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A Review on Emulgel- Method for Delivering Topical Drugs

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ABSTRACT
Nowadays, Drugs are consumed orally in 74% of cases and are not as effective as expected. Transdermal medication delivery method was developed to improve such characteristics. TDDS refers to drug administration by way of the skin to get a systemic impact of a drug. TDDSare pharmaceutical dosing formstransfer to viable epidermal and/or skin's dermal tissues for localised treatment benefit while a significant portion of the drug is carried into the systemic blood circulation. The adherent, of the TDDS is crucial to the product's safety, effectiveness, and quality. [8]
There are different forms of transdermal application like cream,ointment, lotion but Emulgel is effective due to its combine property.Emulgels, which contain a System for double release control that includes both a gel and an emulsion, have become one the imprtant promising topical delivery systems. The main goal of this formulation hydrophobic drugs should be transferred to systemic circulation through the skin. Skin is a target organ that is easily accessibleas a target organ for diagnostic and therapy is a distinctive aspect of topical drug delivery.
Emulgel is the name given to the dosage form created by combining gel with emulsion. Instead of just mixing drugs into the gel base, this may demonstrate higher drug stability and release. Other trimming methods include niosomes and liposomes, which are nanosized and may leak due to their vesicular structure, resulting in less effective entrapment.

TDDS (Transdemal drug delivery system)

Drugs have been administered to the human body by a variety of methods over the years, including oral, sublingual, rectal, parental, etc., to cure diseases. When traditional methods of medication administration fail or when a local skin disease, such as a fungal infection, occurs, the TDDS is often utilised. To achieve a drug's targeting impact or treating skin problem directly, a TDDS applies a formulation or drug containing drug directly to the skin. Although dermatological products used on the skin come in a various formulations and have a range of textures from liquid to powder, semisolid preparations are the most widely used.[2]

The ability to administer drugs more accurately to a specific location, avoiding gastrointestinal incompatibility, and avoiding metabolic degradation associated with oral administration are only a few benefits of TDDS. The physiochemical characteristics of the carrier and the drug used directly affect release of drugs from topical formulations. When a drug is delivered topically, it diffuses from the delivery mechanism, travels to its target location, and is then absorbed by the skin. Hence, speeding up the drug's reaches from the dosage form could enhance percutaneous absorption. Moreover, topical administrations allow a constant distribution for a longer length of time and an enhanced bioavailability by bypassing the liver's first pass metabolism action.

The Benefits of Drug administration via skin include:-[8]

1. Avoidance of presystemic metabolism.
2. Because of the convenience of use, patients can self-administer these products.
3. In an emergency, removing the patch at any moment during therapy can immediately cease medication intake.
4. While the structure and biological composition of skin is almost same in all individuals, there is little inter and intra patient variance.
5. Drug that cause gastric discomfort and absorption can be delivered safely through the skin.
6. Drugs having short biological half-lives that would usually require frequent dosage can be delivered in a continuous, non-invasive manner.
7. Patient compliance improves when dose is lowered.
8. Treatment failures caused by inconsistencies in the dosing with conventional therapies can be avoided.

Disadvantages of TDDS:

1. The medicine and excipients may cause skin irritation in people with contact dermatitis.

International Journal of Pharmaceutical Research and Applications
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2. There is a chance of allergic reactions.

3. An enzyme in the epidermis could denature the medication.

ANATOMY OF SKIN (BARRIER FOR TOPICAL DRUG DELIVERY)

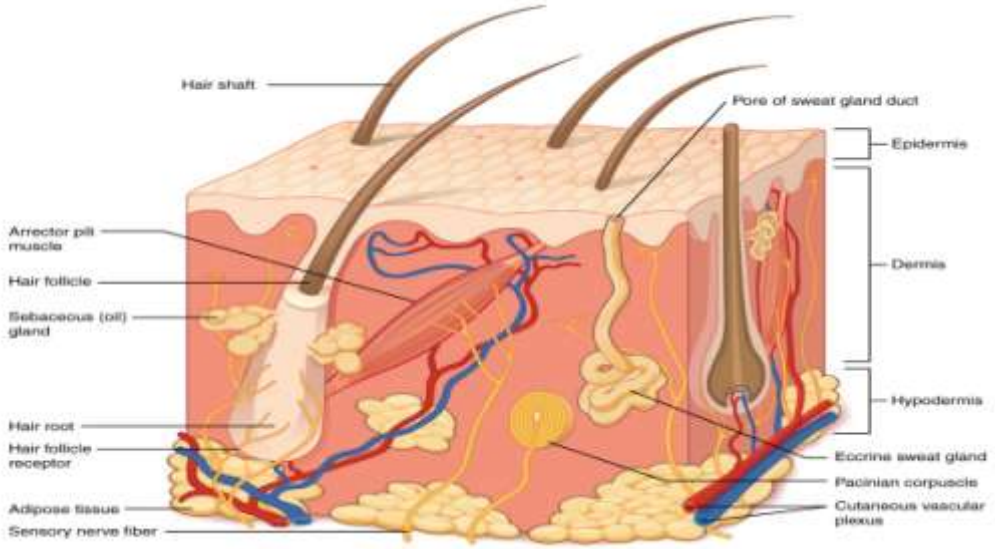
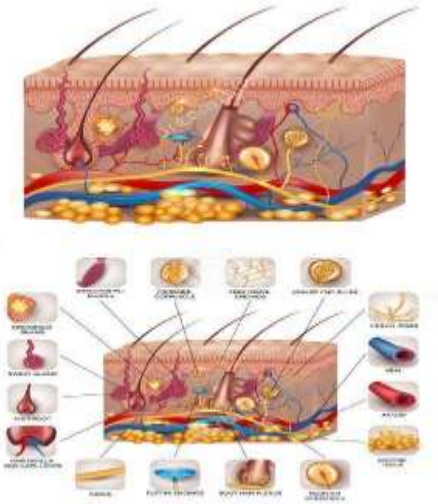


Fig no.1 Structure of skin

Skin is the biggestorgan covering around 20 square feet area. It is quite complex.The skin serves to control body temperature, provides protection from the environment and microorganisms, and allows for perception of touch,heat and cold.The dermal barrier is formed by the dermis& its derivative structures fig .(above fig no mention)



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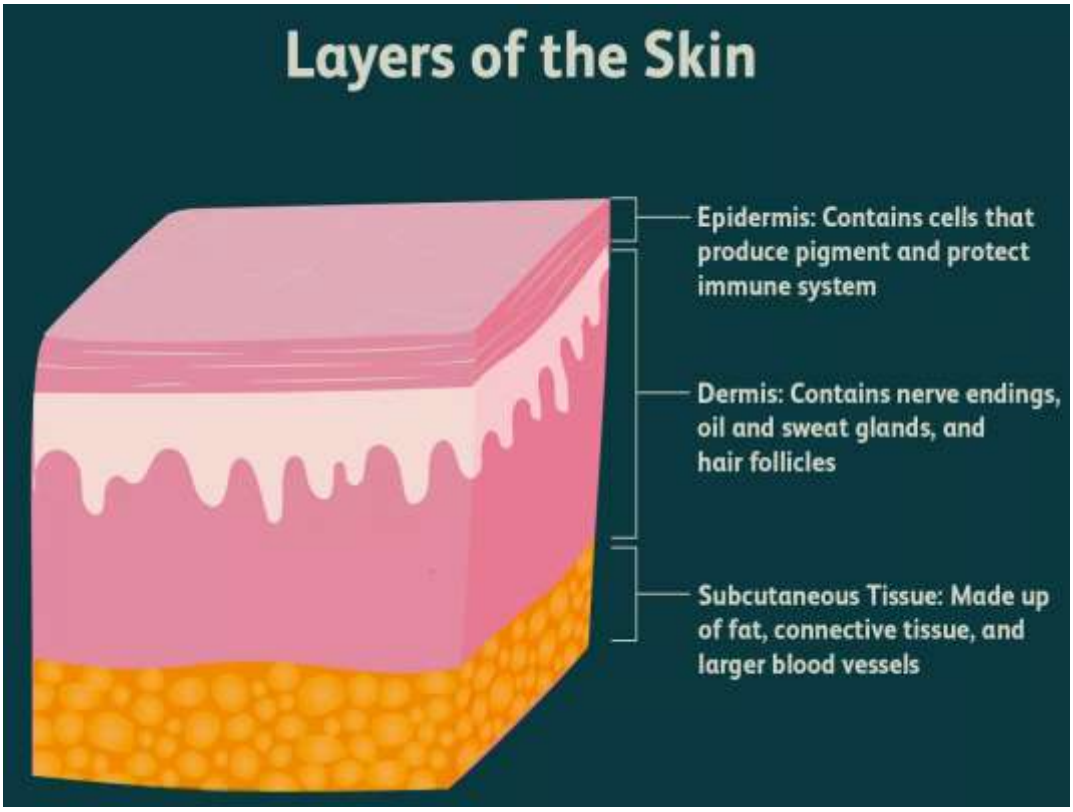

Fig no.2 Layer of skin

The skin include three layers.: the epidermis, the dermis, and subcutaneous tissue

The Epidermis

The epidermis is the Upper layer of skin. Depending on where it lies on the body, it varies in thickness. Its thickness ranging from 50-100 µm.

The epidermis contains five layers:

1) Stratum corneum:
2) Stratum lucidum
3) Stratum granulosum
4) Stratum spinosum
5) Stratum basale

Dermis

The dermis lies just below the viable epidermis.It is a kind of structural fibrin,and histologically, very few cells in normal tissue resemble it. The dermis is a loose connective tissue matrix made of fibrous protein embedded in an amphorphose ground material, with a thickness that ranges from 2000 to 3000 µm

The dermis is split into two parts:

1)Papillary Dermis
2)Reticular Dermis

Subcutaneous tissue :

Subcutaneous tissue is the innermost layer of the skin. primarily consistingof Fat ,Connectivetissues,Larger blood vessels,Nerves.It shields your muscles and internal organs against shocks and falls and insulates you from temperature changes.

Subcutaneous layer also:

1. Gives the body its smooth, contoured appearance
2. Temperature is controlled by the contraction and dilatation of blood vessels.
3. It serves as a binding for bones, muscles, and other organs to the skin, and it contains deep pressure receptors.
4. Produces leptin, a hormone that aids in maintaining homeostasis (balance among all of your body's systems so they can work properly).

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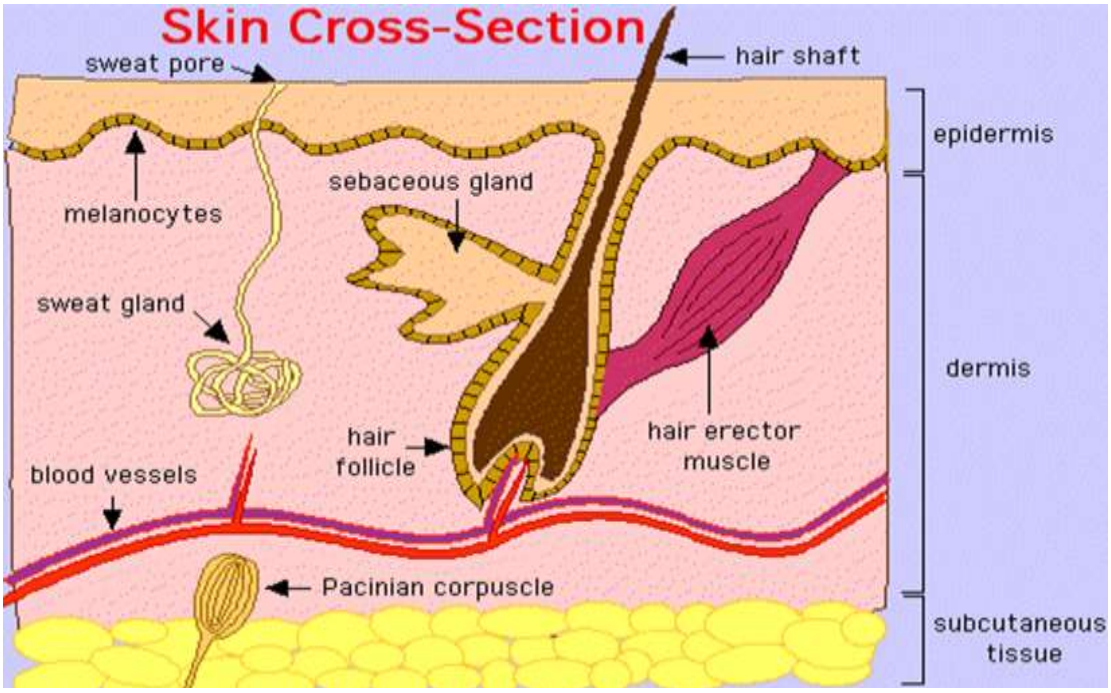

Fig no.3 Cross section of skin

SELECTION OF DRUG CANDIDATE FOR TRANSDERMAL DELIVERY:[8]

Ideal characteristics:

A porous skin barrier

1. Drugs with low molecular weight (<400 dalton)
2. Drugs having lower melting point
3. Drugs which are partially soluble in oil and water

Adequate skin acceptability

1. Non-irritating drugs
2. (Non-metabolizing drugs) Clinically sufficient
3. It is necessary to extend administration.
4. Side effects on target tissues must be minimised.

There are two different categories of topical delivery products. These products are both internal and external. [31]

The consistencies of topical preparations can be categorised. [8]

Table no.1 Classification of topical preparation [32].

Solid Preparation	Liquid Prepartion	Semisolid Preparation	MisllaneousPrepartion
• Powders • plasters	• Lotions, • emulsion	• Ointment • creams • Gels	• Transdermal drug delivery systems • Tapes and Gauzes • Rubbing alcohols • Liquid cleanser • Topical aerosol

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INTRODUCTION:

❖ **Emulgel**:

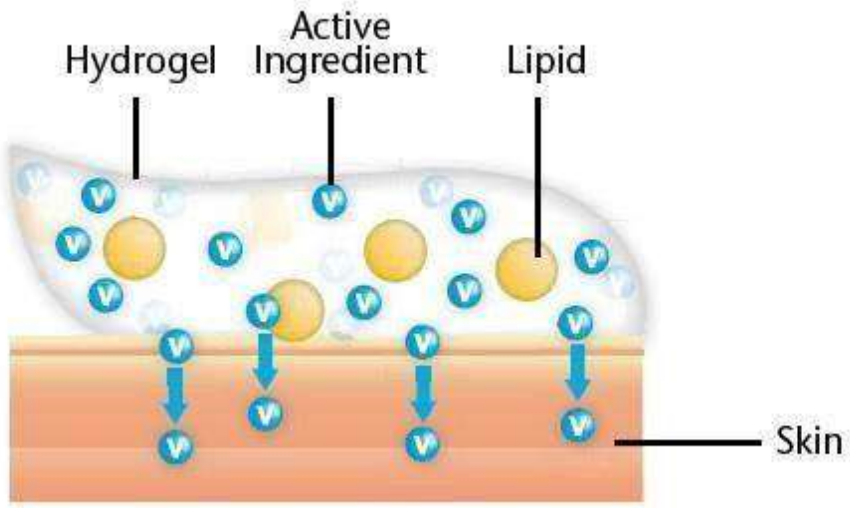

Fig no 4.Schematic Presentation of Emulgel Penetration Through Skin[30]

Gels appear to be more favourable than other semisolid formulations for both medicinal and cosmetic treatments. Emulgel is the term used to describe the gel and emulsion mixture .The potential drug delivery method for hydrophobic drug is emulgel.

Emulgel, new methods of topical medication administration, features two different types of release controls: gel and emulsion.Emulgel's benefits include being transparent, emollient, greaseless, and readily spreadable and washable.[33]

Emulgel is made using the incorporation process. Emulgel are frequently employed for the administration of anti-inflammatories, and antifungals, anti-acne, and other cosmetic compositions. Research on emulgel indicate that it will be possible to give more topical medications in the future due to its benifits over alternatives.[4]

The characteristics of emulsion and gel formulations are unique. .however, the gels have some drawbacks in terms of hydrophobic drug delivery. This limitation is being overcome Using an emulgel. Classical emulsion may beturned to emulgel by using a gelling agent [4].

Components of Emulgel:[10]

A. Emusion

B. Gel

A. Emulsion:

Emulsions are biphasic systems composed of two unmixable liquids that are become mixable by using emulsifying agent. The emulsion is stabilised by the emulsifiers. They are readily removed from the skin and have high penetration.

Methods of preparation of emulsion:

1. O/W emulsion
2. W/O emulsion
3. Phase inversion method

B. Gel:

Gel is a two-component system with a liquid-rich, semisolid character.

Types of emulgels:

1. Macroemulgel

In macroemulgel emulsion has droplet sizes larger than 400nm. Macro emulsions are thermodynamically unstable.

2. Microemulgel

Micro emulsions, which have droplet sizes between 10 and 100 nm, are clear and dynamically stable.

3. Nanoemulgel

These are thermodynamically stable. The globule size in nanoemulsion is less than 100nm.

Constituents of emulgel:

1.Drug:

The qualities of the drug have the greatest impact on its absorption via the skin. These physicochemical and biological characteristics of drugs are essential in the formulation of emulgels

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for topical or transdermal applications. The drug candidate should have a high pKa value, a half-life (t1/2) of less than 10 hours, a smaller molecular size, a molecular mass of 500 daltons or less, a partition coefficient (logP) value of 0.8 to 5, and less polarity. Moreover, the drug candidate should be non-irritating, with a skin permeability value of at least 0.510-3 cm/h[3].

2.Vehicle:vehical to penetration enhancer [34]

- The drug is properly deposited on the skin to create an even film, and the drug is freed from the vehicle so it may go to the active site.
- Drug delivery at a specified site.
- Keep the therapeutic concentration of the drug in the target tissue for an adequate amount of time.

3.Aqueous material:

The aqueous material is used to create the aqueous phase of the emulsion. Water and alcohols are the two most likely agents to be utilised.

4.Oils: [35] [36]

The oils are utilized as vehicle for drug or for their sensory characteristics. Oils provides both laxative effect and as a nutritional supplement. Some e.g., of oils used in emulgel are castor oil, maize oil, arachis oil, lemongrass oil, etc.

5.Emulsifiers:[37]

Non-ionic surfactants are commonly employed as emulsifiers in emulsion. Non-ionic surfactants that are often utilised include Tween 80, Span 80, Span 20, Tween 20, stearic acid, and sodium stearate. Emulsifiers are substances that are used to regulate the stability and emulsification processes.

6.Gelling agents:

Mostly used to improve the uniformity of the dose form. Carbomer grades such as Carbopol 934, Carbopol 940, and Carbopol 941 are the most often used gelling polymers. As gelling agents, gelling polymers derived from natural, synthetic, and semi-synthetic sources are utilized.
Natural polymers include xanthan gum, guar gum, tragacanth gum, and dextran.

7.Penetration enhancers:

Vehicles containing penetration-enhancing ingredients are used to improve drug absorption. These agents act by temporarily disrupting the skin barrier, fluidizing the lipid channels between the corneocytes, altering the partition coefficient of the drug, or otherwise improving drug delivery into the skin. Natural and synthetic penetration enhancers are the most commonly utilised forms.

Mechanism for Improving Drug Penetration & Absorption:

1. Chemical enhancement
2. Physical enhancement
3. Biochemical enhancement
4. Supersaturation enhancement

Advantages of Emulgel:[9]

1. Improved patient acceptance.
2. Provide a specific medicine
3. Simple discontinuance of treatment.
4. Increase bioavailability; even low dosages can be beneficial as compared to other typical semisolid preparations.
5. Stable formulation by lowering surface interfacial tension, resulting in an increase in aqueous phase viscosity, more stable than transdermal preparations, powders are hygroscopic, creams exhibit phase inversion or cracking, and ointment displays rancidity due to oily basis.
6. Hydrophobic drugs can be introduced into emulgels by utilizing emulsion as the durg carrier, which is then dispersed in the gel.
7. Offer a targeted action that enhances the impact of a drug with a short half-life.
8. Simple and inexpensive preparation.
9. Drug incorporation capability is superior to those of other innovative techniques such as niosomes and liposomes.
10.Penetration to skin is increased by Both hydrophilic and hydrophobic nature.

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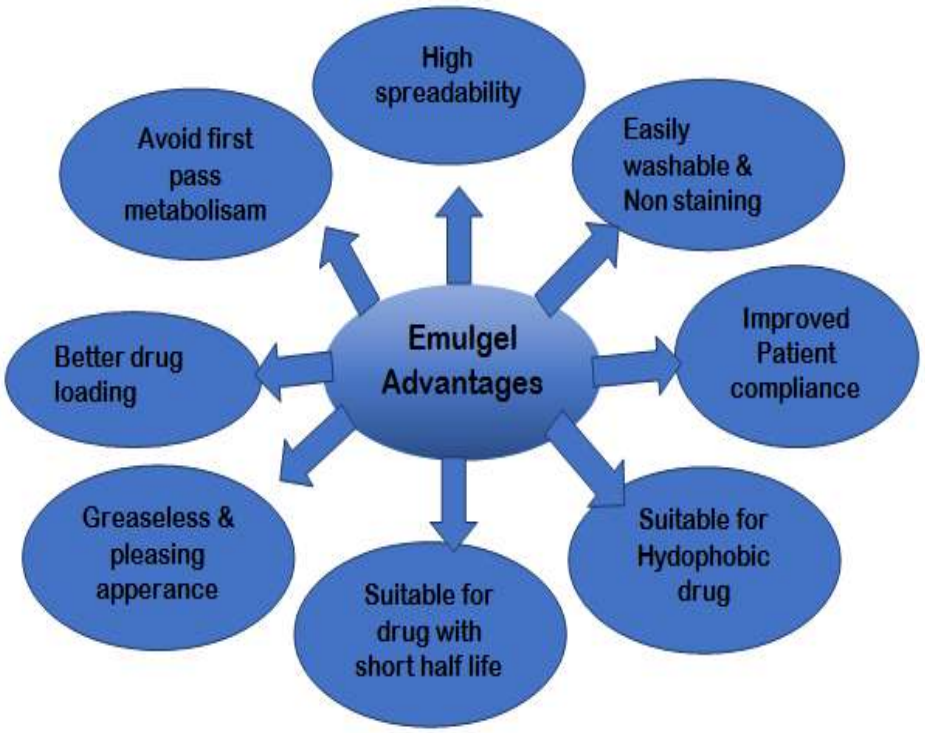


Fig.

Disadvantages of Emulgel [2, 4]:-

1. Weak macromolecule absorption.
2. Bubble entrapment During the formulation process.
3. Hydrophobic drugs are the best choices for these delivery systems.

Rational of emulgel as TDDS:

Topical medications including ointments, creams, and lotions are often used yet have significant drawbacks. When applied, they are extremely sticky and make the patient uncomfortable. They also need rubbing to apply and have a lower spreading coefficient. They also display the stability issue. The usage of gels has used in both cosmetics and medicinal preparations as a function of all these elements under the main category of semisolid preparation.

A gel is a colloid that is normally 99% liquid and is immobilised by surface tension between it and a macromolecular network of fibres made from a small portion of gelatin. Despite the many benefits of gels, one significant barrier is the delivery of hydrophobic medicines. To **overcome this barrier, an emulsion-based technique is being developed**, allowing even a hydrophobic therapeutic moiety to be directly incorporated and delivered through gels [7].

Many medicinal treatments that either improve or restore a basic skin function or pharmacologically modify an activity in the tissues specified are applied to the skin or mucous membrane. These products are known as topical or dermatological products.

Table no.2 Factors Influencing Topical Absorption of Drug:

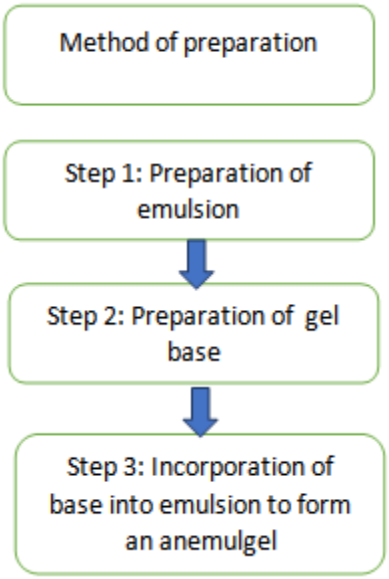
Physiological Factors	Physiochemical Factors	Drug /excipient factor
1. Skin thickness	1. Partition coefficient	1. Effect of Drug
2. Lipid content	2. Molecular weight (<400 dalton)	2. Effect of the vehicle
3. Density of hair	3. Degree of ionization (only	3. Effect of penetration enhancer

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 3 May-June 2023, pp: 45-57 www.ijprajournal.com ISSN: 2249-7781

follicles	unionized drugs gets absorbed well).	
4. Density of sweat glands	4. Effect of vehicles	4. Effect of polymer
5. Skin pH	-	5. Effect of gelling agent
6. Blood flow	-	

METHOD OF PREPARATION FOR EMULGEL

It has a very easy and cost-effective technique of preparation that consists of three phases



Step 1: : Preparation of emulsion

Oil phase: oil phase was prepared by dissolving lipophilic surfactant in oil.

Water phase: The aq. Phase was prepared by dissolving drug in ethanol or hydrophilic surfactant or water and all these solutions was mixed together at constant stirring to prepared aqueous phase

Then both the aqueous phases and oil phase were heated up to 70-80oC. Then oil phase is added into aq. Phase with constant stirring on mechanical stirrer until cooled to room temp.

Step 2: Preparation of gel base

Here, two distinct polymers, were used to develop the gel basis. In 100 ml of pure water, the gelling polymers were dissolved with constant stirring on a mechanical stirrer. TEA was used to bring the pH to a range of 6-6.5.

Step 3: Incorporation of base into emulsion to form an anEmulgel

The gel base and emulsion were mixed in 1:1 ratio to prepared the emulgel by constant stirring on mechanical stirrer

Evaluation of Emulgel:

1. Physical Examination:

The colour, homogeneity, consistency, and phase separation of the prepared emulgelformulations are visually evaluated.

2. Rheological Studies:

At 25°C, the viscosity of the various emulgel formulations is measured using a cone and plate viscometer with spindle 52 (Brookfield Engineering Laboratories,) which is coupled to a thermostatically regulated circulating water bath.

3. Spreading Coefficient:

Spreadibility is assessed using Mutimer et al (1956) equipment, which is adapted in the laboratory and utilised for the investigation. It is made up of a wooden block with a pulley at one end. This results in a distance of 7.5 cm. A shorter interval denotes more spreadability

International Journal of Pharmaceutical Research and Applications
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4. Extrudability Study of Topical Emulgel (Tube Test):

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 therheogramcorresponding to a shear rate exceeding the yield value and exhibiting consequent plug flow.

5. Drug ContentDetermination:

Take 1gm of emulgel to determine the drug content. Combine it with a suitable solvent. To get a clear solution, filter it. Use a UV spectrophotometer to determine its absorbance. In the same solvent, a standard plot of drug is created. Concentration and drug content may be calculated using the same standard plot by putting the absorbance value into the standard plot equation.
Drug content = (Concentration × Dilution factor × Volume taken) × Conversion factor.

6.Skin Irritation Test:

The preparation is applied to properly shaved rat skin, and its adverse effects, such as colour change and skin morphology, should be monitored for up to 24 hours. The study can utilise a total of eight rats. If no irritation develops, the test is considered successful. The trial should be repeated if the skin irritation symptom arises in more than two animals.

7. Determination of pH:

A digital pH metre is used to determine it. The pH metre is immersed into the emulgel and the pH is measured three times.

8. Globule size and its distribution in Emulgel:

The Malvern zeta sizer determines globule size and distribution. To get a homogeneous distribution, a 1.0 g sample is dissolved in purified water and stirred. The sample was injected into a zeta sizer photocell. The mean globule diameter and distribution are calculated.

Packaging of Emulgels

Emulgel is often packaged in membrane-sealed lacquered aluminium tubes with an inner coating of a phenoxy-epoxy based lacquer and a propylene screw cap, or aluminium laminated tubes with a moulded seal and a propylene screw cap (Public Assessment Report of Voltaren Emulgel). These lamination tubes combine the advantages of aluminium tubes with the look of plastic. The latest generation of laminate tubes use trimming technology to create tubes with maximal graphic area. The laminate layer stops light, air, and moisture from passing through.

It is made up of two layers: an aluminium layer for integrity and shelf-appealing plastic tubes. The protective barrier serves several purposes, including providing a high gloss protective lacquer, a resistant barrier for items that require optimal compatibility, and flavour and aroma protection with limited absorption [55].

Material for laminates tubes:

Foil laminates:

These materials act as a barrier against moisture, air, and light. It decreases the aroma's absorption (flavor and fragrance). Moreover, it exhibits aluminium characteristics with a plastic-like appearance.

All laminated plastic:

It features a barrier that resists chemicals. It provides a plastic-like look and feel and aids in maintaining shape and form. It seems to be both opaque and translucent.

Table no.3 Marketed Formulations of Emulgel

Marketed formulation	API	Manufacturer	Use	product
1.Voltaren emulgel	Diclofenac diethyl ammonium	Novartis Pharma	Anti-inflammatory	

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 3 May-June 2023, pp: 45-57 www.ijprajournal.com ISSN: 2249-7781

2.Miconaz-H-emulgel	Miconazole nitrate, Hydrocortisone	Medical union Pharmaceutical	Topical corticosteroid & antifungal	
3.Levorag emulgel	Hibiscus, licorice, natural extracts	THD Ltd	Emollient	
4.Isofen emulgel	Ibuprofen	Beit Jala pharmaceutical	Anti-inflammatory	
5.Cataflam emulgel	Diclofenac dimethylammonium	Novartis Alcon	Anti-inflammatory	

Table no.4 Applications of Emulgel with use and Route of application

Sr.No	Drug	Route	Applications	References
1	Mangostin Extracts	Topical Emulgel	Food Supplements, Pharmaceuticals and Cosmetics.	[7]
2	Metronidazole	Topical Emulgel	Rosacea	(8)
3	Propolis	Topical Emulgel	Burn and Wound	[13]
4	Dexibuprofen-Capsaicin	Topical Emulgel	Acne	17)
5	C. tamala Leaves Extract	Topical Emulgel	Skin Photo-Damaging Effects	19)
6	Tretinoin	Topical Emulgel	Anti-Inflammatory Activity	20
7	Acyclovir	Topical Emulgel	Cold Sores	26
8	Desoximetasone	Topical Emulgel	Plaque Psoriasis	29
9	Atorvastatin	Topical Emulgel	Wound Healing	31
10	Diclofenac Diethylamine	Topical Emulgel	Analgesic	36
11	Brucine	Topical Emulgel	Anti-Inflammatory and Anti-Nociceptive Activities	38
12	Meloxicam	Topical Emulgel	Rheumatism	39
13	Curcumin	Topical Emulgel	Anti-Inflammatory Activity	40
14	Melatonin	Topical Emulgel	An Anti-Aging and Skin Protective Agent.	43
15	Betamethasone Sodium	Ophthalmic	Ocular Drug Delivery	47
16	Itraconazole And	Topical	SporothrixBrasiliensis	53

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 3 May-June 2023, pp: 45-57 www.ijprajournal.com ISSN: 2249-7781

	Clotrimazole Emulgels			
17	Furbiprofen	Topical	Arthritis	54
18	Ofloxacin	Topical Emulgel	Site Specific Delivery	55

NEG as an Advanced Approach in Topical Drug Delivery

NEG is a trimming method used in the topical delivery of hydrophobic drugs. The nanoemulsion and a gelling agent are combined to create the NEG. Most research is now focused on the transdermal administration of hydrophobic medicines using NEG technology. Because of the poor drug permeability through the skin caused by large particle size, the therapeutic uses of many traditional dosage forms, such as creams, ointments, gels, emulsions, and emulgels, are constrained. The NEG concept was developed as a result in order to solve the permeability issue

In NEG, a nanoemulsion is a solvent droplet that is stabilised by surfactants without using penetration enhancers[32]. Many investigations found that nanoemulsions delivered drugs to the skin more effectively than traditional emulsions, gels, creams, and ointments[33,34]. substantial voids and gaps in the skin samples treated with nanoemulsions as well as the drug extent retention at the site of action show that lipid bilayer rupture may be the cause of the increased permeability of medications from topical formulations of nano dimensions[35,36]. While nanoemulsion has several benefits, its low viscosity, spreadability, and stability restrict its use on the skin[37].

Future Perspectives

The formulation researcher's key challenge is to create a novel formulation in order to deliver hydrophobic medications because of their poor water solubility, which eventually reduces the bioavailability of drugs. As 40% of the drugs are hydrophobic, it has proven difficult to transfer them to the biological system. As a result, one of the key strategies for overcoming the drawbacks of oral medication delivery, such as drug solubility and bioavailability, is topical drug administration. The topical distribution of these kinds of hydrophobic drugs has been said to be improved by using emulgel, one of the several topical formulation techniques

A dual control release mechanism is produced when an emulsion is added to gel. Moreover, issues with emulsion creaming and phase separation are fixed, and its stability is increased. Due to the largre particle size of emulgel, drug permeability is its main drawback; this issue can be resolved by NEG systems, which include nanoemulsion into the gel matrix.

The NEGis made by including active ingredients that are efficient against bacterial, fungal, viral, or even melanoma infections. Nevertheless, additional molecular analysis on the medication absorption mechanism should be required. Hence, emulgel or NEG might be a possible drug delivery vehicle to treat certain dermatological conditions and numerous systemic diseases.

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