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Review Article

Emulgel: - A New Approach for Topical Drug Delivery

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ABSTRACT

Over the last decades the treatment of disease has been accomplished by administering drug to human body via various routes namely oral, sublingual, rectal and parenteral etc. The topical drug delivery system generally used when the systems of drug administration fails or in local infection like fungal infection. The topical application of the drug offer the potential advantages for delivering the drug directly to the site of action and delivering the drug for extended period of time at the affected site that mainly acts at the related region. Topical drug delivery can be defined as the application of a drug containing formulation to the skin to directly treat cutaneous disorder e.g. acne or cutaneous disorder. The various groups of semisolid preparations, the use of gels has expanded both in cosmetics and in pharmaceutical preparations. Despite of several advantages of gels there is a major limitation in delivery of hydrophobic drug moiety. This limitation can be overcome by the use of novel topical drug delivery.

INTRODUCTION

Topical has been used for centuries for the treatment of dermatological disorders. The spectrum of drugs/agents applied directly to the skin ranges from anti-inflammatory, antiseptic, antibacterial, antifungal, antiviral, anti-acne, antipigmentary, anesthetic compounds to skin emollients and protectants. The topical route has the main advantage of the direct delivery of drug to the target tissue i.e. skin and mucous membranes, bypassing the first-pass effect.

However, skin permeation of a drug moiety from the topical formulation is a multi-step process.[1] Dermatological products are diverse in the formulation and varied in consistency from liquid to powder but the most popular products are semisolid preparations. Within the major group of semisolid preparations, the use of clear, translucent gels has expanded both in cosmetics and in pharmaceutical preparations. Gels are a somewhat newer class of dosage form formed by entrapment of large amounts of aqueous or hydroalcoholic liquid in a complex of colloidal

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solid particles. Gel formulations usually provide faster drug release as compared with traditional ointments and creams. Rather than the many advantages of gels, a major limitation is a difficulty in the delivery of hydrophobic drugs. To minimize this limitation emulgels are prepared so that even a hydrophobic drug can enjoy the unique properties of gels. When gels and emulsions are used in combined form the dosage forms are known as Emulgels. The presence of a gelling agent in the water phase converts a traditional emulsion into an emulgel. The oil-in-water system is used to entrap lipophilic drugs while hydrophilic drugs are captured in the water-in-oil system.[2]

Now emulgels have been used for the treatment of various kinds of skin diseases such as those infected by fungal, bacterial, and viral species (acne, eczema, Herpes simplex). Research works on the antifungal drugs incorporated into emulgel have been carried by different scientists to judge their efficacy against fungal infections such as candidiasis. Species causing candidiasis are *Candida tropicalis*, *Candida albicans*, *Candida parapsilosis*, *Candida glabrata*, and *Candida krusei*. Formulating the emulgels was found useful in combating fungal infection. Scientists have been trying to develop emulgel of various drugs to treat various kinds of skin diseases.[3]

Emulgel:-

Emulgel is known as an emulsion that has been gelled by using a gelling agent. They can be made either o/w or w/o type. Emulgel is a stable and superior system that incorporates poor water-soluble drugs. In brief, emulgel is a combination of emulsion and gel. Despite the numerous advantages of gels, one significant disadvantage is the delivery of hydrophobic medications. As a result, an emulsion-based solution is being used to overcome this limitation, allowing even

hydrophobic therapeutic moieties to benefit from the unique properties of the gel.

Emulgel can deliver both hydrophilic and lipophilic drugs due to the presence of both aqueous and non-aqueous phases. In recent years, they have been used as a control release formulation.

These are biphasic systems that have better drug loading capacity and better stability.[4],[5] Emulgel has several good properties, such as good spreadability, greaseless, thixotropic, good shelf life, odorless, and a pleasant appearance over the conventional topical formulation.

Emulgel has both gel and emulsion properties and functions as a dual control release system.[6]

EMULGEL $\rightleftharpoons$ EMULSION + GEL

Types Of Emulgel: -

I. Microemulsion: -

Microemulsions are isotropic mixtures of a biphasic o/w system stabilized with a surfactant that is thermodynamically stable and optically clear. Droplets vary in size from 10 to 100nm and do not coalesce. It is made up of specific amounts of oil, co-surfactant, surfactant, and water. Microemulsions may have unique properties, including extremely low interfacial tension, a broad interfacial region, and the ability to dissolve both aqueous and oil-soluble compounds. The ingredients in microemulsion could help the drug permeate faster by lowering the stratum corneum's diffusion barrier.

However, because of their low viscosity, the use of microemulsions in the pharmaceutical industry is limited due to their low skin retention ability. To address this limitation, gelling agents like HPMC K100M, Carbopol 940, and guar gum are added to



the microemulsion to form microemulsion-based gels with a viscosity appropriate for topical application.[7],[8],[9]

II.Nanoemulsion :-

Nanoemulsion is transparent (translucent) oil-water dispersions that are thermodynamically stable due to surfactant and cosurfactant molecules with a globule size range from 1nm to 100 nm. When the emulsion is mixed with gel, the term Nanoemulgel is used. Many drugs have higher transdermal permeation with Nanoemulsion than with traditional formulations such as emulsions and gels. The Nanoemulsion possesses enhanced transdermal and dermal delivery properties in vivo as well as in vitro. Because of its high loading capacity and small globule size, the drug easily penetrates the skin and provides less therapeutic effect in a short period.

Emulgel with emulsion droplet particle sizes greater than 400nm. They are physically invisible, but under a microscope, the individual droplets can be seen clearly. Macroemulsions are thermodynamically unstable, but surface-active agent.

Rational :-

Various topical formulations such as creams, ointments, and lotions have several drawbacks. Some are greasy and sticky, which is a problem for patients who apply it, and there is little multiplication and the need for massaging. It can also be a stability problem for making hydrophilic drugs. Because of these disadvantages and the semi-solid product group, the use of gels has been expanded in medical and cosmetic products.

Sun is a colloidal arrangement that contains 99% of the water component in a macromolecular network of fibers made from a gelling agent and

water that is immobilized between them due to surface tension. Despite the benefits, the biggest problem is hydrophobic drug delivery. Emulsification strategies can be used to introduce lipophilic drug components into the topical system to overcome this problem.[10]

Factors Affecting Topical Absorption of Drug:- [11,12]

There are some factors which affect the absorption of drugs. Few of them are listed below.

I. Physiochemical Factor:-

- Partition coefficient
- Molecular weight (<500 Dalton)
- Degree of ionization
- Effect of vehicles

II.Physiological Factors:-

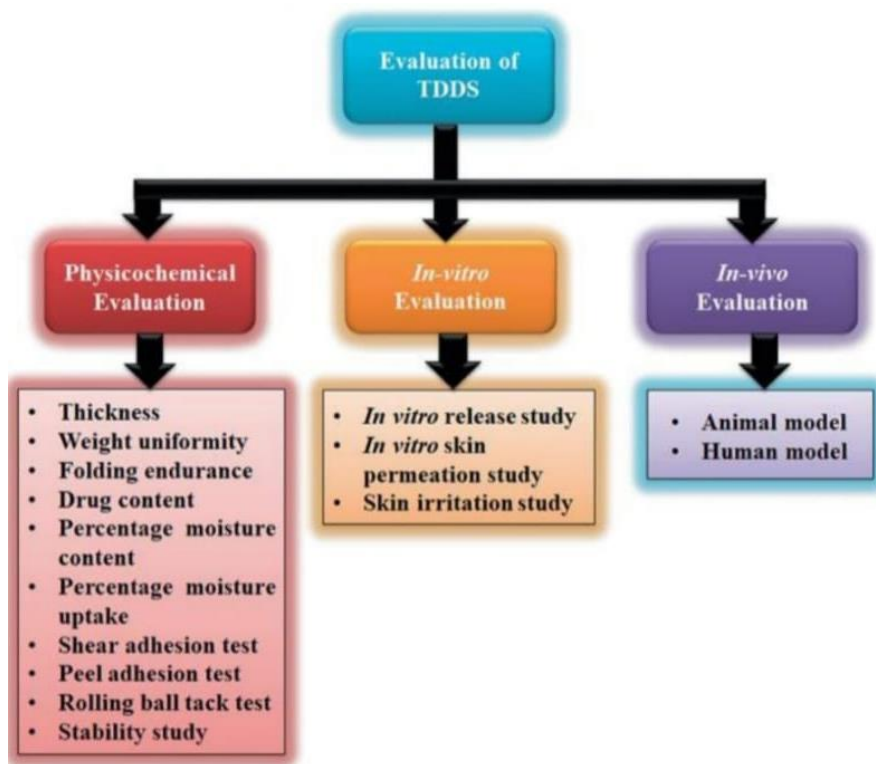
- Skin thickness
- Density of hair follicles
- Density of sweat gland
- Blood flow
- Hydration of skin
- Inflammation of skin

Type Of Skin:-

- Skin pH
- Lipid contents

Classification Of Topical Drug Absorption:-





Physiology Of Skin:-[13,14]

Most of the topical preparations are meant to be applied to the skin. So basic knowledge of the skin and its physiology function are very important for designing topical. The skin of an average adult body covers a surface area approximately 2m² and receives about one third of the blood circulating through the body. An average human skin surface is known to contain, on the average 40-70 hair follicles and 200-300 sweat ducts on every square centimeter of the skin. The pH of the skin varies from 4 to 5.6. Sweat and fatty acid secreted from sebum influence the pH of the skin surface. The skin can be considered to have Three distinct layers of tissue.

- Non-viable epidermis
- Viable epidermis
- Viable dermis

Subcutaneous Connective Tissue :-

I.Non- Viable Epidermis :-

Stratum corneum is the outer most layer of skin, which is the actual physical barrier to most substance that comes in contact with the skin. The stratum corneum is 10 to 20 cell layer thick over most of the body. Each cell is a flat, plate- like structure - 34-44 µm long, 25-36 µm wide, 0.5 to 0.20 µm thick - with surface area of 750 to 1200 µm stocked up to each other in brick like fashion. Stratum corneum consists of lipid (5-15%) including phospholipids, glycosphingolipid, cholesterol sulfate and neutral lipid, protein (75-85%) which is mainly keratin.

II.Viable Epidermis :-

This layer of the skin resides between the stratum corneum and the dermis and has a thickness ranging from 50–100 µm. The structures of the cells in the viable epidermis are physiochemically similar to other living tissues. Cells are held together by tonofibrils. The density of this region

is not much different than water. The water content is about 90%.

III.Dermis :-

Just beneath the viable epidermis is the dermis. It is a structural fibrin and very few cells are like it can be found histological in normal tissue. Dermis thickness ranges from 2000 to 3000 μm and consists of a matrix of loose connective tissue composed of fibrous protein embedded in an amorphous ground substance.

Subcutaneous Connective Tissue :-

The subcutaneous tissue or hypodermis is not actually considered a true part of the structured connective tissue is composed of loose textured, white, fibrous connective tissue containing blood and lymph vessels, secretory pores of sweat gland cutaneous nerve.

Emulsion :- [15]

Emulsion are generally thermodynamically unstable two phase system with two or more immiscible liquids one of it dispersed in the form of small droplets in other liquid due to dispersion

the system become unstable. An emulsifying agent is used or the stabilization of the biphasic system. There are both O/W or W/O type of emulsion are exists which are used as vehicles to deliver drug. Emulsion are stabilized by use of emulsifying agent.

I.Macroemulsion :-

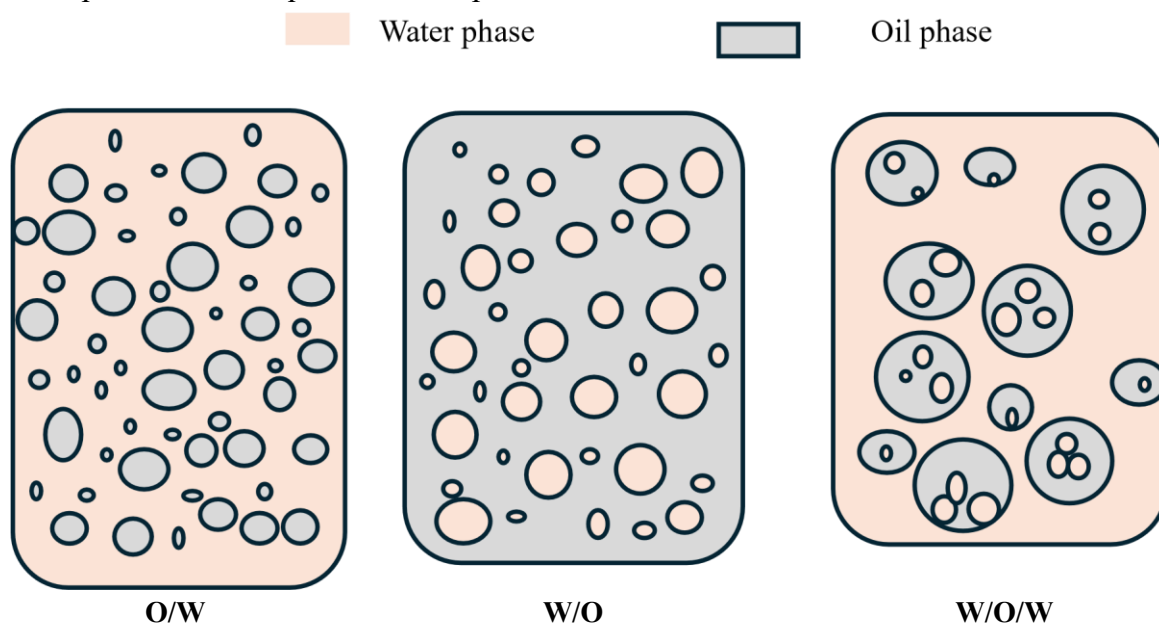
These macroemulsions are most common type of emulsions the particle size of this emulsion is about 400 nm and these macro emulsions are observed by microscope. By using surface active agents we can make thermodynamically stable macro emulsion.

Depending on the method of emulsification and nature of emulsifier the macro emulsion either

O/W or W/O.

II.Microemulsion :-

Microemulsions are basically thermodynamically stable and optically transparent. This microemulsion is mono dispersed spherical droplets and has the diameter of 20 nm to 200 nm.



ADVANTAGES :-[16]

- Incorporation of hydrophobic drugs
- Better loading capacity
- Better stability
- Controlled release
- No intensive sonication
- Avoiding first pass metabolism
- Avoiding gastrointestinal incompatibility
- More selective for a specific site
- Improved patient compliance
- Convenient and easy to apply

DISADVANTAGES :- [17]

- Skin irritation on contact dermatitis
- Possibility of allergenic reactions
- Poor permeability of some drugs through the skin
- Drugs of large particle size are not easy to absorb through the skin

Composition Of Emulgel Preparation :-[18,19]

I. Aqueous Substances :-

Water and alcohol are commonly used to form aqueous phase of the emulsion.

Eg. water & alcohol.[18]

II.Oils :-

These agents form the oily phase if the emulsion. For externally applied emulsions, mineral oils, either alone or combined with soft or hard paraffin, are widely used both as the vehicle for the drug and for their occlusive and sensory characteristics. Widely used oils in oral preparations are non-biodegradable mineral and castor oils that provide a local laxative effect, and fish liver oils or various fixed oils of vegetable origin (e. g, Arachis, cottonseed, and maize oils) as nutritional supplements.[19]

III.Emulsifiers :-

Emulsifiers are used to control and stabilize the emulsification process. Because emulsions are thermodynamically unstable, they can be made more stable by including a suitable emulsifying agent. E.g; Span 80, Tween 80, Stearic acid, Sodium stearate.[18]

IV.Permiation Enhancers:-

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

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

V.Gelling Agents :-

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

E.g. HPMC-2910, SodiumCMC, Carbopol-934, Carbopol-940 [19].

Properties Of Penetration Enhancers :-

1. They should be non-toxic, non-irritating and non-allergenic.



2. They would ideally work rapidly, and the activity and duration of effect should be both predictable and reproducible.
3. They should have no pharmacological activity within the body i.e. should not bind to receptor sites.
4. The penetration enhancers should work unidirectional.[18]

Method Of Preparation Of Emulgel :- [20]

Step-1: Oil/water or water/oil emulsion.

Step 2: Formation of gel base.

Step 3: Incorporation of emulsion in gel base.

1.Preparation Of Gel Phase :-

The gel phase in the formulations is prepared by dispersing polymer in purified water with constant stirring at a moderate speed using mechanical shaker, then the pH was adjusted to 6–

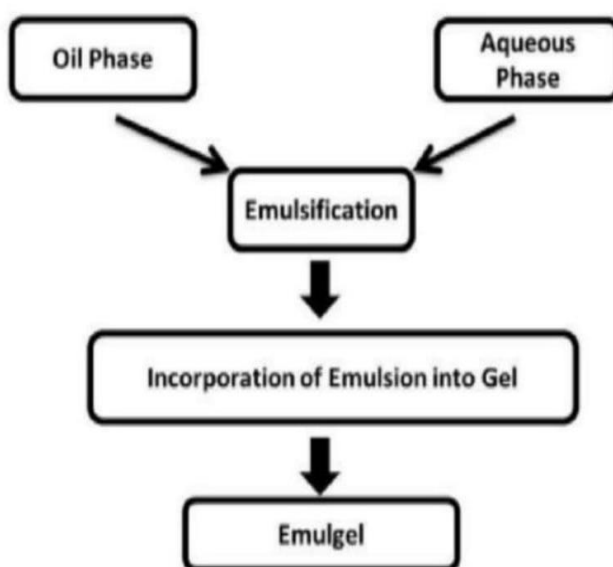
6.5 using tri ethanol amine (TEA).

2.Preparation Of Oil Phase Of Emulgel :-

Oil phase of the emulsion is prepared by dissolving emulsifier. e.g. span 20 in oil phase like light liquid paraffin.

3.Preparation Of Aqueous Phase :-

The aqueous phase is prepared by dissolving emulsifier. e.g. tween 20 in purified water.



Characteristics Of Prepared Gel:-

A ground glass slide having same dimension as that of the fixed ground slide was provided with the hook. Weight of 20 gm was placed on the top of the two slides for 5 minutes to expel air and to provide a uniform film of Emulgel between the two slides. Measured quantity of weight was placed in the pan attached to the pulley with the

help of hook. The time (in seconds) required by the top slide to separate from ground slide was noted [23].

The spreadability is calculated by using the Formula.

$$S = \frac{M \cdot L}{T}$$

Where , M= wt. tied to upper slide.

L= Length of glass slide.

T= Time taken to separate the slides.

Evaluation Parameters of Emulgel: -

I. Physical Appearance: -

The prepared Celecoxib Emulgel was inspected visually for their colour, consistency, homogeneity and phase separation [21]

II. PH Determination: -

The pH values of prepared Emulgel formulation were determined by using 1% w/v aqueous solutions of the prepared emulgel by digital meter. One gram of Emulgel was dissolved in 100 ml was dissolved in 100 ml of distilled water and it was placed for two hours. The measurement of pH of each formulation was done in triplicate and average value was calculated [22]

III. Spreadability Study: -

Spreadability coefficient was to be determined by apparatus suggested by Mutimer. The apparatus consists of wooden block, which is attached to a pulley at one end. Spreading coefficient was measured on the basis.

IV. Extrudability: -

A 15 gm of Emulgel was filled in aluminum tube. The plunger was adjusted to hold the tube properly. The weight of 1 kg/cm² was applied for 30 seconds the quantity of Emulgel extruded was weighed [24].

V. Rheological Study: -

Viscosity of the prepared Emulgel was determined using digital viscometer (Labman LMDV60 Digital Rotational Viscometer L2415) at the temperature of 37°C. The formulation was added

to the beaker, Spindle number III was lowered perpendicular in to the centre of Emulgel taking care that spindle does not touch bottom to the jar and rotated at a 10 (minimum) and 100 (maximum) rotations per minute, the viscosity was noted down [25].

VI. Drug Contain Determination: -

Drug concentration in emulgel was calculated by spectrophotometric method. Celecoxib content in emulgel was estimated by dissolving 1 gm of emulgel in 100 ml solvent (methanol) by sonication (Ultrasonic Probe Sonicator).

Aliquots of different concentrations were prepared by suitable dilution after sonication and filtering the stock solution and absorbance was measured 254 nm in UV-VIS spectrophotometer (Systronic PC Based Double Beam Spectrophotometer 2202). Drug content was calculated using the equation, which was obtained by linear regression analysis of calibration curve [26].

VII. In – Vitro Drug Release: -

The in vitro drug release studied of the Emulgel was carried out on Franz diffusion cell using egg membrane. Take a fresh egg and put into the concentrated HCL for 15 min. and then remove into the HCL and put into the fresh water for 5 min. and then remove the egg membrane. This egg membrane was clamped carefully between donor and receptor compartment. Emulgel (1 gm) was applied on to the surface of egg membrane. The receptor chamber was filled with freshly prepared Phosphate buffer solution (5.5) to solubilize the drug the drug. The receptor chamber was stirred by magnetic stirrer. 5 ml aliquots were withdraw at 10, 30, 60, 90, 120, 180, 240, 300, 360, 420, 480 minutes. The samples after filtrations were assayed spectrophotometrically at 254 nm.[27].

VIII. Spreadability: -



The spreadability of an emulgel is measured by the diameter of the circle of emulgel formed and is measured when the emulgel is placed between two glass plates of a given weight. A quantity (350 mg) of emulgel was placed on a glass plate and another glass plate was dropped from a distance of 5 cm. The diameter of the distribution circle of the emulgel measures [28].

IX. 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 hours. 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 [29]. 10. Accelerated stability studies of Jellified Emulsion Stability studies were performed according to ICH guidelines. The formulations were stored in hot air oven at $37 \pm 2^\circ$, $45 \pm 2^\circ$ and $60 \pm 2^\circ$ for a period of 3 months.

The samples were analysed 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. [30].

X. Globule Size and Size Distribution of Emulgel: -

Globule size and size distribution are determined by the Malvern Zetasizer. 1.0 g sample is dissolved in purified Water and agitated to get homogeneous dispersion. The sample is then injected into the photocell of Zetasizer [31 -33].

XI. Pharmacokinetic Study: -

The pharmacokinetic study is performed for those Emulgel formulations which show systemic absorption On transdermal applications. The animals like rats are Used to assess the various pharmacokinetic parameters Such as peak plasma concentration (Cmax), the time to reach

Cmax (Tmax), the total Area Under the Curve (AUC_{0-∞}). To estimate the aforementioned parameters, the blood sample is collected from the animal via the Retro-orbital vein after a specific time interval on topical Administration. The samples are then centrifuged at 15000 rpm for 10 min at 4° temperatures. The separated Plasma (100 µl) is then mixed with acetonitrile (1 ml) which causes protein precipitation. Further, the samples are centrifuged again at 15 000 rpm, 4° for 5 min and the supernatant (20 µl) is collected. Finally, the sample is analysed using High-Performance Liquid Chromatography (HPLC).[34].

Marketed Preparation: -

Table No. 3. Various marked Emulgel

Sr. No.	Brand name	Active ingredients	Manufacturer	Use
1	Voltarol 16% Emulgel	Diclofenac diethylammonium salt	Novartis	Anti- inflammatory
2	Micronaz- H Emulgel	Miconazole, nitrate, hydrocortisone	Medical union pharmaceutical	Topical corticosteroid & Antifungal
3	Dinacin Emulgel	Clindamycin phosphate	Beit ,jhala pharmaceutical	Anti-acne
4	Diclone Emulgel	Diclofenac diethylamine	Medpharma	Anti-inflammatory



5	Cataflam Emulgel	Diclofenac potassium	Novartis	Anti-inflammatory
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Future Prospects: -

Hydrophobic behavior of drugs is one of the most common problems faced during formulation and development of any new formulation, as this behavior is responsible for poor water solubility and bioavailability of drugs. Many drugs are hydrophobic in nature and their delivery to the biological system has been challenging. For topical delivery of drugs, different delivery systems such as ointments, lotions, creams, and pastes are applied; however, these topical formulations generally include a large number of oleaginous bases such as petrolatum, beeswax, or vegetable oils that themselves are hydrophobic in nature and do not allow the inclusion of water or aqueous phase. This makes them excellent emollients but retards the release of drugs and makes the product thick and greasy, whereas gels provide an aqueous environment to the drug, favor its dissolution, and provide quicker release of the drug as compared to other topical delivery systems. Emulsion-based gels provide a suitable medium for delivery of such hydrophobic drugs where such drugs can be incorporated into its oily phase and delivered to skin. All such advantages of Emulgel over other topical delivery system make them more efficient and productive in future these properties will be used to deliver more numbers of topical drugs in the form of Emulgel.

CONCLUSION: -

The advantage of topical drug delivery system is having will better patient compliance. And emulgels are said to be one of the best approach for topical administration and various hydrophobic drugs are formulated as Emulgel for better results. Various penetration enhancers are used for

potentiate the effect. Emulgels also possesses an edge in terms of spreadibility, adhesion, viscosity and extrusion, they will become a popular drug delivery system. Emulgels are said to be best conventional systems available in market.

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