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A REVIEW ARTICLE: ON TOPICAL DRUG DELIVERY SYSTEM OF EMULGEL.

NAME OF 1ST AUTHOR: **MR. SHUBHAM BHIMRAO MAHALI** (M.PHARM)

NAME OF 2ND AUTHOR: DR. A.A.HARSULKAR (PhD, M.pharm)

NAME OF DEPARTMENT: INDUSTRIAL PHARMACY (MASTER OF PHARMACY)

NAME OF ORGANISATION: SUDHAKARRAO NAIK INSTITUTE OF PHARMACY PUSAD Ta. PUSAD Dist. YAVATMAL (M.S)

ABSTRACT:

The topical drug delivery system uses the ophthalmic, cutaneous, vaginal, and rectal channels to administer the medication locally in the body. Topical formulations are primarily utilized for dermatological or cosmetic purposes in skin diseases. Osteoarthritis, both acute and chronic pain, migration, suffering, colic, and other ailments and injuries are all treated with emulgel. The systemic inflammatory response syndrome may be treated with the medication. The physico-chemical qualities of the topical medication preparation might be designed as solid, semisolid, or liquid. They are also referred to as hydrophobic medicines. Emulgel is the term for the combination of gel and emulsion. An emulsion is gelled by combining it with a gelling agent, which is called emulgel. The prepared emulgel was tested for a number of parameters, including pH, viscosity, spreadability, globule size, greaselessness, and shelf life. Emulgels are utilized in a variety of analgesic, anti-inflammatory, antifungal, and anti-acne medication delivery systems.

KEYWORDS: Topical Drug Delivery, Emulsion, Emulgel, Gel, Gelling agent, Penetration Enhancer etc.

INTRODUCTION:

The study of pharmaceutical science has progressed and is now highly relevant in the current battle against illness. The use of bio-molecules, such as medications and proteins, to treat disease is a field of study that has made tremendous progress in recent years. Medication can enter the human body through a number of routes, including the sublingual, parenteral, rectal, inhalation, and oral routes. Even though the oral route is thought to be the most practical, it still has disadvantages such poor absorption and solubility. In this case, topical medicine delivery systems can be an option. Topical treatment avoids absorption-related concerns such as different enzymes, pH changes, and stomach emptying time, as well as first pass metabolism, intravenous therapy challenges, and stomach emptying time. Due to the topical gel drug delivery method's hydrophobic moiety, it is still difficult to transmit drugs across the skin. A topical drug delivery system is a way to treat dermatological conditions or induce a localizing impact of a treatment by applying it directly to the skin. Topical administration can be used to provide controlled and sustained drug release. Since this is a noninvasive technique of administering medication, there is no chance of infection. Treatments for dermatological skin care range in consistency and formulation from liquid to powder, with semisolid preparations being the most popular. Topical dose forms most commonly include solutions,

suspensions, emulsions, semisolids (such as foams, ointments, pastes, creams, and gels), solids, and sprays.), solids, and sprays are the most widely used types of topical medication delivery systems. Topical drug delivery is usually used when other forms of medication delivery (oral, sublingual, rectal, and parental) are not working or when a local skin condition like a fungal infection is present. Topical drug delivery is a preferred strategy for both local and systemic therapy. One essential element of dermatological care is the skin's direct interaction and simple accessibility as a target for diagnosis and treatment. [1-7]

CLASSIFICATION OF TOPICAL DRUG DELIVERY SYSTEMS: [5]

1. Solid preparation: poultices, plaster ointments, and topical powders.
2. Preparations that are semi - solid: creams, poultices, gels, pastes, and ointments.
3. Liquid preparation: paints, tinctures, lotions, liniments, suspensions, and emulsions.
4. Other preparation items include topical spray, liquid cleanser, rubbing alcohol, tapes and gauzes, and transdermal drug delivery devices.

Factors affecting topical absorption of drug*: [5-6]*
Physiological factors
1. Thickness of skin.
2. Lipid content.
3. Density of hair follicles.
4. Density of sweat glands.
5. pH of skin.
6. Blood flow.
7. Skin hydration.
8. Inflammation of skin.

Physicochemical factors
1. Partition coefficient.
2. Molecular weight (<400 Dalton).
3. Degree of ionization.
4. Effect of vehicles.

Physiology of skin:

The majority of topical preparations are intended for application on the skin. Therefore, a basic understanding of the physiology and function of the skin is crucial for the design of topical medications.

There are four different tissue layers that make up the skin:

1) Non-viable skin layer:
2) Viable skin layer:
3) Dermis:
4) Connective tissue under the skin:

1) The outer layer of skin is called the non-viable epidermis. The cell measures 10–20 μm thick, 34 - 44 μm long, and 25–36 μm broad.
2) Viable epidermis: 10–50 μm thick, it lies between the stratum corneum and dermis.
3) Dermis: Also referred to as viable dermis. Range of thickness: 2000–3000μm.
4) Subcutaneous connective tissue: Comprising blood and lymph vessels, fibrous connective tissue, and a loose texture, it is regarded as real connective tissue.

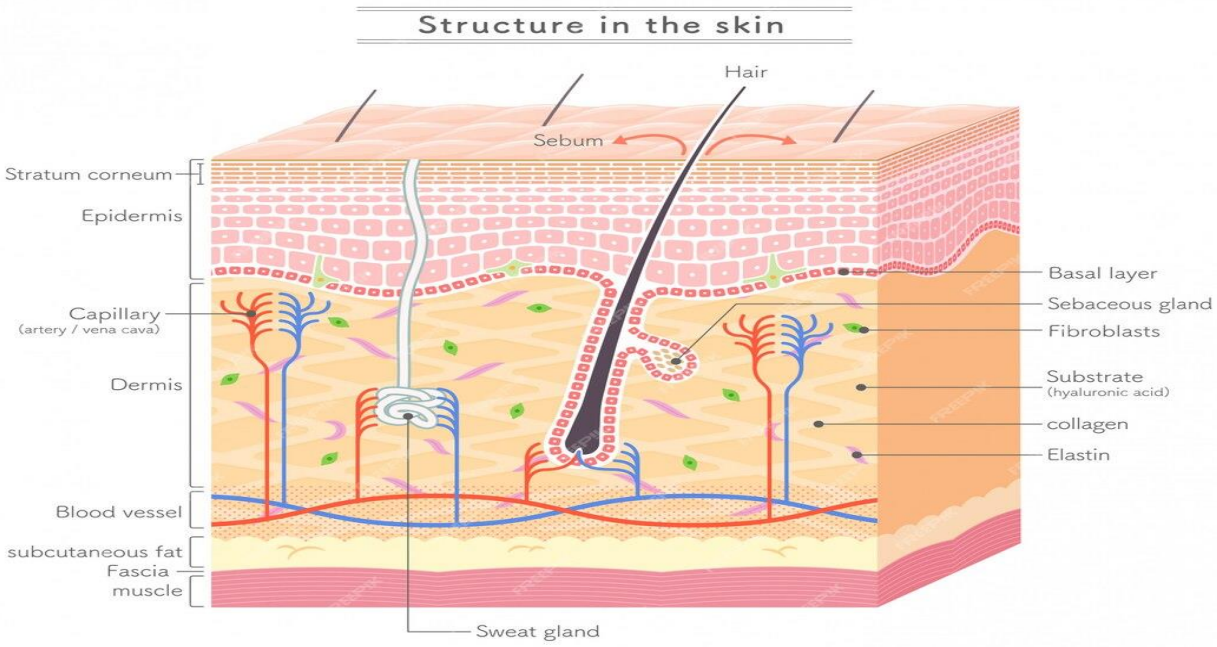

Fig1. Physiology of skin

Things to think about while selecting a topical preparation:

1. The ability to enrage or irritate. Ointments and creams containing water and oils tend to be less irritating than gels. If an allergy to preservatives or emulsifiers is a worry, ointments don't contain these ingredients.
2. Align the preparation kind with the lesions type.
3. Align the site-appropriate level of preparation. (For hairy regions, use lotion or gel).

Function of Skin:

***1) Protection*:** The skin serves as the body's main line of protection against external factors, including infections, dehydration, UV rays, and mechanical injury.
2) Creation of Vitamin D: The sun's UV rays change the lipid basis material in skin, known as dehydrocholesterol, into vitamin D.
3) Body temperature regulation: The skin helps maintain the body's homeostatic and water balance as well as thermal regulation by absorbing and releasing heat. One of sin's primary roles is thermoregulation.
4) Absorption: Transdermal patches; examples include nicotine and hormone replacement medication.
5) Excretion: Sweat contains sodium chloride, and the skin excretes fragrant compounds like garlic.
6) Exocrine activity: This is brought on by the release of ammonia, urea, and water. The skin secretes pheromones, sebum, and sweat. It also secretes bioactive molecules like cytokines, which are essential for immune function.

Advantages of Topical Drug Delivery System:

1. Clear of the primary pass metabolism.
2. It is simple to stop taking the drug.
3. Simple to apply and utilize.
4. Prescriptions sent to designated locations.
5. There will be no gastrointestinal incompatibility.
6. Self-administration of drugs.
7. Improved adherence from patients.
8. Prevents variations in medication dosages and hazards.

Disadvantage of Topical Drug Delivery System:

1. The potential for skin irritation when the product is applied.
2. Certain medications that have low permeability don't pass through the skin.
3. Drug-induced contact dermatitis could happen.
4. The potential for allergic responses.
5. It is harder to permeate drugs with bigger particle sizes.

Drug delivery across the skin:

The dermis and the epidermis are the two key layers of skin involved. The subcutaneous layer is located beneath the skin and has a large distribution of blood vessels. Drug absorption through the skin occurs primarily through three mechanisms: follicular, transcellular, and intercellular. The pilosebaceous route is the other and most popular distribution method. Permeation usually happens via the intercellular matrix, but it has been demonstrated that the transcellular pathway offers highly polar molecules a quicker alternative route. It is well known that the horny layer's mostly non-polar lipid intercellular cement and keratinized corneocytes play a key role in maintaining effective drug barriers in normal, intact skin. DMSO, propylene glycol, and surfactants are examples of organic solvents that can improve medication penetration through the skin.

Through a variety of mechanisms, such as improving solubility, dividing the stratum corneum, and fluidizing its crystalline structure, the permeation enhancers modify the barrier characteristics of the stratum corneum. For years, topical creams and gels have been used to effectively treat infections and pain without the need for prescription drugs. Other medications can now be absorbed through the skin thanks to new technologies. Through a systemic approach, they can be utilized to treat the entire body in addition to the skin's afflicted areas.

ADVANTAGES AND DISADVANTAGES OF EMULGEL: [2]

ADVANTAGES:

1. Adding hydrophobic medications
2. Increased loading capability
3. Increased steadiness
4. Release under control
5. No vigorous sonication
6. Steer clear of first pass metabolism
7. Steer clear of gastric intolerances
8. More tailored to a particular location
9. Enhanced patient adherence
10. Easily applied and convenient.

DISADVANTAGES:

1. Itchy skin associated with contact dermatitis
2. The potential for allergic responses
3. The inadequate skin permeability of certain medications
4. It is difficult for drugs with big particle sizes to pass through the skin.
5. The bubble that appears when emulgel is being formulated.

Types of Emulgel: [4]

1) Micro Emulsion:

Micro emulsions are thermodynamically stable, optically transparent mixes of a biphasic o/w systemic stabilized with a surfactant. Droplets don't agglomerate and range in size from 10 to 100nm. It contains specified quantities of water, surfactant, co-surfactant, and oil. Extremely low interfacial tension, a wide interfacial area, and the capacity to dissolve both aqueous and oil-soluble substances are just a few of the special qualities that micro emulsions may possess. Because the stratum corneum's diffusion barrier is lowered by the components of micro emulsion, the medicine may penetrate the tissue more quickly. Micro emulsions have a low skin retention capacity because to their low viscosity, which limits their usage in the pharmaceutical sector.

2) Nano emulgel:

A transparent oil-water dispersion known as a nanoemulsion is thermodynamically stable because it contains molecules of cosurfactant and surfactant with globule sizes ranging from 1 nm to 100 nm. The word Nanoemulgel is used when the emulsion and gel are combined. Comparing Nanoemulsion to more conventional formulations like emulsions and gels, several medicines exhibit increased transdermal penetration. The Nanoemulsion has improved transdermal and dermal distribution capabilities both in vivo and in vitro. Due to its tiny globule size and high loading capacity, the medication readily enters the skin and has a short-lived therapeutic impact.

3) Macro emulsion gel*:*

Emulgel that contains emulsion droplets with a particle size higher than 400 nm. The individual droplets are not visible to the naked eye, yet they are plainly apparent under a microscope. Surface-active substances can aid in stabilizing macroemulsions, which are thermodynamically unstable

Ideal characteristics of emulgel:

1) Being greaseless.
2) Easily spreadable.
3) Easily removable.
4) Emollient.
5) Non-staining.
6) Longer shelf-life,
7) Bio-friendly.
8) Pleasing appearance.

Ideal properties of emulgel to formulate as emulgel:

Properties	**Criteria**
Effective concentration	Less than 10 mg
$t_{1/2}$	≤ 10hr.
Molecular mass	800 Dalton or less ; Desirably 500 Dalton or less.
Log p value	0.8-5
Skin permeability coefficient	≥ 0.5 x 10-3 cm/hr.
Skin irritation	Non irritating
Polarity	less
Molecular size	Small

Important Constituents For The Preparation Of Emulgel:

1) Vehicle:

As the composition of the vehicle may significantly affect the pace and amount of absorption, comprehensive pharmaceutical research has demonstrated that the vehicle is a key connection between medication potency and therapeutic efficacy. In other cases, substances in the vehicles, such humectants, which have a strong affinity for water, may dry the stratum corneum and reduce penetration. They also have an impact on medication absorption by causing skin surface water vapor to evaporate.

The vehicle has the following characteristics:
a) During distribution, place the medicine on the skin.
b) Drug migration at the site of action is unrestricted.
c) Send the medication to the desired location and keep it there.
d) Specifically developed to address the anatomic spot being treated.

Aqueous Material:

The aqueous phase of an emulsion is formed by aqueous material. Water and alcohols are among the often utilized substances.

Oils:

The oily phase of the emulsion is formed by oils. Fish liver oils, different fixed oils of vegetable origin, non-biodegradable mineral castor oils that have a local laxative action, and other topically applied emulsions.

Quantity of vehicles used in emulgel:

Chemicals	Quantity	Dosage Forms
Light liquid paraffin	7.5%	Emulsion and Emulgel
Isopropyl palmitate	7-7.5%	Emulsion
Isopropyl stearate	7-7.5%	Emulsion
Isopropyl myristate	7-7.5%	Emulsion
Propylene glycol.	3-5%	Gel

2) Emulsifier:

The main purpose of an emulsifying agent is to facilitate the emulsification of oil and water during formulation. They make the emulsion more stable and extend its shelf life, which for commercial preparation might range from days to months or years. This delays the emulsion's phase separation. As emulsifying agents, sorbitan monooleate (Span 80), polyoxyethylene sorbitan monooleate (Tween 80), stearic acid, and sodium stearate are the main ingredients in emulgel

3) Gelling Agents:

These substances are used to create gel bases so that emulsion may be added to them to create emulgel. By expanding in the aqueous phase and forming a gel-like structure, gelling agents are used to enhance the consistency of any dosage form. They are utilized in emulgel as a thickening agent.

Gelling Agents	***Quantity***	***Dosage forms***
Carbopol-940	1%	Emulgel
Carbopol-934	1%	Emulgel
HPMC-2910	2.5%	Emulgel
Sodium CMC	1%	Gel
HPMC	3.5%	Gel.

4) Penetration Enhancers:

These are the substances that are utilized to boost a drug's ability to penetrate the skin. They facilitate drug absorption through the skin and momentarily disturb the stratum corneum skin barrier's highly organized structure, fluidize the lipid channels between corneocytes, change how the drug is partitioned into the skin's structures, or improve skin delivery. Penetration Enhancer used in emulgel.

Penetration Enhancer	*Quantity*	*Dosage Form*
Oleic acid	1.5%	Gel
Lecithin	4.5%	Gel
Urea	8.0%	Gel
Isopropyl myristate	5.0%	Gel
Linoleic acid	4.5%	Gel
Menthol	4.5%	Emulgel
Clove oil	7.0%	Emulgel

Ideal Properties Of Additives:

1) They should be nontoxic.
2) They should be easily available.
3) They should be cheap.
4) They do not be contraindicated.
5) They should chemically and physically be stable.

Method of preparation of emulgel: [2]

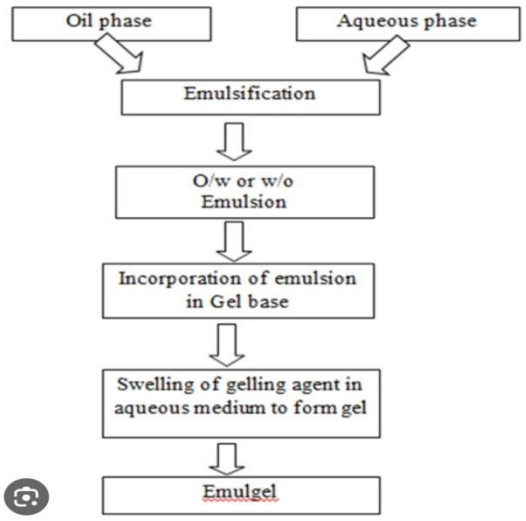

Fig.2: Method of preparation of emulgel

Step1: Preparation of gel using the gelling agent:

Sufficient quantity of Carbopol 940 (1% w/w) was weighed and sprinkled onto warm distilled water with continuous stirring. The dispersion was allowed to hydrate for 1-2 hours. Other ingredients like propylene glycol (10% w/w) and glycerol (10% w/w) were added subsequently to the aqueous dispersion with continuous stirring. A required quantity of drug (1% w/w) was added and properly dispersed. The dispersion was neutralized to pH 6 using tri ethanolamine and the final weight was adjusted with distilled water.

Step 2: Preparation of Emulsion:

Depending upon whether oil in water or water in oil emulsion was formulated.

Step 3: Incorporation of the emulsion into gel base:

Hence, the emulsion was incorporated in gel base to form emulgel.

Evaluation of Emulgel: [3]

1 .Physical appearance:

The colour, homogeneity, consistency and pH The pH values of 1% aqueous solutions of the prepared Gellified Emulsion were measured by a pH meter (Digital pH meter).

2. Spreadability:

Spreadability is checked by "slip" and "drag" character of emulgel. The 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. A ground glass slide is fixed on this block. An excess of emulgel 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 indicate 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.

3. Extrudability study:

It is a usual empirical test to measure the force required to extrude the material from tube. The method applied for 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 upon the quantity in percentage of emulgel and emulgel extruded from lacquered aluminum collapsible tube on application of weight in grams required to extrude at least 0.5 cm ribbon of emulgel in 10 seconds. More quantity extruded better is extrudability. The measurement of extrudability of each formulation is in triplicate and the average values are presented. The extrudability is than calculated by using the following formula:

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

4. Globule size and its distribution in emulgel:

Globule size and distribution was determined by Malvern zetasizer. A 1.0 gm sample was dissolved in purified water and agitated to get homogeneous dispersion. Sample was injected to photocell of zetasizer. Mean globule diameter and distribution was obtained.

5. Rheological Study:

The viscosity of the different emulgel formulations is determined at 25°C using a cone and plate viscometer with spindle 52 and connected to a thermostatically controlled circulating water bath.

6. Swelling Index:

To determine the swelling index of prepared topical emulgel, 1 gm of gel is taken on porous aluminum foil and then placed separately in a 50 ml beaker containing 10 ml 0.1 N NaOH. Then samples were removed from beakers at different time intervals and put it on dry place for some time after it reweighed. Swelling index is calculated as follows:

$$\text{Swelling Index (SW)} \% = [(Wt - Wo) / Wo] \times 100.$$

Where, (SW) % = Equilibrium percent swelling,

Wo = Original weight of emulgel at zero,

Wt = Weight of swollen emulgel aftertime t

7. Ex–vivo Bioadhesive strength measurement of topical emulgel:

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

8. Drug Content Determination:

Take 1 gm of emulgel. Mix it in suitable solvent. Filter it to obtain clear solution. Determine its absorbance using UV spectrophotometer. Standard plot of drug is prepared in the some solvent. Concentration and drug content can be determined by using the same standard plot by putting the value of absorbance in standard plot equation.

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

9. In Vitro Release/Permeation Studies:

Franz diffusion cell (with effective diffusion area 3.14 cm2 and 15.5 ml cell volume) was used for the drug release studies. Gellified Emulsion (200 mg) was applied onto the surface of egg membrane evenly. The egg membrane was clamped between the donor and the receptor chamber of diffusion cell. The receptor chamber was filled with freshly prepared PBS (pH 5.5) solution to solubilize the drug. The receptor chamber was stirred by magnetic stirrer. The samples (1.0 ml aliquots) were collected at suitable time interval. Samples were analyzed for drug content by UV visible spectrophotometer after appropriate dilutions. Cumulative corrections were made to obtain the total amount of drug release at each time interval. The cumulative amount of drug released across the egg membrane was d etermined as a function of time.

10. Microbiological assay:

Ditch plate technique was used. It is a technique used for evaluation of bacteriostatic or fungistatic activity of a compound. It is mainly applied for semisolid formulations. Previously prepared Sabouraud's agar dried plates were used. Three grams of the Gellified Emulsion are placed in a ditch cut in the plate. Freshly prepared culture loops are streaked across the agar at a right angle from the ditch to the edge of the plate. After incubation for 18 to 24 hours at 25°C, the fungal growth was observed and the percentage inhibition was measured as follows.

% inhibition = L2 / L1 × 100

Where, L1 = total length of the streaked culture , and

L2 =length of inhibition.

11. Skin irritation test:

The preparation is applied on the properly shaven skin of rat and its adverse effect like change in colour, change in skin morphology should be checked up to 24 hrs. The total set of 8 rats can be used of the study. If no irritation occurs the test is passed. If the skin irritation symptom occurs in more than 2 rats the study should be repeated.

12. Accelerated stability studies of Gellified Emulsion:

Stability studies were performed according to ICH guidelines. The formulations were stored in hot air oven at 37 ± 2°, 45 ± 2° and 60 ± 2° for a period of 3 months. The samples were analyzed for drug content every two weeks by UV-Visible spectrophotometer. Stability study was carried out by measuring the change in pH of gel at regular interval of time.

Packaging Of Emulgels:

Emulgels are packaged in either an aluminum laminated tube with a moulded seal and a propylene screw cap, or in aluminum tube with a membrane seal and an interior coating of phenoxy-epoxy lacquer.

Materials for tubes with laminates

1) Laminated foil

It offers a barrier against light, air, and moisture.

2) All laminated plastic

It features a barrier that resists chemicals.

Marketed Formulation of emulgel:

Sr.no	Brand Name	Active Pharmaceutical Ingredient.
1.	Adwiflam Emulgel	Diclofenac diethylamine, Methyl Salicylate &Menthol
2.	Avindo Gel	Azithromycin
3.	Cataflam Emulgel	Diclofenac Potassium
4.	Diclomax Emulgel	Diclofenac Sodium
5.	Diclona Emulgel	Diclofenac Diethylamine
6.	Denacine Emulgel	Clindamycin Phosphate
7.	Isufen Emulgel	Ibuprofen
8.	Miconaz-H-Emulgel	Miconazolenitrate ,Hydrocotisone
9.	Nucoxia Emulgel	Etoricoxib
10.	Volini Gel	Diclofenac Diethylamine
11.	Nadicin cream	Nadifloxacin
12.	Lupigyl gel	Metronidazole
13.	Cloben gel	Neomycin
14.	Topinate gel	Clabetasol propionate

Conclusion:

In the recent years, topical medication delivery has been increasingly popular in recent years. Emulgel will be a well-liked drug delivery method since it has an advantage in terms of spreadibility, adhesion, viscosity, and extrusion. Additionally, they will be used as a loading hydrophobic drug solution in water soluble gel bases. Because it is non-greasy, gel-like, and devoid of oily bases, it delivers higher drug release when compared to other topical drug delivery systems. When emulsion is introduced, gel transforms into a dual control release system that improves stability and resolves problems with phase separation and emulsion creaming. Emulgel has demonstrated efficacy in treating a number of cutaneous disorders, making it a viable medicine delivery approach in the field of dermatology. Emulgel is a better topical medication delivery technology than the ones currently in use since it has many penetration enhancers that can increase the impact. The use of emulgel can be expanded to encompass different cosmetic formulations, analgesics, anti-inflammatory, antifungal, and anti-acne products.

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