



Review on Emulgel: A Promising Formulation for Antifungal Drug for the treatment of Seborrheic dermatitis

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Abstract

This review aims to demonstrate the effects and advantages of emulgel-containing antifungal medicines and suggest a technique for administering them. Because fungal infections such as seborrheic dermatitis are the most frequent global skin health concern, topical fungal medication is usually suggested due to its specific therapy and fewer adverse effects. Emulgel is one such topical medication delivery administration that combines emulsion and gel features and features a dual-release control system. Emulgel is a thermodynamically stable formulation with low interfacial tension derived from the combination of a surfactant and a co-surfactant. Emulgel gives improved stability, loading capacity, penetrability, and controlled drug release with a short half-life. The main objective of emulgel is to administer hydrophobic drugs through the skin so that through the skin, allowing a hydrophobic moiety to benefit from the special features of gels. Many medications in the antibacterial, antiviral, and nonsteroidal anti-inflammatory categories are now being researched for topical delivery via emulgel formulation, and a few are already on the market.

Because of the numerous dermatological benefits offered by the emulgel formulation, it is a benefit in the derma care and cosmetology fields, as well as in enhancing patient compliance. This review summarizes new advanced approaches used in topical carriers to enhance antifungal drug clinical outcomes. Other parameters include pH, rheology, particle size, zeta potential, drug content, skin irritation test, in-vitro and in-vivo tests, and other properties of the prepared formulation and evaluation.

Key Words: Emulgel, Hydrophobic drug, Antifungal, Seborrheic dermatitis, Surfactant, Cosmetology

Introduction

"Seborrheic" refers to "sebaceous glands" and "derma" means "skin" and is called dandruff. It is a common skin condition that causes an itchy rash with scaly flakes and also affects the scalp. It causes redness on fair skin and light patches on darker skin. It is also called psoriasis, cradle cap, seborrhoea, seborrheic eczema and seborrheic psoriasis. It seems just like psoriasis, eczema or a hypersensitive reaction. It usually occurs on the scalp, but it can also occur on other parts of the

body such as the face, eyebrows, eyelids, behind the ears, under the armpits, and on the legs. [1]

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How does Seborrheic dermatitis affect the patient?

There are two clinical types:

Adult seborrheic dermatitis: It usually affects areas of the skin with a lot of sebum production and it usually starts in late adolescence. It most frequently affects elderly individuals and young adults. It is also known as pityriasisiform seborrheic and also affects the scalp, neck, and trunk.

Infantile seborrheic dermatitis: Candle cap or pityriasis capitis are other names for it. Another name for it is "napkin dermatitis." With a peak incidence at 3 months old, it is most frequently observed in infants between the ages of 3 weeks and 12 months. Even when generalized, the rash does not tend to be particularly unpleasant, but the baby frequently experiences it without interruption.[2]

Causes:

Malassezia furfur yeast is present on the scalp which is the root cause of seborrheic dermatitis (SD) when an excess of oil or sebum gets secreted from the scalp. Malassezia yeast absorbs nutrients from the sebum or oil and starts its growth, leading to a fungal infection that causes seborrheic dermatitis.

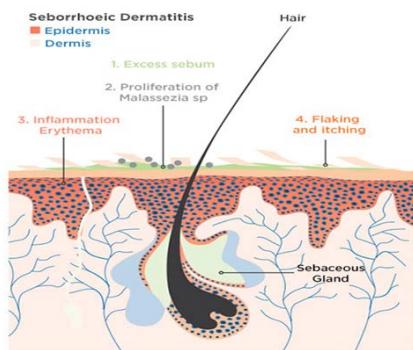


Figure 1: Fungal infection on the scalp [10]

Symptoms:

Seborrheic dermatitis symptoms may include:

- Flaking skin (dandruff) on your scalp.
- Thickening of stratum corneum and abundant dandruff.
- Skin flaking.
- Loss of hair and oily scalp and tingling (pruritus).

- Greasy skin and flaky white or yellow patches on the scalp.
- Rash that can appear reddish or pink in people with white skin and darker or lighter in people with brown or black skin.
- Annular (ring-shaped) rashes are indicative of petaloid seborrheic dermatitis.

Treatment:

Topical antifungal medications alone may even be sufficient for minor, localized infections, however, some corticosteroids and keratolytic are also used to treat seborrheic dermatitis (SD). Antifungal ointment exhibits promising results against Malassezia furfur yeast or *Staphylococcus aureus*. Additionally effective against both organisms are salicylic acid. Itraconazole and metronidazole, two additional topical antifungals, are less efficient.

The drawbacks of topical therapy include issues with compliance for severe disease and the inability to eradicate organisms from unaffected skin, which is essential in clinical circumstances with seborrheic dermatitis epidemics.[3]

Topical drug delivery:

The application of a formulation containing a drug to the skin to treat disorders is known as topical drug delivery. An efficient medication delivery method that avoids first-pass metabolism and increases the therapeutic potency of the medicine is topical drug administration. Topical treatments have localized effects at the place of application due to penetration into the underlying layers of skin or mucous membranes. The topical delivery method allows medications to be delivered more selectively to a specific spot (local site), which is the most advantageous feature of topical delivery. It allows medications with a short biological half-life and a small therapeutic window to extend the activity duration. The ocular, rectal, vaginal, and cutaneous topical routes are used to deliver drugs to the body. The method of administration is determined by the nature and severity of the condition. The topical approach is preferable for skin problems [4,5]. A topical drug delivery system provides several benefits, including the capacity to administer medications more precisely to a particular spot. To minimize gastrointestinal discomfort and metabolic breakdown brought on

by oral dosing, topical application is used. Additionally, due to the direct relationship between the physicochemical characteristics of the carrier and the medication used, topical distribution offers enhanced bioavailability and consistent delivery of pharmaceuticals at extended-release rates from topical preparation.[6]

Anatomy and physiology of skin:

The skin is the biggest organ with a weight of 15% or more of the entire human body. It performs a variety of essential tasks, such as protecting the body from external physical, chemical, and biological invaders, preventing excessive water loss from the body, and regulating body temperature. The mucous membrane that lines the body's surface are part of the continuous skin. [7,8]

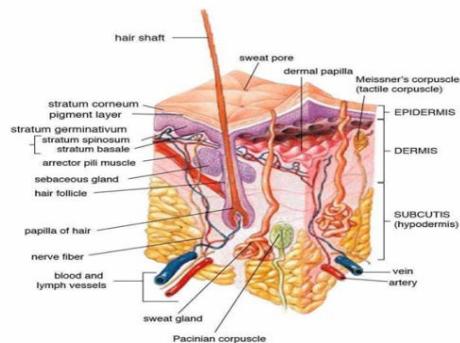


Figure 2: Anatomy of the skin [8]

The pH of the skin ranges from 4 to 5.6. The following list of various tissue layers might be considered to make up the skin.

a) Epidermis:

The "Epidermis," which is around 150 m thick, is the skin's outermost layer. The epidermis (outer layer), which is made up of five layers, is devoid of blood vessels.

The epidermis's other layers are:

- Stratum Corneum (Horny Layer)
- Stratum Lucidum (Dead skin Layer)
- Stratum Granulosum (Granular Layer)
- Stratum Spinosum (Grumpy cell Layer)
- Stratum Germinativum (Growing Layer)
- Malpighian Layer (Pigment Layer) [9]

b) Dermis:

Between the epidermis and the subcutaneous fatty tissue is the nondescript area. Collagen, reticulum, and elastin make up the majority of its structural protein fibre network, which is embedded in the

mucopolysaccharide "ground material," a semi-gel matrix which has a thickness that ranges from 2000 to 3000 m, is made up of fibrous proteins.

c) Subcutaneous tissue:

This layer is made up of a film of fat-rich areolar tissues called superficial fascia that connects the dermis to the underlying structure. The subcutaneous tissue, also known as the hypodermis, is not regarded as a real element of the organized animal tissue, which consists of loose textured, white, fibrous animal tissue containing lymphatic and blood vessels, sebaceous gland secretory holes, and cutaneous nerves. [10,11]

The basic principle of permeation:

According to research, there are three basic ways that drugs usually penetrate the skin.

- Intercellular route;
- Intracellular route; or
- Via a sweat gland and hair follicles. [12,13]

Molecules that are sufficiently soluble in water and oil, with a log of oil/water partition coefficient between 1 and 3, and have a relative molecular mass of less than 0.6 kDa, may pass through the skin.

As a result, only hydrophobic and low-molecular-weight medicines may be administered topically. Most anticancer medications do not easily permeate the corneum because they are hydrophilic and have low oil/water partition coefficients, large molecular weights, and ionic properties. [14]

Fick's second law is commonly used to explain drug permeability via the corneum;

$$J = DmCvF/L$$

Where,

J = flux,

F = drug partition coefficient,

Dm = diffusion coefficient of the drug within the membrane,

Cv = drug concentration within the vehicle,

L = corneum thickness [15]

Drug delivery across the skin:

The two layers of skin are the epidermis and dermis. Blood vessels are distributed within the subcutaneous layer.

Mechanisms for drug absorption through the skin are:

- Intercellular
- Follicular
- Transcellular

The permeation enhancers altered the stratum corneum's barrier properties by mechanisms including enhancing solubility, partitioning the stratum corneum, and fluidizing the crystalline structure of the stratum corneum. [16,17]

Creams and gels that are rubbed onto the skin are used for years for effective treatment against infections and pain by medication. New technologies allow other drugs to be absorbed through the skin and treat the affected area and the whole body by systemic route.

Pilosebaceous permeation is the next most prevalent method of permeation that occurs through the intercellular matrix, although it has given a speedier alternative route for highly polar compounds via the transcellular pathway. It has been proven that the keratinized corneocytes and hence the mostly nonpolar lipid intercellular cement of the appealing layer are the major components involved in the preservation of efficient drug barriers in normal undamaged skin. Organic solvents such as propanediol, surfactants, and methanol are frequently used to improve medication penetration through the skin.[18]

Routes of administration:

Topical delivery generally refers to the direct application of a drug to the site of action to achieve the desired pharmacological response; however, it has some limitations, such as the applied drug must cross various skin barriers to succeed in circulation, such as rectal, nasal, and vaginal, which must be investigated. Direct administration of the medicine to the mucus membrane increased the pace and extent of drug absorption from the delivery mechanism, hence boosting its efficacy.[19]

Factors affecting topical absorption of the drug:

a) Physiological factors:

- I. The thickness of the skin: Skin thickness varies from the epidermis to the subcutaneous tissue. The epidermis has a thick layer of roughly 100-150m. The skin of the bottom and palm has a high diffusion rate.
- II. Lipid content: It is an excellent water barrier; when lipid weight in the stratum

corneum is low, percutaneous penetration increases.

- III. Hair follicle density: The hair follicle infundibulum has a far larger storage capacity than the stratum corneum.
- IV. Skin pH: Sweat and fatty acid excretion affect the pH of the skin's surface.
- V. Blood circulation.
- VI. Skin hydration: Hydration can improve drug penetration.
- VII. Skin inflammation: A break in the stratum corneum's continuity enhances permeability.
- VIII. Skin temperature: A rise in temperature causes an increase in the rate of skin permeability.

b) Physicochemical factors:

- I. Partition coefficient: The greater the value of $\log P$, the easier the medicine will be absorbed percutaneously.
- II. 400 Dalton is the molecular weight.
- III. Ionization degree: Only un-ionized medicines are well absorbed.
- IV. Vehicle effect: Hydroalcoholic gel absorbs the most efficiently through the skin. [20]

Method to enhance drug penetration and absorption:

- Chemical enhancement
- Physical enhancement
- Biochemical enhancement
- Supersaturation enhancement [21]

Introduction to emulgel

Gels have numerous advantages. The delivery of hydrophobic medicines is a serious constraint. To address this limitation, an emulsion-based technique is being developed, allowing even a hydrophobic medicinal moiety to benefit from the unique features of gels. When gels and emulsions are combined, the dosage form is referred to as emulgel.

In recent years, there has been a significant amount of discussion about the usage of new polymers. The skin's direct approachability as a target organ for diagnosis and treatment is a distinguishing aspect of dermatological pharmacology. Both hydrophilic and hydrophobic chemicals are blocked by the clustering of

hydrophilic cornified cells in hydrophobic intercellular material. Transparent gels have experienced a significant increase in use within the major groups of semisolid preparations, both in cosmetics and pharmacological preparations. Because the gelling capacity of these compounds allows the formulation of stable emulsions and creams by reducing surface and interfacial tension and increasing the viscosity of the aqueous phase, the polymer can function as both an emulsifier and a thickening. [22,23]

The inclusion of a gelling ingredient in the aqueous phase allows a traditional emulsion to be converted into an emulgel. In various ways, this emulgel has a significant advantage over both innovative and conventional vesicular systems, because various permeability enhancers can boost the effect, and emulgel can be used as improved topical drug delivery systems over current techniques.

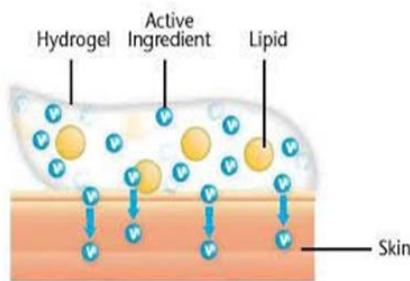


Figure 3: Emulgel Structure [23]

Advantages of using emulgel as a topical drug delivery system

- Improved loading capacity
- Improved stability
- Controlled release
- No intensive sonication
- Avoiding first-pass metabolism
- Avoiding gastrointestinal incompatibility
- More selective for a specific spot
- Improved patient compliance
- Convenient and simple to use [23]

Limitation of using emulgel as a topical drug delivery system

- Skin irritation due to contact dermatitis
- The chance of allergic responses
- The poor permeability of some medications via the skin
- Drugs with large particle sizes are difficult to absorb through the skin

- The presence of bubbles during emulgel formation

Basic components of emulgel

Emulgel formulation includes an aqueous stage, oils and emulsifiers for emulsion formation, gelling agents, and penetration enhancers to improve drug flow through the dermis.

a) Aqueous material:

This is the emulsion's aqueous phase. Water and alcohol are two commonly used agents.

b) Oils:

These substances are incorporated into the oily emulsion process. Mineral oils, alone or in conjunction with soft or hard paraffin, are commonly utilised as a carrier for the substance as well as for its occlusive and sensory properties in externally applied emulsions. Non-biodegradable mineral or roast oils that cause a local laxative effect are employed in large amounts in oral formulations, and nutritional supplements include fish liver oils or different fixed vegetable oils. Examples: Propylene glycol, Light Liquid Paraffin etc.

c) Emulsifiers:

Emulsifying agents are used to enhance emulsifiers during preparation as well as to control shelf life for pharmaceutical formulations ranging from days to months or years. Examples: Span 80, Tween 80 etc.

d) Gelling Agents:

Gelling substances are used in the manufacture of emulsions to shape a gel foundation. Gelling agents are substances that enhance the consistency of any substance by swelling and forming jelly-like forms in the aqueous medium. Examples: Carbopol-934, Carbopol-940 etc.

e) Penetration Enhancers:

Vehicles frequently incorporate penetration-enhancing chemicals that disturb the skin barrier, the main reason lipid channels between follicular cells, change the distribution of the medication in skin structures, or achieve better skin delivery in an attempt to increase drug absorption. Examples: Oleic acid, Methanol etc.

f) pH adjusting agent:

A pH adjuster is a component (or mixture of substances) used to set and maintain the pH of

a cosmetic/skincare formulation. This is critical in ensuring the proper stability and effectiveness of the completed product and/or key constituents in a specific formula. Example: Triethanolamine etc.

g) Preservatives:

Typically, preservatives are used to protect pharmaceutical products against microbial contamination. Example: Benzyl alcohol etc. [24,25]

Ideal properties of additives

- They should not be poisonous.
- They must be easily available.
- They should be inexpensive.
- They have no contraindications.
- Both physically and chemically stable

Method of preparation of emulgel:

- i. Phase 1: Preparation of gel by continuous stirring and pH optimization utilizing gelling agent and water.
- ii. Phase 2: Preparation of o/w or w/o Emulsions by a valued process utilizing the oil and water step.
- iii. Phase 3: Emulsion immersion in water.

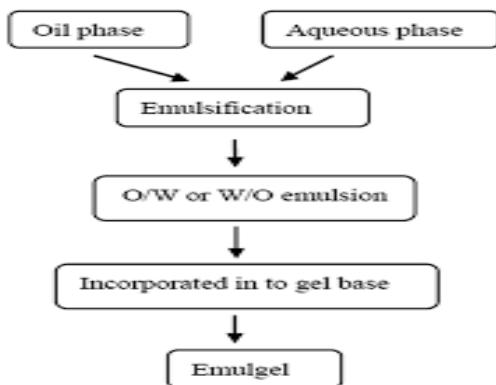


Figure 4: Methods of preparations of emulgel

Evaluation of emulgel:

a) Physical appearance:

The colour, homogeneity, consistency, and phase separation of the prepared emulgel formulations were determined.

b) Globule size and distribution in emulgel:

A Malvern Zeta-sizer is used to determine it. The emulgel is dissolved in water and stirred

or it is placed into the device and the value is determined.

c) Determination of pH:

A digital pH meter is used to determine it. The pH meter is put into the emulgel as well as the pH is measured three times.

d) Rheological study:

A brook field viscometer was used to measure the viscosity of an emulsion-based gel composition at 37°C.

e) Drug content determination:

Take 1 g of the emulsion-based gel. Add a suitable solvent and combine. To obtain a clear answer, filter it. Calculating its absorption with a UV spectrophotometer. The same solvent is used to produce the drug's standard formulation. Using an appropriate standard plot and the value of absorbance, concentration and drug content are typically calculated.

Formula to calculate drug content determination:

Drug content = (Concentration × Dilution factor × Volume taken) × Conversion factor.

f) Spread ability measurement:

The emulgel qualities "slip" and "drag" are used to evaluate spreadability. A glass plate with a circle pre-marked 1 cm in diameter was placed atop another glass plate to contain 0.5gm of emulgel to test its spreadability. For five minutes, a weight of 500 gm was allowed to lie on the top glass plate. It was seen that the diameter spreading had increased.

g) Extrudability (Tube test):

This empirical test is a standard method for determining the amount of force needed to extrude the cloth from the tube. This is based on the number of grams needed to extrude a minimum of 0.5 cm of emulsion-based gel in 10 seconds, divided by the amount of gel and gel extruded from the aluminium collapsible tube. Extrudability is improved by greater extrusion volume.

Formula to calculate extrudability:

Extrudability = Applied weight to extrude emulgel from tube (gm) / Area (cm²). [26]

h) Skin irritation test:

Animal skin is used for this test. The animals are then placed back into their cages after

having the emulgel applied to their skin. Animals are tested 24 hours later. The emulgel is then taken off the area and cleaned with tap water.

i) **Microbiological assay:**

The ditch plate approach evaluated the effectiveness of the bacteriostatic or fungistatic activity. It is mostly used for semisolid compositions that are semisolid. The Sabouraud's agar-dried plates were previously produced. 3gm of gel emulsion is poured into the plate's ditch. Newly-made culture loops are scattered evenly across the agar from the ditch to the plate's edge.

j) ***In-vitro* release study/ permeation studies:**

A Franz diffusion cell with a 3.14 cm² effective diffusion area and a 15.5 ml cell volume were used for the drug release studies. A homogenous layer of emulsion-based gel (1 gram) was placed on the cellophane membrane's surface. Between the donor and the receptor chambers of the diffusion cell, the cellophane membrane was squeezed. Methanol into the receptor chamber. The samples were taken at regular intervals. After the proper dilutions, samples were tested for drug content using a UV spectrophotometer at a suitable wavelength. The amount of medication dispersed throughout the mice's shaved skin was calculated as a function of time.

k) ***Ex-vivo* measurement of Bio-adhesive strength measurement:**

Bio-adhesive strength measurement *ex vivo*, the modified approach is used to assess bio-adhesive strength. The newly formed skin is divided into pieces and cleaned with 0.1N NaOH. Since one glass slide is fixed to the wooden piece and another piece is tied to the balance on the right-hand side, two pieces of skin were tied to the two glass slides. By putting more weight on the left-hand pan, the right and left pans were balanced. In order to sandwich the two pieces of hairless skin, a 1gm quantity of topical emulsion gel is inserted between the two slides. The excess weight from the left pan is then removed, and the two skin pieces are then subjected to

pressure to release the air pressure. This balance is maintained for five minutes. Even until the patch detached from the skin's surface, weight was gradually added to the left-hand pan at a rate of 200mg per minute. The quantity of bio-adhesive strength was measured by the weight in grammes necessary to detach the emulsion gel from the surface of the skin.

The formula of bio-adhesive strength is calculated by:

$$\text{Bio-adhesive strength} = \frac{\text{Weight required (gm)}}{\text{Area (cm}^2\text{)}}.$$

l) **Stability studies:**

The resulting emulsion-based gel packing was carried out in aluminium collapsible tubes (5gm), and stability analyses were performed under the following restrictions. 50°C, 250°C at 60% relative humidity, 300°C at 65% RH, or 400°C at 75% RH for three months. Samples were kept for 15 days at a time, and their physical characteristics, pH, rheological characteristics, drug content, and drug release profiles were all measured. [27,28,29]

Conclusion

The use of emulgel as a smart drug delivery technology to deliver medication to both local and systemic areas of action has been studied by researchers. These formulas have a lot of positive impacts and very few negative ones. We come to the conclusion that designed emulgel have produced great outcomes in terms of aesthetics, homogeneity, viscosity, rate of drug absorption through skin, drug release profile, and therapeutic outcomes. Emulgel are more beneficial and lucrative than other topical drug delivery systems due to all these reasons. These physical and physicochemical qualities will be used in the future to deliver more topical drugs, including emulgel.

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