.

Microemulsions themselves can be classified based on their composition either water-in-oil (w/o) if they are rich in oil, or oil-in-water (o/w) if they are rich in water. Careful observation is essential during this process to ensure that only stable systems are considered, and temporary or unstable (metastable) systems are not mistakenly included.



3. Pseudo-ternary phase: The water titration method is used to create phase diagrams that help us understand what kind of structures form during emulsification and how mixtures behave when diluted. In this process, a pseudo-ternary phase diagram is prepared using oil, water, and a surfactant–cosurfactant mixture, keeping their ratio constant.

To do this, the ingredients are mixed in a vial, and water is slowly added. As more water is introduced, the emulsification region begins to form. We can identify whether the system is monophasic or biphasic just by observing it. A monophasic system looks clear and transparent after stirring, showing that a microemulsion has formed. On the other hand, a biphasic system becomes cloudy and eventually separates into layers.



. Figure 2: Pseudo-ternary phase diagram

7. Formulation Method of Microemulgel :

Step 1: Preparation of oil in water or water in oil microemulsion using oil phase and water phase.

Step 2: Preparation of gel using gelling agent and water by constant stirring and optimization of pH.

Step 3: Incorporation of microemulsion into the gel base to formulate Microemulgel.

8. Evaluation of Microemulsion :

1.Droplet size microemulsion: Globule size distribution of microemulsion is set by using particle size analyzer.

2.Zeta potential measure: Zeta potential is used to determine the charge on the drop. In an exceedingly standard emulsion, the charge on oil droplets is negative because of the presence of fatty acids.

3. Viscosity: The viscosity of prepared microemulsion is to be determined by Brookfield viscometer.

4. Centrifugation: It is used to measure the physical stability of microemulsion centrifuge at 5000 rpm for 10 min at close temperature and value for creaming and phase separation visually. Conductivity measure offers a plan concerning the sort of microemulsion if fashioned, whether or not it is oil in water or water in oil emulsion visually.

9. Evaluation of Microemulgel :

9.1 Physical Examination: The prepared microemulgel formulations are visualized for their physical appearance such as color, texture, phase separation, homogeneity and pH.

9.2 Spreadability Study: The effectiveness of a microemulgel largely depends on how well it spreads on the skin. Good spreadability ensures that the gel can be easily applied and evenly distributed, which improves its performance. To measure spreadability, a fixed amount of gel is placed within a pre-marked circle of 1 cm diameter on a glass plate. Another glass plate is then carefully placed on top of it. A weight of 500 g is placed over the upper plate and allowed to rest for 5 minutes. After that, the increase in the diameter of the gel spread is measured and used to calculate the spreadability using a standard formula $S = M \times L/T$.

9.3 Extrudability Study: The extrudability of the microemulgel refers to its ability to be smoothly and continuously expelled from the nozzle of a collapsible tube. To evaluate this, a closed collapsible tube containing the microemulgel is firmly pressed at the crimped end, and a clamp is applied to prevent any backward movement. The cap of the tube is then removed, allowing the microemulgel to be extruded. The amount of gel expelled is collected, weighed, and used to calculate the extrudability.

9.4 Drug content determination: The drug content of the microemulgel is measured using a spectrophotometer. To do this, a known amount of the microemulgel is first dissolved in a suitable solvent and then sonicated to ensure it mixes properly. After that, the absorbance of both the sample and a standard solution is measured at a specific wavelength Drug Content = Concentration×dilution issues ×Volume taken ×Conversion factor

9.5 In-vitro diffusion study: In-vitro drug release is carried out using a Franz diffusion cell (with a diffusion area of 3.14 cm^2 and a cell volume of 15.5 ml). The microemulgel is evenly applied onto the surface of the membrane, which is then placed between the donor and receptor compartments. The receptor chamber is filled with a suitable solvent. Samples are withdrawn at regular intervals, appropriately diluted, and analyzed for drug content using a UV spectrophotometer at a specific wavelength. The cumulative amount of drug released through the membrane is then calculated over time.

9.6 Microbiological assay: The ditch plate technique is used to evaluate antimicrobial activity. Nutrient agar is first prepared and allowed to solidify at room temperature. A bacterial suspension is then spread evenly over the surface of the agar using a sterile cotton swab. A ditch is carefully cut into the agar, and the gelled emulsion is placed into it. The plate is then incubated in an anaerobic jar at 37 °C for 48 hours. After incubation, the zone of inhibition is observed, measured, and its diameter is recorded.

9.7 Stability studies: The prepared microemulgels are subjected to stability studies under different conditions: 5 °C, 25 °C/60% RH, 30 °C/65% RH, and 40 °C/75% RH for a period of three months. Samples are taken at 15-day intervals and evaluated for their physical appearance, pH, rheological properties, drug content, and drug release profile.

9.8 pH determination: A 1% aqueous solution of the prepared microemulgel is made by dissolving 1 g of the formulation in 100 ml of distilled water. The solution is then kept aside for 2 hours to allow the pH to stabilize. After that, the pH is measured using a digital pH meter at room temperature, and the readings are taken in triplicate to ensure accuracy.

9.9 Determination of viscosity: To determine the viscosity 20gm of microemulgel is filled in a 25ml beaker is subjected to Brookfield viscometer assembled with spindle number S6.

9.10 Rheological study: The viscosity of the prepared microemulgel is determined using a Brookfield viscometer (Brookfield LV, spindle no. 64). The microemulgel sample is placed in a glass container, and the spindle is allowed to rotate at predetermined speeds of 5, 10, 20, 30, 40, 50, 60, and 100 rpm. The viscosity is recorded for each speed after 30 seconds of rotation.

9.11 Swelling index: The swelling index of the formulated microemulgel is determined using a specific procedure. First, 1 gram of the microemulgel is carefully placed on a piece of porous aluminum foil. The foil with the microemulgel is then placed into a beaker containing 50 ml of 0.1 N NaOH solution, which acts as the swelling medium. The microemulgel is allowed to soak in the solution for a predetermined period of time.

9.12 Centrifugation Study: The centrifugation study is carried out to evaluate the stability of the microemulgel formulation, typically one week after preparation. For this, the microemulgel sample is placed in suitable containers, such as centrifuge tubes, and carefully loaded into a minicentrifuge set to 3000 rpm, ensuring proper balancing. The sample is centrifuged at this speed for 30 minutes. After centrifugation, the sample is examined for any changes, such as phase separation, creaming, or alterations in appearance or consistency. Any significant changes indicate instability or lack of homogeneity. This study helps assess the ability of the microemulgel to maintain stability and resist phase separation under centrifugal forces.

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Conclusion:

Microemulgel is considered as a best approach for topical delivery as it has many favourable properties such as easily spreadable, easily removable, biofriendly and has longer shelf life. It is particularly useful for delivering hydrophobic drugs, as it combines a microemulsion system within a gel base, thereby offering the advantages of both formulations. Although only a limited number of microemulgel products are currently available in the market, this system presents significant potential for further research and development. In the future, microemulgels are expected to play a major role in dermal care applications.

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