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# EMULGEL: A COMPREHENSIVE REVIEW

**Noman Khan[1], Dr. Shalini Kumari[2*]**

[1]Research scholar, Moradabad Educational Trust Group of Institutions, Faculty of Pharmacy, Ramganga Vihar Phase - 2, Moradabad, Uttar Pradesh, India[1]

[2*]Assistant Professor, Moradabad Educational Trust Group of Institutions, Faculty of Pharmacy, Ramganga Vihar Phase - 2, Moradabad, Uttar Pradesh, India[2]

***Corresponding Email: [2*]nomankhan190801@gmail.com**

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**ABSTRACT:**

Topical drug administration is a popular and advanced technique that focuses on applying pharmaceuticals directly to the skin to treat and diagnose various diseases and ailments, such as rheumatism, inflammation, and urticaria. The main goal of a topical medicine delivery system is to enhance the drug's permeation through the skin's barrier and promote effective skin diffusion. Emulgel has great potential as a drug delivery system, particularly for medications that are not soluble in water. This novel medication delivery system has a dual release control mechanism that encompasses both gel and emulsion. Emulgel has many benefits, such as being non-greasy, readily applicable, rapidly removed, moisturising, and transparent. Emulgel is often used for the delivery of analgesics, anti-inflammatory agents, anti-fungal drugs, and anti-acne treatments, along with other cosmetic preparations. The research on Emulgel has the potential to revolutionize the administration of a broader spectrum of topical drugs, offering a more promising future.

**Keywords:** Topical drug delivery, Emulsion gel, hydrophobic drug, Skin diffusion, Controlled release of drug, Localised action.

## 1. INTRODUCTION

Topical medication delivery involves putting a drug-containing formulation to the skin to treat a cutaneous ailment. Applying a formulation containing medicine to the skin to treat a cutaneous condition is known as topical medication delivery. This tactic is employed when dealing with localised skin conditions like fungal infections or when traditional pharmaceutical distribution techniques like oral, sublingual, rectal, and parental are insufficient[1]. Both local and systemic disorders may be successfully treated with topical drug administration. In this delivery technique, the medication enters the body via the skin and travels to the targeted site of action, where it exerts its therapeutic effect. The rate of drug release from a topical preparation is directly impacted by the physiological characteristics of the carrier. One important benefit of topical administration devices is their ability to avoid first-pass metabolism[2]. Among the four drug classes categorised by the BCS, Class II medications have poor solubility and high permeability. It is obvious that class II medications' low dissolution tendency poses more of a challenge to their overall pace and degree of absorption than does their membrane-passing capability. As a result, emulgels may be a better option for topical drug delivery of poorly water-soluble medications. For drugs that are hydrophobic or poorly soluble, emulsified gel has shown to be a more reliable and efficient delivery method[3].

**Gel**

When it comes to getting active substances to their site of action, gel is the most practical and recommended dosage form. Gel's three-dimensional structure and crosslinking help it to trap tiny medication particles and facilitate their controlled release. There are many solvent molecules that can get ensnared in the three-dimensional network, which is made up of macromolecules[53]. Gels' mucoadhesive quality prolongs the drug's duration in contact with the skin[54].Gels are thixotropic, spreadable, greaseless, and non-staining, but they have a significant disadvantage when it comes to delivering hydrophobic medications to the skin. Hydrophobic active substances are not acceptable to add to the gel basis because they show inefficient drug release in gels because they are not soluble in the aqueous phase[55,56]. Therefore, emulsion-gel based drug delivery technologies are being developed to overcome these limitations.

**Emulsion**

Typically, emulsions are thermodynamically unstable two-phase systems. They are made up of two or more immiscible liquids, and when one of them diffuses into the other in the form of small droplets, the system becomes unstable. An emulsifying agent is used to stabilise the biphasic system. There are two kinds of emulsions that are used as drug delivery systems: o/w and w/o. Emulsions are stabilised by the employment of emulsifying chemicals. They have good skin penetration and are easily removed from the skin[13].

**Emulgel**

A combination of gels and emulsions is called emulgel. It is made up of emulsions that have either been water-in-oil (w/o) or oil-in-water (o/w) gelled by the addition of a gelling agent. Emulgel performs better than ordinary gels in therapeutic applications[3]. An emulsion-based gel is used in the inclusion and administration of the hydrophobic bioactive component to promote its solubility and simplify skin penetration[4]. Emulgel, which functions as a dual-control drug release mechanism, thereby combines the advantages of gel and emulsion[57,39].

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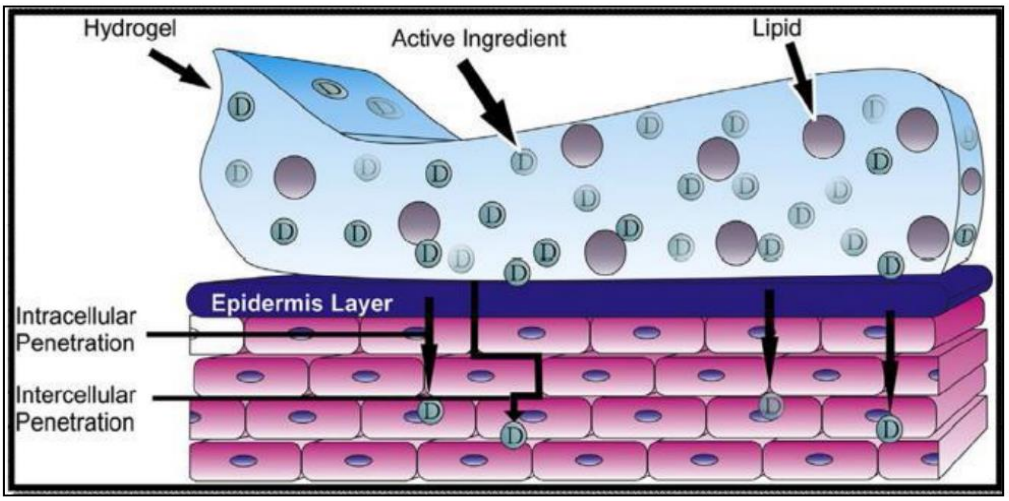



**Figure 1:**Represents the pathways for drug penetration.[33]

**Anatomy Of Skin**

With an area of around 1.7 square metres, the skin is the biggest organ in the body, accounting for 16% of an average person's total weight[5]. Its primary role is to serve as the body's barrier of defence, guarding against a variety of external hazards such as allergens, chemicals, UV radiation, pathogens, and moisture loss. The epidermis, dermis, and hypodermis are the three main layers of skin that operate as a barrier of defence and regulate how the body interacts with its surroundings.[6]

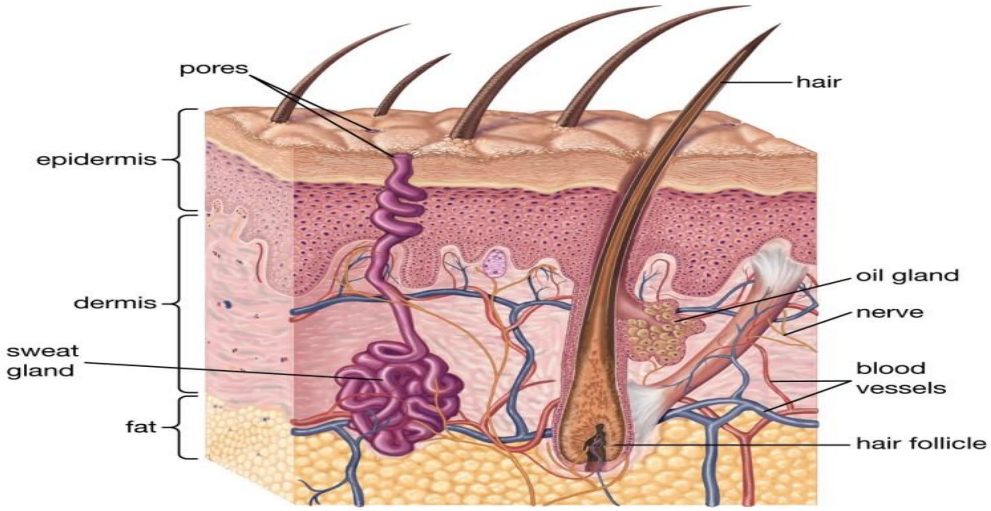



**Figure 2 :**Represents the skin anatomy[17]

**Epidermis**

The thickness of the layers that make up the epidermis varies. The eyelids measure around 0.06 mm while the palms and soles measure 0.8 mm. Curiously, this layer is devoid of blood vessels, thus the epidermal cells must transfer nutrients and remove waste materials across the epidermal-dermal interface in order to reach the dermal cutaneous circulation.[6]

**Dermis**

The dermis, which has a thickness of 2-3 mm, is predominantly made up of elastin and collagenous fibres, which make up around 70% of the tissue and give the skin its flexibility and strength. Blood vessels are essential to this layer because they provide nutrition to the

dermis and the epidermis. To further improve its performance and responsiveness, the dermis also contains neurons, macrophages, and lymphatic veins[7].

**Hypodermis**

The word hypodermis, often known as subcutaneous tissue, refers to the layer located under the dermis. The makeup of it consists of elastin and loose connective tissue. The subcutaneous layer contains the vascular plexus, which comprises the arteries and veins responsible for draining the dermis. Dermal arteries infiltrate the papillary dermis layer, producing a complex framework of capillary loops inside the skin. Multiple lymphatic veins pass the hypodermis to reach the specific lymph nodes responsible for emptying the dermis. Interestingly, a significant amount of adipose (fat) tissue is mostly stored in the hypodermis[8].

**Types of Emulgel**

**Macroemulsion gel**

Emulgel that contains particles larger than 400 nm in size is referred to as macroemulsion gel. The tiny drops are fully visible under a microscope, but they are literally undetectable. Although surface-active substances have the potential to stabilize macroemulsions, they are thermodynamically unstable[43].

**Microemulgel**

Micro-emulsions do not merge and have droplet sizes ranging from 100 to 400 nm, making them transparent and thermodynamically stable. In certain ratios, water, surfactant, oil, and co-surfactant form microemulsions[44,45].

**Nanoemulgel**

Gel containing nano-emulsion is known as nano-emulgel. Transparent, thermodynamically stable nanoemulsions containing water and oil are stabilised by an interfacial layer of surfactant and cosurfactant molecules with globule diameters smaller than 100 nm.[46]

**Objectives of Emulgel**

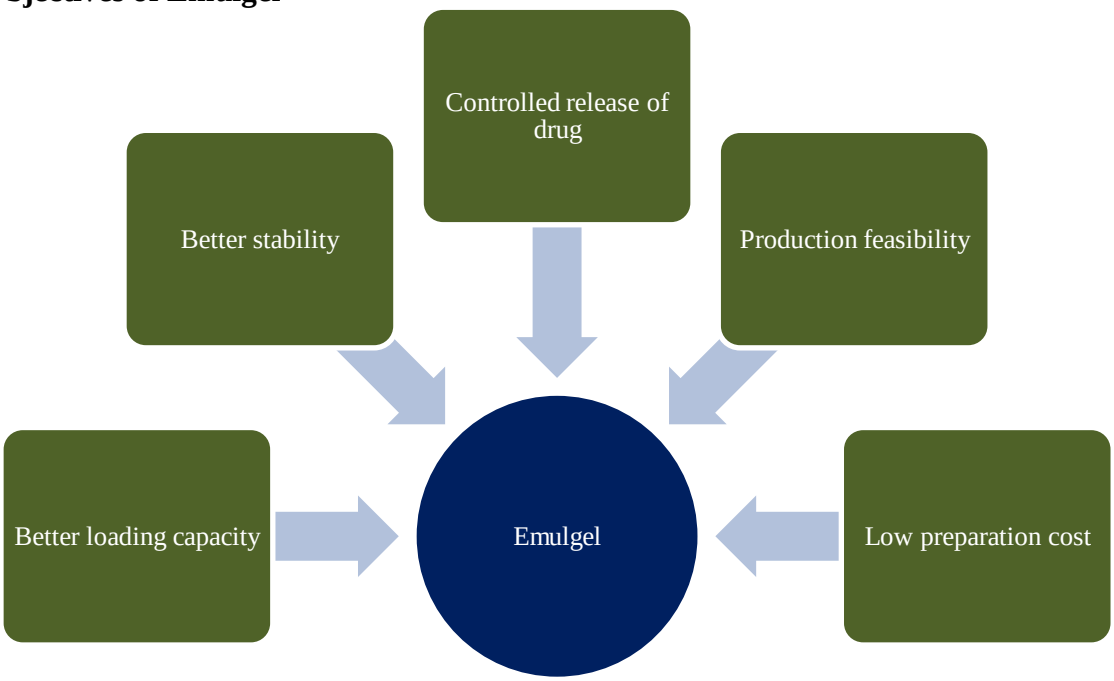



**Figure 3** : Represents the objectives of emulgel.[34,35]

**The Following Products Are Available For Topical Delivery:**

- External topicals are administered, sprayed, or smeared over the cutaneous tissues in a different manner to cover the desired area.
- For a localised impact, internal topicals are applied to the mucous membrane or rectal tissues.

**Factors Influencing Drug Absorption Topically**[9]

**Physiological Elements**

1. pH of the skin
2. Lipid content
3. Skin thickness
4. Blood circulation
5. Skin Hydration

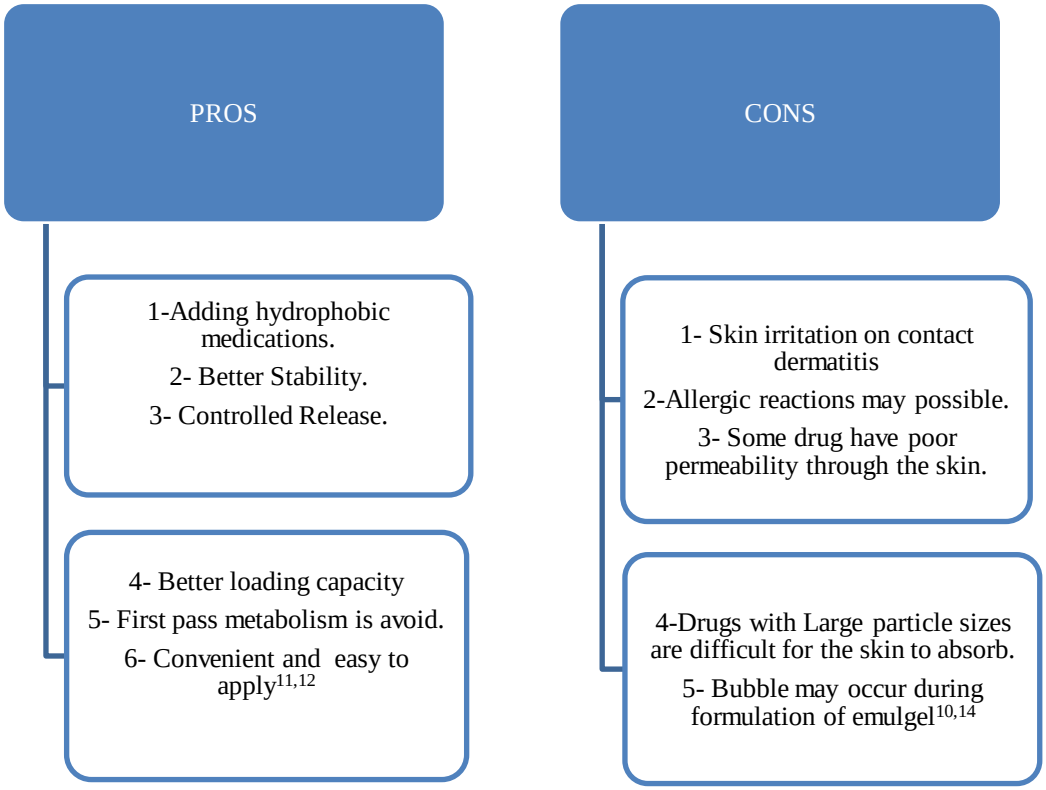
**Physicochemical Elements**

1. Effect of the vehicle
2. Molecular mass (less than 400 daltons)
3. Coefficient of partition
4. Ionization level

**How to Improve Drug Absorption and Penetration**[10]

1. Improvement of Physical
2. The improvements of Chemicals
3. Improvement of Super saturation
4. Improvement of Biochemistry

**Emulgel's Pros and Cons**



**The Challenges That Need To Be Faced While Developing Topical Emulgels Are[38]:**

1. Recognizing non-sensitizing, non-toxic, non-irritating, and non-comedogenic systems.
2. Creating a splendid cosmetic emulgel.
3. The emulgel formulation needs to be highly biocompatible, have a small risk for allergies, and have good physiological compatibility.

**Future Perspectives**

Different emulsification methods, such as high shear homogenization, ultrasonication, microemulsification, etc., can be used to produce emulgels, as can a variety of gelling agents, including gelatin, hydroxypropyl cellulose, and carbopol. Emulsifiers, surfactants, and gelling polymers can all be chosen carefully to assist obtain the required release kinetics and physicochemical properties for various applications[40]. In addition to characterizing the particle size, viscosity, pH, spreadability, and drug release, assessing elements such as skin hydration, drug loading, and drug penetration can offer valuable information into how well emulgel formulations work.Topical emulgels have promise for cosmetics, skin care, and hair care. Drugs can be administered systemically by parenteral emulgels in a regulated way. Drug absorption for both lipophilic and hydrophilic substances can be enhanced by oral emulgels[41].By creating innovative gelling agents, permeation enhancers, solubilizers, and emulsification processes, emulgel formulations can be greatly improved. Emulgels can provide synergistic formulations with increased efficacy when combined with hydrogels, micro-emulsions, and nanotechnology[42].

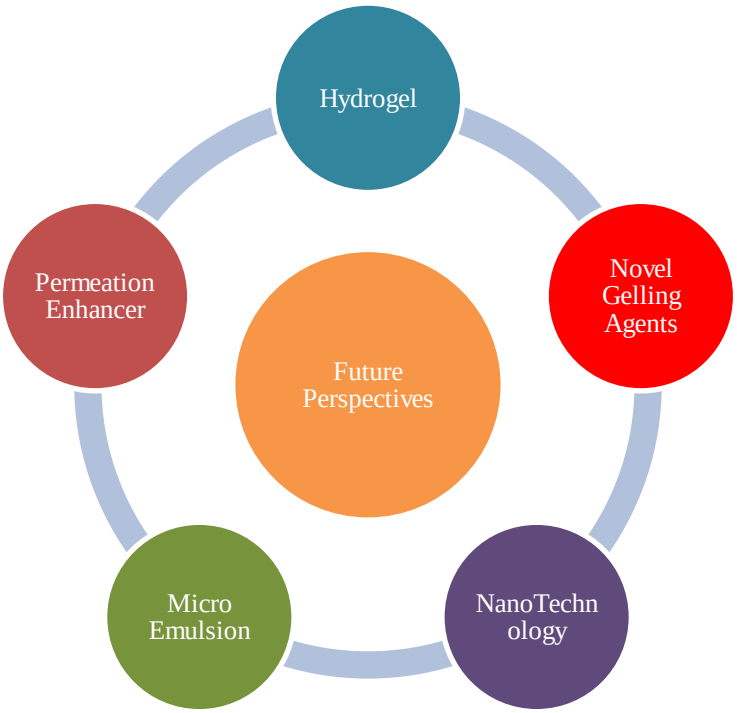



**Figure 4**: Represents the future perspectives of emulgel.

**Formulation of Emulgel**

In the formulation of emulgel, various components, including the drug, are employed, such as:

- **Vehicle** - Enhancing medication absorption via the skin is mostly dependent on the vehicle used in emulgel formulation.[15]
- **Aqueous Material** - Commonly used substances like water and alcohols are employed to generate the aqueous phase of the emulsion[16].

- **Oils** - The type and quantity of oil used as one of the emulsion phases is intimately related to the emulgel's intended application. Furthermore, these oil phases have a substantial impact on the emulsion's viscosity, permeability, and stability[3].
- **Emulsifiers** - The addition of the proper emulsifying agents helps stabilize an emulsion, which is a thermodynamically unstable system. These materials have a major role in decreasing interfacial tension, which boosts the stability of emulsions. For instance, stearic acid, Tween 20, Span 80, Tween 80, etc.[3].
- **Gelling Agents** -Gelling agents, also known as cross-linking agents, are essential in the emulgel formulation because they add thixotropic qualities to the system. Their principal role is to thicken the dosage form, improving both the texture and quality. E.g. Carbopol 934, Carbopol 940,HPMC, etc [18].
- **Penetration Enhancer** -These chemicals are primarily used to promote medicine transdermal distribution. The penetration enhancers used in the emulgel should be non-irritating, have low toxicity, and promote penetrability. E.g. Oleic acid, lecithin, clove oil, menthol, eucalyptus oil, etc[3,19].
- **Humectant** - They are employed to stop the formulation from losing moisture. By reducing emulgel drying, these ingredients improve consistency, ease of application, and other attributes. E.g. Propylene glycol, glycerine[15]

**Method Of Preparation** – Three basic stages that must be followed in order to prepare emulgel are also shown.[20]

**Step 1**

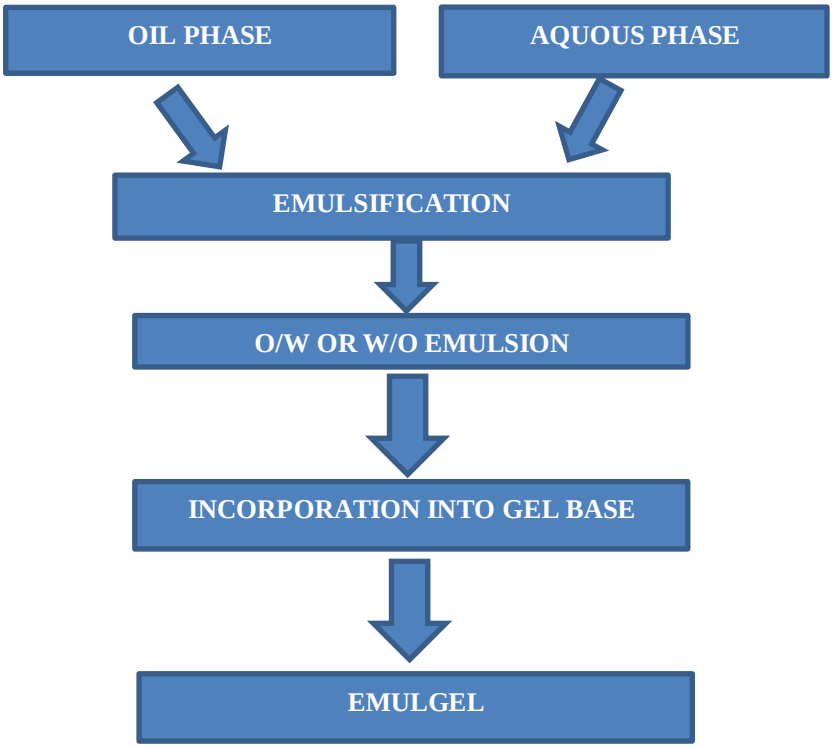
The preparation of an emulsion can result in either an oil-in-water (O/W) or water-in-oil (W/O) arrangement.

**Step 2**

Gelling agents and water must be consistently mixed while the pH is being adjusted in order to create a gel base.

**Step 3**

It takes constant stirring and heating to incorporate the emulsion into the gel base.



**Marketed preparation available as emulgel**[21,22]

| S.No. | | Product Name | Drug | Manufacturer |
|---|---|---|---|---|
| 1. | 01 | Miconaz-H-emulgel | Miconazole nitrate, Hydrocortisone | Medical union Pharmaceuticals |
| 2. | 02 | Excex gel | Clindamycin, Adapalene | Zee Laboratories |
| 3. | 03 | Lupigyl gel | Metronidazole | Lupin Pharma |
| 4. | 04 | Topinate gel | Clobetasol propionate | Systopic Pharma |
| 5. | 05 | Pernox gel | Benzoyl peroxide | Cosme Remedies Ltd |
| 6. | 06 | Avindo gel | Azithromycin | CosmePharma Lab. |
| 7. | 07 | Diclon emulgel | Diclofenac diethylamine | Medpharma |
| 8. | 08 | Cataflam gel | Diclofenac Potassium | Novartis |
| 9. | 09 | Pennsaid | Diclofenac Sodium | Nuvopharma |
| 10. | 10 | Denacine Emulgel | Clindamycin phosphate | Beit jala pharmaceutical company |

**Table 1**: Represents the commercially available products in emulgel dosage form, marketed names and manufacturing companies.

## APPLICATIONS OF EMULGEL

### A. Topical Applications

- Skin Care: Emulgels are used to cure inflammation, dullness, roughness, and other problems. They are also used as moisturizers and emollients. Aloe vera, chamomile extract, cetyl alcohol, glycerin, and other ingredients are added[47].
- Hair Care: Emulgels that are loaded with proteins, oils, keratin, and other ingredients are used as styling tools, dandruff remedies, and conditioners. Common uses include glycerin and coconut oil[42].
- Cosmetics: Emulgels are applied as sunscreens, lip balms, foundations, and more. To achieve the desired effects, ingredients might include emulsifiers, silicones, waxes, and colors. The amount of sunscreen and emulgent applied determines the sun protection factor[47].

### B. Parenteral applications

- Emulgels deliver a continuous release of medication by injection. Long-term medication release lowers dosage frequency and maintains appropriate drug levels. Commonly used medications include antibiotics and water-soluble corticosteroids[48].

### C. Oral Applications

Oral medication delivery techniques based on emulsions comprise:

- Emulgels: Emulgels are composed of both gels and emulsions for regulated medication release. Depending on the drug's solubility, emulsions of water in oil or oil in water are utilized[49].

- Liquid filled gelatin capsules (LFGCs): Capsules made of gelatin that contain emulsions. The medicine may be released at designated locations using LFGCs, which can float, sink, or remain buoyant. Used for release particular to a site[50].
- Self-emulsifying drug delivery systems (SEDDS): include solvents and emulsifiers to create fine O/W or W/O emulsions when they dissolve in low-energy aqueous medium. Boost the solubility, absorption, and bioavailability of medications[51].
- Microemulsions: Isotropic, thermodynamically stable, and possess droplet sizes less than 100 nm. Microemulsions improve solubility and maximize surface area for absorption. Lipophilic, amphiphilic, and hydrophilic medications work well with them[52].

**Evaluation of Emulgel**

**Drug-Excipients Interaction Studies**

In order to create a stable product, it is necessary to determine if the medication and excipients interact chemically or physically. In interaction research, methods including thermal analysis, FT-IR studies, UV, and chromatography are often employed. Their assay, melting endotherms, characteristic wave numbers, and absorption maxima are compared, along with their physiochemical properties.[32]

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**Physical Appearance**

Colour, homogeneity, consistency, and pH levels of the emulsion compositions were evaluated visually. A pH metre was used to test the pH of the gelled emulsion that was formed in 1% aqueous solutions.[23]

**Swelling Index**

To determine the swelling index, 1 gramme of an emulgel is deposited on porous aluminum foil and then separately placed into 50 millilitre beakers with 10 millilitres of 0.1 N NaOH. Subsequently, the samples are taken out of the beakers at various intervals and weighed again for analysis.

The swelling index may be calculated using the following formula:

Swelling Index (SW) percentage = [(Wt – W0) / W0] × 100

Where W0 is the emulgel's starting weight, Wt is the emulgel's weight at time, and (SW)% is the equilibrium percent swelling.[24]

**Spreadability**

The therapeutic effects of a formulation are also influenced by its spreading qualities. After two slides are inserted between the emulgel and loaded to a certain extent, spreadability is measured in seconds. A shorter time between slides is an indicator of higher spreadability.

S = M. L / T is the formula employed to calculate it,

where M=wt. connected to the top slide

L is the glass slide length.

T is the amount of time needed to divide the slides.[25]

**Skin Irritation Test**

Each rabbit had two sites on its skin, measuring about 1" by 1" (2.54 x 2.54 cm2), where 0.5 g of the test material was applied under a double gauze covering. After the rabbits' skin was treated with the Gellified Emulsion, the creatures were put back in their cages. After being exposed for a full day, the Gellified Emulsion was removed, and any test material that remained washed away at the test sites using tap water[26].

**Drug content determination**
Sonication is used to dissolve a known quantity of emulgel in an appropriate solvent, such as ethanol, in order to identify the drug concentration in the emulgel. After the appropriate dilution, the solution is filtered, and the absorbance at the medication's maximum wavelength is measured using an Ultraviolet-Visible (UV/Vis) spectrophotometer. Use the standard equation below to get the drug content.
Drug Content = (Concentration × Dilution Factor × Volume Taken) × Conversion Factor.[27]

**In Vitro drug release**
The Franz diffusion cell is one equipment used to check for medication release. 200 mg of the gellified emulsion are applied consistently to the surface of the egg membrane. The membrane that separates the donor and receptor chambers of the diffusion cell is then installed. To aid in the solubilization of medications, newly made PBS (Phosphate Buffered Saline) solution at pH 5.5 is poured into the receptor chamber. The fluid within the receptor chamber is stirred by a magnetic stirrer. At certain intervals, 1.0 mL samples are obtained and suitably diluted so that a UV visible spectrophotometer can assess the drug concentration. The total amount of medication administered via the egg membrane is calculated over time.[28]

**Stability study**
According to the International Council on Harmonization's (ICH) criteria, the emulgel stability evaluation is conducted. Aluminium tubes that can be folded up are first used to package the emulgel mixtures. After that, the tubes are kept for three months at four distinct temperatures and relative humidity levels: five degrees Celsius, twenty-five degrees Celsius with sixty percent relative humidity, thirty degrees Celsius with sixty percent relative humidity, and forty degrees Celsius with seventy-five percent relative humidity. Samples are collected every 15, 30, 60, and 90 days throughout the storage period. Following that, a number of parameters are assessed for these samples, such as their physical characteristics, viscosity, pH, drug concentration, in vitro drug release, and other significant tests.[29]

**Rheological studies**
The viscosity of various emulgel formulations is measured using a cone and plate viscometer with a thermostat-controlled water bath that is attached to a spindle 52 at a temperature of 25°C.[30]

**Determination of pH**
A digital pH metre is used to measure the pH of the formulation. Prior to putting the pH metre electrode into the liquid, it undergoes a cleaning process using distilled water. This procedure was conducted on three occasions, and the pH measurements were documented throughout every stage.[30]

**Photomicroscopy**
The spherical arrangement inside the gel matrix of the emulgel was examined using a light microscope. The emulgel was suitably diluted and applied onto a glass slide using a light microscope with a 40x magnification.[37]

**Globule Size**
For globule size determination, Zetasizer (Malvern Instrument 3000HSA, UK) is utilized. The globule size was evaluated at 25 C and the sample was sufficiently diluted[31].

**Packaging of Emulgel**

Emulgels are often packaged in aluminum lacquered tubes that are inside coated with phenoxy-epoxy lacquer and sealed with a membrane. A commonly used option for closure is either an aluminium laminated tube that is sealed with a moulded seal or a propylene screw cap.[22]

## 4. CONCLUSION

A major advantage of topical medication administration approaches is increased patient compliance. When synthesizing hydrophobic medications, emulgels are an excellent topical administration technique. These formulas are more effective, and to maximize their benefits, they are sometimes combined with penetration enhancers. It has been shown that Emulgel is the most amazing, easy, and effective new delivery technology. Comparing it to conventional topical administration systems, it has good medicine release and gel-like qualities due to its non-greasy composition and absence of oily bases. Emulgel has a large capacity for loading medicines and is widely utilized. The delivery of drugs to the intended site is effective. The skin's tiny size makes medication penetration through it effective. This approach boosts medication effectiveness and increases patient compliance.

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