

**FORMULATION AND EVALUATION OF EMULGEL FOR TOPICAL
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Article Received on 28 August 2026,

Article Revised on 18 Sept. 2026,

Article Published on 01 Oct. 2026,

<https://doi.org/10.5281/zenodo.23032779>***Corresponding Author****Avi**Research Scholar of JCDM College of
Pharmacy, Sirsa.**How to cite this Article:** Avi^{1*}, Kaur Loveleenpreet², Mehta Rachna³ (2026). Formulation And Evaluation Of Emulgel For Topical Drug Delivery. World Journal of Pharmaceutical Research, 15(19), 206–219.

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ABSTRACT

Topical drug delivery systems offer a convenient and effective mode of delivery of drugs to the skin surface, which increases local concentration of the drug while minimizing systemic adverse effects. Emulgels are considered as one of the potential dosage forms, which offer solution for topical drug delivery. They are mixtures of an emulsion and gel matrix and allow delivery of both hydrophilic and hydrophobic drugs. This article highlights a discussion on topical drug delivery and emulgels, including their types, formulating ingredients, methods of preparation, and evaluation parameters. A brief description on the anatomy of the skin and its barrier properties towards topical drug delivery is also presented. Emulgels are described with a focus on

the aqueous and oily phases, emulsifying agents, permeation enhancers, and gelling agents. The physiological, physicochemical, and formulation factors that may influence topical drug absorption are also outlined. Moreover, the article discusses the various types of emulgels: macroemulgels, microemulgels, and nanoemulgels, and their characteristics such as particle size and stability. Other evaluation parameters include physical appearance, pH, viscosity, stability, irritation, and zeta potential, particle size distribution, polydispersity index, swelling index, drug content, spreadability, and extrudability. Emulgels can be used as a versatile topically applicable dosage form due to their enhanced spreading ability, patient acceptability, high drug loading, stability, and controlled release property. Future work

focused on the evaluation and formulation of emulgels would be of paramount importance in topical and transdermal drug delivery.

KEYWORDS: Topical drug delivery, Emulgel, Emulsion, Gel, Skin permeation, Permeation enhancer, Lipophilic drugs.

1. INTRODUCTION

1.1 Topical drug delivery

A Topical Drug Delivery System (TDDS) is a pharmaceutical dosage form that delivers a drug to the skin or mucous membrane, in which the drug acts locally, although some drugs may be absorbed into the systemic circulation. Topical drug delivery system has received much attention because it delivers the drug directly to the site of application, thus reducing adverse effects. It is used in the treatment of dermatological diseases, wound healing, pain, fungal and bacterial infections, inflammatory skin diseases, and cosmetics.^[1]

Topical medication administration is a straightforward method for treating native and general conditions. The direct accessibility of the skin as an organ for diagnosis and therapy is a novel aspect of dermatological pharmacology. Topical drug delivery systems provide various advantages like the capacity to administer a large amount of medicine to a specific region, avoiding gastrointestinal incompatibility and metabolic degradation associated with oral administration. Many over topical treatments provide improved bioavailability by avoiding the first pass metabolism by the liver thus ensuring steady distribution for a long time. Dissolution and diffusion of the drug in the delivery of hydrophobic medications and permeation through the stratum corneum in the administration of hydrophilic pharmaceuticals are the major drawbacks of topical dosage forms. In emulgel formulation, both oil-in-water and water-in-oil emulsions are widely utilized as carriers to deliver both hydrophilic and hydrophobic medications to the skin. They're also good in dissolving drugs and penetrating skin.^[2]

Topical formulations include ointments, creams, gels, lotions, pastes, sprays, foams, emulsions, and emulgels. Among these, emulgels have emerged as an advanced topical dosage form because they combine the advantages of emulsions and gels. They are particularly suitable for incorporating hydrophobic drugs and herbal extracts, improving drug stability, spreadability, patient acceptability, and controlled drug release.^[3]

1.2 Anatomy of Skin

Skin is the largest organ of the human body. It is about 1.5% of the total adult body weight. It serves numerous essential functions, such as safeguarding against external physical, chemical, and biological invader, preventing excessive water loss from the body, and contributing to thermo-regulation. The skin is composed of three main layers: the epidermis, dermis, and hypodermis (subcutaneous tissue). Each layer has distinct characteristics and functions.^[4]

1.2.1. Epidermis

The epidermis is the skin's most superficial layer, made up of stratified keratinized squamous epithelium that varies in thickness across the body. The palms of the hands and the soles of the feet are the thickest. The epidermis lacks blood arteries and nerve endings, but it is bathed in interstitial fluid from the dermis, which gives oxygen and nutrients and is drained away as lymph.^[5]

1.2.2. Dermis

The dermis is a strong and flexible layer of skin. The matrix is made up of collagen fibers interwoven with elastic fibers and is made up of connective tissue. When the skin is overstretched, elastic fibers rupture, resulting in persistent striae, or stretch scars, which can occur during pregnancy and obesity. Collagen fibers bind water and provide tensile strength to the skin, but as this ability deteriorates with age, wrinkles appear. The major cells found in the dermis include fibroblasts, macrophages, and mast cells. Areolar tissue and various levels of adipose tissue lie underneath its lowest layer (fat).^[6]

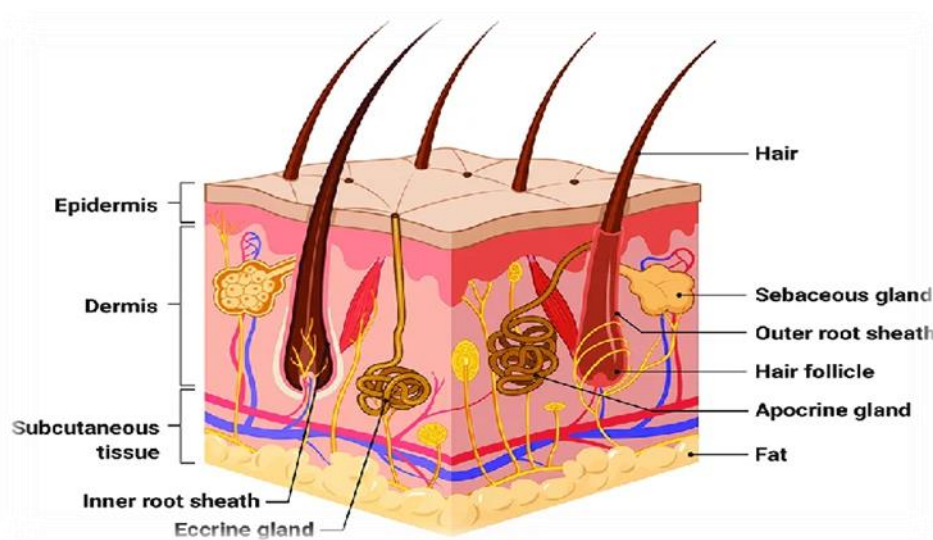


Figure 1: Structure of skin.

1.3. Emulgel

Many widely used topical formulations like ointments, creams, lotions, gel are associated with disadvantages like stability problems, stickiness and lesser spreading abilities, irritation, allergic reactions, poor permeability and poor absorption. Most of the topical delivery systems have been failed in the administration of hydrophobic drug. To overcome this limit, approach of emulgel has been designed.^[7]

Emulgel is a new field for topical medication administration. When emulsions are incorporated into gel bases, the dosage forms are referred as emulgels. Emulgels are emulsions, either of the oil-in-water or water-in-oil type, which is gelled by mixing with a gelling agent. Water-in-oil emulsions are employed more extensively for emollient actions and for the treatment of dry skin while oil-in-water emulsions are most useful in general cosmetic, acts as a water washable drug bases. Hydrophobic drugs can be formulated as emulgels because it contains both oil and aqueous phase. Now a days Emulgels are emerging as a potential drug delivery system in the area of dermatology.^[8]

The emulgel is specifically designed to enhance the absorption and permeation of the active pharmaceutical ingredient through the skin to the site of action.

Emulgel Is Made Up of Two Components.^[9]

1. Emulsion: An emulsion is a biphasic system made up of two immiscible liquids, which is one of finely and consistently propagated as globules throughout the other to form an emulsion.

2. Gel: According to the U.S.P., gels are semisolid systems made up of a dispersion whether large organic molecules or small inorganic particles that are encased and penetrated by liquid.

1.3.1. Advantages^[10,11]

- Drugs that are hydrophobic are included.
- Improved loading capacity and stability.
- Controlled release is a term used to describe when something is released in a controlled manner.
- There will be no intensive sonication.
- Avoiding the first-pass metabolic process.
- Keeping gastrointestinal incompatibility to a minimum.
- More focused on a single location.

- Patient compliance has improved.
- Convenient and simple to use.

1.3.2. Disadvantages^[12]

- Skin irritation is caused by contact dermatitis.
- It is possible to have an allergic reaction.
- Certain medications have a low ability to pass through the skin.
- It is difficult for drugs which have large particles to be absorbed through the skin.
- The occurrence of a bubble when carrying out the emulgel formulation process.

1.4 Types of Emulgel^[13]

1.4.1. Macroemulsions Gel

The most frequent type of emulgel is one in which the particle size of the emulsion droplets is greater than 400nm. Macroemulsions are thermodynamically unstable, although surface active substances can help to stabilize them.

1.4.2. Nanoemulgel

Nanoemulgel is the term used when nanoemulsion is mixed into a gel. Nanoemulsions are transparent (translucent) dispersions of oil and water that are stabilised by an interfacial coating of surfactant and co-surfactant molecules with droplet sizes smaller than 100 nm.

1.4.3. Microemulsion Gel

Because their droplet sizes range from 10 to 100 nm and they do not coalesce, microemulsions are transparent and thermodynamically stable.

2. Rationale of Emulgel

Many of the most commonly used topical treatments, such as ointment, cream and lotion, have many disadvantages. They are very sticky when applied and cause discomfort to the sufferer. They also have a lower spreading coefficient and have to be applied by rubbing. They have difficulty with stability as well. All of these variables in the principal group of semisolid preparations have resulted in an increased use of transparent gels in cosmetics and medicinal preparations.

A gel could be a mixture that's ninety-nine % liquid by weight and is immobilized by physical phenomenon between it and an organic compound network of fibers formed by a bit quantity

of gelatin. To solve this problem, an emulsion-based technique is being employed to successfully integrate and transport even a hydrophobic medicinal component via gels.^[14]

3. Constituents for Emulgel preparation

3.1 Aqueous Substances^[15]

The aqueous phase of the emulsion is formed by this. Water and alcohols are commonly utilized agents.

E.g. Alcohols, Water.

3.2. Oils^[16]

The oily phase of the emulsion is formed by these components. Mineral oils, either alone or in combination with soft or hard paraffins, are commonly employed as the drug's vehicle as well as for their occlusive and sensory properties in topically administered emulsions. Nonbiodegradable mineral and castor oils, which have a local laxative action, are commonly used in oral preparations, as are fish liver oils or various fixed vegetable oils (e.g., arachis, cottonseed, and maize oils) as nutritional supplements.

E.g. Light Liquid Paraffin, Isopropylmyristate, Isopropyl stearate, Isopropyl palmitate, Propylene glycol.

3.3. Emulsifiers^[17]

Emulsifiers are used to control and stabilize the emulsification process. Because emulsions are thermodynamically unstable, they can be made more stable by including a suitable emulsifying agent. Surfactants with HLB values more than 8, such as nonionic surfactants (spans, tweens), are employed in the formulation of o/w emulsions, whereas mineral oils with HLB values less than 8, such as liquid paraffin, are utilized in the formation of water-in-oil emulsions.

E.g. Span 80, Tween 80, Stearic acid, Sodium stearate.

3.4. Permeation Enhancers^[18]

These are agents that partition into skin constituents and interact with them to cause a temporary and reversible increase in skin permeability.

E.g. Oleic acid, Lecithin, Urea, Linoleic acid, Clove oil, Menthol.

3.5. Gelling Agents^[19]

These area units the agents want to increase the consistency of any dose type may also be used as thickening agent.

E.g. HPMC-2910, Sodium CMC, Carbopol-934, Carbopol-940.

4. Factors affecting topical absorption of drug^[20]

4.1. Physiological Factors

1. Thickness of skin
2. Hydration of skin
3. Blood flow
4. Skin temperature
5. Site of application
6. Content of lipids.
7. Hair follicle density is the number of hair follicles in a given area.
8. Sweat gland density is a measure of how dense sweat glands are.
9. The pH of your skin.

4.2. Physiochemical Factors

1. Molecular size
2. Partition coefficient
3. Drug concentration
4. Degree of ionization
5. Melting point

4.3 Formulation Factors

1. Types of dosage form
2. Vehicle
3. pH
4. Viscosity
5. Drug excipient interaction

5. Formulation of Emulgel^[21]

Step 1: Preparation of gel

A sufficient amount of Carbopol 940 (1 percent w/w) was weighed and continuously stirred into warm distilled water. For 1-2 hours, the dispersion was allowed to hydrate. Other

chemicals such as propylene glycol (10% w/w) and glycerol (10% w/w) were added to the aqueous dispersion after that, with constant stirring. A needed amount of medication (1% w/w) was added and spread properly. Triethanolamine was used to neutralize the dispersion to pH 6, and distilled water was used to adjust the final weight. To remove air bubbles, the gel was sonicated for 15 minutes and left overnight.

Step 2: Preparation of Emulsion

Depending on whether the emulsion was created with oil in water or water in oil.

Step 3: Emulsion incorporation into gel base

Finally, emulsion was mixed into the gel basis to create emulgel.

Table 1: Marketed formulation of emulgel.^[22]

S No.	Marketed Formulation	API	Manufacturer	Use
1.	Diclobar emulgel	Diclofenac diethyl amine	Barakat Pharma	Anti-inflammatory, analgesic
2.	Voltaren emulgel	Diclofenac diethyl ammonium	Novartis Pharma	Anti-inflammatory
3.	Miconaz-H-emulgel	Miconazole nitrate, Hydrocortisone	Medical union Pharmaceuticals	Topical corticosteroid and antifungal
4.	Diclomax emulgel	Diclofenac sodium	Torrent Pharma	Anti-inflammatory
5.	Levorag emulgel	Hibiscus, licorice and natural extracts	THD Ltd.	Emollient

6. Evaluation of Emulgel

6.1 Physical appearance^[23]

The color, consistency and homogeneity of the prepared formulation are visually inspected for observations of physical properties.

6.2 pH measurement^[24]

A digital pH meter is used to determine the pH of all prepared emulgel. Calibration of the pH meter is performed before using a standard buffer solution. 1 gm of the formulation is dissolved in distilled water until a uniform suspension is formed and is kept aside for 2 hours. After 2 hours the glass electrode is dipped in the suspension and the pH is measured.

6.3. Rheological study^[25]

The viscosity of the prepared formulation is determined at 370C using a cone and plate Brookfield viscometer.

6.4. Stability study^[26]

Stability studies are carried out by inducing stress at different temperatures and humidity (room temperature of $300\text{C}\pm 20\text{C}$, RH of $65\%\pm 5\%$ and room temperature of $400\text{C}\pm 20\text{C}$, RH of $75\%\pm 5\%$) using a stability chamber with proper excipient quantity (API-0.1gm, oil-2.5gm, surfactant-6.665gm co-surfactant-13.33gm, double-distilled water 27.15ml).

The study is done for 1 month and observation is done for physical changes such as a change in clarity, observance of turbidity and detection of particle growth.

6.5. Skin irritation test

Skin irritation test is usually done in skin of human volunteers with proper written consent. The prepared formulation is applied to the skin of the hand and observation is done to check for any undesirable effects.

6.6. Zeta potential^[27]

The Zeta potential of the emulgel preparation is determined by zetasizer (Malvern Zetasizer). The formulation is placed in a clear, disposable zeta cell, and the result is determined. Before experimenting, cuvettes are washed with methanol and then the sample is placed.

6.7. Swelling Index^[28]

1 mg of gel is placed on porous aluminium foil separately in a 50 ml beaker that contained 10 ml of 0.1 N NaOH. The sample is removed from the beaker at various time intervals and kept in a dry place for some time after it is reweighed^{38,39}. Swelling index (SW) = $[(W_t - W_o)/W_o] \times \text{a hundred}$. Where (SW) % = Equilibrium percentage swelling. W_o = Original weight of emulgel at zero time, where time t , W_t = Weight of swollen emulgel

6.8. Drug Content determination^[29]

A spectrophotometer is used to determine the drug concentration in the emulsion. The drug content of an emulsion is determined by sonicating a known amount of emulsion in a solvent (Methanol). In a UV/VIS spectrophotometer, absorbance is measured after appropriate dilution.

6.9. Spreadability^[21,30]

Spreadability is determined by apparatus suggested by Mutimer et al (1956) which is suitably modified in the laboratory and used for the study. It consists of a wooden block, which is provided by a pulley at one end. By this method, spreadability is measured on the basis of

‘Slip’ and ‘Drag’ characteristics of emulgels. A ground glass slide is fixed on this block. An excess of emulgel (about 2 gm) under study is placed on this ground slide. The emulgel is then sandwiched between this slide and another glass slide having the dimension of fixed ground slide and provided with the hook. A 1 Kg weight is placed on the top of the two slides for 5 minutes to expel air and to provide a uniform film of the emulgel between the slides. Excess of the emulgel is scrapped off from the edges. The top plate is then subjected to pull of 80 gms. With the help of string attached to the hook and the time (in seconds) required by the top slide to cover a distance of 7.5 cm be noted. A shorter interval indicates better spreadability. Spreadability was calculated by using the formula, $S = M.L/T$

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

6.10. Extrudability study^[30,31]

It is a usual empirical test to measure the force required to extrude the material from the tube. The method applied for the determination of applied shear in the region of the rheogram corresponding to a shear rate exceeding the yield value and exhibiting consequent plug flow. In the present study, the method adopted for evaluating emulgel formulation for extrudability is based on the quantity in the percentage of emulgel and emulgel extruded from the lacquered aluminum collapsible tube on the application of weight in grams required to extrude at least 0.5 cm ribbon of emulgel in 10s. More quantity extruded better is extrude ability. The measurement of extrudability of each formulation is in triplicate, and the average values are presented. The extrude ability is then calculated using the following formula.

Extrudability = Applied weight to extrude Emulgel from the tube (in g)/Area (in cm²)

7. CONCLUSION

Emulgel has emerged as a promising and versatile topical drug delivery system that combines the advantages of emulsions and gels. The incorporation of an emulsion into a gel base provides a convenient, non-greasy, easily spreadable, and patient-friendly formulation, making it suitable for the topical delivery of a wide range of therapeutic agents, particularly poorly water-soluble and lipophilic drugs. The formulation approach can improve drug solubilization, enhance local drug availability, and provide sustained or controlled drug release depending on the composition of the system.

The formulation and evaluation of emulgels require knowledge about the choice of gelling agents, emulsifying agents, oils, penetration enhancers and other excipients. Important evaluation parameters such as appearance, pH, viscosity, spreadability, extrudability, drug content, in- skin permeation, stability, and rheological properties are essential for establishing the quality, performance, and stability of the developed formulation. The combined properties of the emulsion and gel phases can also overcome some of the limitations of conventional topical dosage forms.

8. ACKNOWLEDGEMENT

I express my sincere gratitude to Pt. B. D. Sharma University of Health Sciences (Govt. of Haryana), Rohtak, Haryana, for providing the academic environment and facilities necessary for the preparation of this review article at JCDDM College of Pharmacy, Sirsa, Haryana.

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