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A Short Review: Emulgel Approach to Formulation Development

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ABSTRACT:-
Many advantages of gels a major limitation is in the delivery of hydrophobic drugs. So to overcomethis limitation an emulsion based approach is being used so that even a hydrophobic therapeutic moiety can enjoy the unique properties of gels. When gels and emulsions are used in combined form the dosage form are referred as emulgel. In recent years, there has been great interest in the use of novelpolymers. A unique aspect of dermatological pharmacology is the direct accessibility of the skin as a target organ for diagnosis and treatment. The combinationof hydrophilic cornified cells in hydrophobic intercellular material provides a barrier to both hydrophilic and hydrophobic substances. Within the major group of semisolid preparations, the use of transparent gels has expanded both in cosmetics and in pharmaceutical preparations. Polymer can function as emulsifiers and thickeners because the gelling capacity of these compounds allows the formulation of stable emulsions and creams by decreasing surface and interfacial tension and at the same time increasing the viscosity of the aqueous phase. In fact, the presence of a gelling agent in the water phase convertsa classical emulsion into an emulgel. These emulgel are having major advantages on novel vesicular systems as well as on conventional systems in various aspects. Various permeation enhancers can potentiate the effect; Soemulgels can be used as better topical drug delivery systems over present systems. The use of emulgels can be extended in analgesics and antifungal drugs.
Many advantages of gels a major limitation is in the delivery of hydrophobic drugs. So to overcomethis limitation an emulsion based approach is being used so that even a hydrophobic therapeutic moiety can enjoy the unique properties of gels. When gels and emulsions are used in combined form the dosage form are referred as emulgel. In recent years, there has been great interest in the use of novel polymers. A unique aspect of dermatological pharmacology is the direct accessibility of the skin as a target organ for diagnosis and treatment. The combinationof hydrophilic cornified cells in hydrophobic intercellular material provides a barrier to both hydrophilic and hydrophobic substances. Within the major group of semisolid preparations, the use of transparent gels has expanded both in cosmetics and in pharmaceutical preparations. Polymer can function as emulsifiers and thickeners because the gelling capacity of these compounds allows the formulation of stable emulsions and creams by decreasing surface and interfacial tension and at the same time increasingthe viscosity of the aqueous phase. In fact,

KEYWORDS: Emulgel, GellingAgent, Surfactant

I. INTRODUCTION:-

Topical drug administration is a localized drug delivery system anywhere in the body through ophthalmic, rectal, vaginal and skin as topical routes. These are apply a wide spectrum of preparations for both cosmetic and dermatological, to their healthy or diseased skin.1 These formulations range in physicochemical nature fro m solid through semisolid to liquid. Drug substances are seldom administered alone, but rather as part of a formulation, in combination with one or more non medicated agents that serve varied and specialized pharmaceutical function. Drugs are administered topically for their action at the site of application or for systemic effects.2 Drug absorption through the skin is enhanced if the drug substance is in solution, if it has a favourable lipid/water partition coefficient and if it is a nonelectrolyte. For the most part, pharmaceutical preparations applied to the skin are intended to serve some local action and as such are formulated to provide prolonged local contact with minimal systemicdrug absorption. Drug applied to the skin for their local action include antiseptics, antifungalagent, skin emollients and protectant. The main advantages of topical delivery system are tobypass first pass metabolism. Avoidance of the risks and inconveniences of intravenous therapy and of the varied conditions of absorption like pH changes, presence of enzymes, gastric emptying

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time are other advantages of topical preparations.3- 4 The topical drug delivery system is generally used where the others system of drug administration f ails or it is mainlyused in fungal infection. Human skin is a uniquely engineered organ that perm its terrestriallife by regulating heat and water loss from the body whilst preventing the ingress of noxiouschemicals or microorganisms. It is al so the largest organ of the human body, providi ng around 10% of the body mass of an average person, and it covers an average area of 1.7 m 2 .Whilistsuch a large and easily accessible organ apparently offers ideal and multiple sites to administer therapeutic agents for both local and syst emic actions, human skin is a highly efficient self- repairing barrier designed to keep the inside s in and the outside outGels are a relatively newerclass of dosage form created by entrapment of large amounts of aqueous or hydroalcoholic liquid in a network of colloidal solid particles, which may consist of inorganic substances, such as aluminum salts or organic polymers of natural or synthetic origin.6 They have a higher aqueous component that permits greater dissolution of drugs, and also permit easy migration of the drug through a vehicle that is essentially a liquid, compared with the ointment or cream base.7 These are superior in terms of use and patient acceptability. In spite of many advantages of gels a major limitation is in the delivery of hydrophobic drugs. So to overcome this limitation, emulgels are prepared and used so that even a hydrophobic therapeutic moiety can be enjoy the unique properties of gel.

Drug delivery across the skin:- The epidermis is the most superficial layer of the skin and is composed of stratified keratinised squamous epithelium which varies in thickness in different parts of the body. It is thickest on with elastic fibres. The skin forms a relatively waterproof layer that protects the deeper and more delicate structures. Blood vessels are distributed profusely beneath the skin. Especially important is a continuous venous plexus that is supplied by inflow of blood from the skin capillaries. In the most exposed areas of the body-the hands, feet, and ears blood is also supplied to the plexus directly from the small arteries through highly muscular arteriovenous anastomoses. A unique aspect of dermatological pharmacology is the direct accessibility of the skin as a target organ for diagnosis and treatment. The skin acts as a two-way barrier to prevent absorption or loss of water and electrolytes. There are three primary mechanisms of topical drug absorption: transcellular, intercellular, and follicular. Most drugs pass through the torturous path around corneocytes and through the lipid bilayer to viable layersof the skin. The next most common (and potentially under recognized in the clinical setting) route of delivery is via the pilosebaceous route. The barrier resides in the outermost layer of the epidermis, the stratum corneum, as evidenced by approximately equal rates of penetrationof chemicals through isolated stratum corneum or whole skin. Creams and gels that are rubbed into the skin have been used for years to deliver pain medication and infection fighting drugs to an affected site of the body. These include, among others, gels and creams for vaginal yeast infections, topical creams for skin infections and creams to soothe arthritis pain. New technologies now allow other drugs to be absorbed through the skin (transdermal). These canbe used to treat not just the affected areas (for example, the skin) but the whole body.

II. PHYSIOLOGY OF SKIN

The skin is treated with topical formulations. As a result, a basic understanding of the skin's physiology and function is essential for developing topical dosage forms. The human skin covers about 2m2 of surface area and provides one-third of systemic circulation through the skin. Per square centimeter of human skin, there are approximately 200-300 sweat ducts and 40 50 hair follicles. The human skin pH ranges between 4.7 to 5.7 3,

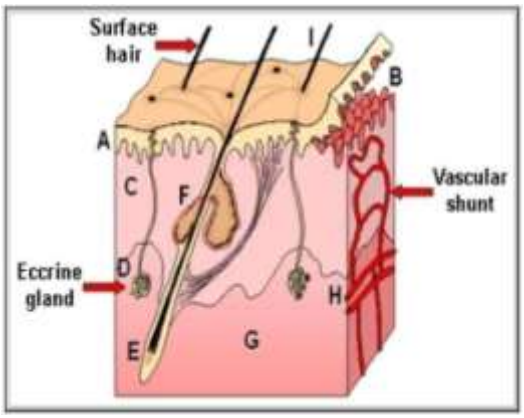

Fig.No:1 Skin of physiology

III. PHYSIOLOGICAL FACTORS:-

- **Lipid Content:** Skin is an important water barrier; when the lipid weight in the stratum corneum of skin is minimal, percutaneous

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penetration increases.

- **Skin Thickness:** The thickness of the skin varies from the epidermal layer to the subcutaneous layer. The epidermal layer is thick, measuring 100–150 m.
- **The Density of Sweat Glands.**
- **Hair Follicle Density:** The storage capacity of the hair follicle's infundibulum is approximately ten times that of the stratum corneum.
- **The pH of Skin:** Skin pH increases due to an increase in the secretion of fatty acidsandsweat at the surface of the skin.
- **Skin Temperature:** As the temperature increases, the rate of skin permeation increases.
- **Hydration of Skin:** Enhance the permeation of the drug.
- **Skin Inflammation:** As the stratum corneum is disrupted, the permeability increases5,6.

Method to Enhance Drug Penetration and Absorption

1) Chemical enhancement
2) Physical enhancement
3) Biochemical Enhancement
4) Supersaturation enhancement

Introduction to 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 thegel.

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 10,11. Emulgel has several good properties, such as good spreadability, greassess, 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 .

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IV. NEED OF STUDY :

Flurbiprofen belongs to the class II of the BCS system of drugs and oral administration of Flurbiprofen is associated with severe gastric irritation therefore to overcome this problem emulsion based gel form was formulated.

Flurbiprofen is hydrophobic in nature therefore it reports a problem of solubility in water this can be solved by adding drug in oil phase of emulsion.Emulgel overcomes the problems associated withemulsion (i.e. stability) and gel (i.e. syneresis) alone. Emulgel are alternative to the solid dispersiongel.

Advantages of emulgel

1. Using water/oil/water emulsions, hydrophobic drugs can be quickly implemented intothe gel base.
2. Improved stability and load capacity.
3. Easy for production and a low-cost mechanism.
4. Avoid sonication.
5. The first metabolism is avoided.
6. Avoid gastrointestinal incompatibility.
7. Target drug delivery on the body.
8. Improved patient compliance.
9. Improved patient acceptability and suitability for self-medication.

Disadvantages of emulgel

1. The drug and/or excipients can lead to skin irritation in people with contact dermatitis.
2. Some medications have low permeability through the skin.
3. Possibility of allergenic reactions.
4. Larger-particle-size drugs are not easily incorporated into the skin

- **The rationale of emulgel as topical drug delivery:-**

Various semisolids and other preparations are available on the market for restoring the skin's fundamental role or pharmacologically altering an operation to the underline tissue 18. The formulations, such as lotions, ointments and creams have several drawbacks, including being sticky, having a low spreading coefficient, and having stability issues. Only transparent gels have exposure in pharmaceutical and cosmetic preparations due to overall limitations within the semisolid preparations 19. As a result, an emulsion-based solution is used to address this limitation. Hence, the hydrophobic moiety of the drug should be incorporated and provided through gels.

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Drug/oil/water emulsions may be used to integrate hydrophobic drugs into emulgel. Since solubility acts as a barrier, most drugs cannot be inserted directly into gel bases, causing problems during drug release. The emulgel system helps to incorporate a hydrophobic drug into the oil phase, after which oily globules are easily dispersed into the aqueous phase, resulting in an oil/water emulsion. The emulsion can be mixed into the gel base. This may result in enhanced drug stability and release over simply incorporating the drug into the gel base.

A gel is colloid that is typically 99% wt liquid, which is immobilized by surface tension between it and a macromolecular network of fibers built from a small amount of a gelating substance present. In spite of many advantages of gels a major limitation is in the delivery ofhydrophobic drugs. So to overcome this limitation an emulsion based approach is being usedso that even a hydrophobic therapeutic moiety can be successfully incorporated and delivered through gels.

V. COMPONENTS OF EMULGEL:-

Oils :-are used as an oil phase to prepare an emulsion. Mineral oil and soft or hard paraffin are commonly used, either alone or in combination, in topically applied emulsions.
Example: castor and mineral oils, which have laxative effects, are the most commonlyused oils for oral and topical preparations 21,22.

Table 1: Use of oils

Chemical	Dosage form
Light Liquid Paraffin	Emulsion and Emulgel
Isopropylmyristate	Emulsion
Isopropyl stearate	Emulsion
Isopropyl palmitate	Emulsion
Propylene glycol	Gel

- **Vehicles:**-In the emulgel preparation, oily and aqueous vehicles are used, and both hydrophobic and hydrophilic drugs are used.

1. Examples of vehicles such as alcohol, water, and other aqueous materials are used inaqueos phase emulsions 22.

- **Emulsifiers :**-To improve shelf-life stability, an emulsifier is used to increase the emulsification of the preparation. Examples of emulsifying agents are Tween 80, Span80, Tween 20, stearic acid, etc 23.
- **Gelling agent:**-Gelling agents are used for preparing gels for any dosage form. It enhances the consistency of any formulation. Some examples of gelling agents are Carbopol 940, Carbopol 934, HPMC-2910, etc 24.
- **pH adjusting agent:-** These agents are used to maintain the pH of the formulation. Example: triethylamine, NaOH, etc
- **Permeation enhancers**- These are agents that partition into and interact with skinconstituents to induce a temporary and reversible increase in skin permeability

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 beboth predictable and reproducible.
3. They should have no pharmacological activity within the body i.e. should not bindtoreceptor sites.
4. The penetration enhancers should work unidirectional i.e. should allow therapeuticagents into the body whilst preventing the loss of endogenous material from the body.
5. The penetration enhancers should be appropriate for formulation into diversetopcal preparations, thus should be compatible with both excipients and drugs.
6. They should be cosmetically acceptable with an appropriate skin ‘feel’.

Mechanism of penetration enhancers

Penetration enhancers may act by one or more of three main mechanisms:

1. Disruption of the highly ordered structure of stratum corneum lipid.
2. Interaction with intercellular protein.
3. Improved partition of the drug, co-enhancer or solvent into the stratum corneum.

The enhancers act by altering one of three pathways. The key to altering the polar pathway isto cause protein conformational change or solvent swelling. The fatty acid enhancers increased the fluidity of the lipid-protein portion of the stratum corneum. Some enhancers act on both polar and non-polar pathway by altering the multi-laminate pathway for penetration. Enhancerscan increase the drug diffusivity through skin proteins. The type of enhancer employed has a significant impact on the design and development of the product.

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Types of Emulgel:-Microemulsion

Microemulsions are isotropic mixtures of a biphasic o/w systemic stabilized with a surfactant that is thermodynamically stable and optically clear. Droplets vary in size from 10 to 100nmand 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 interfacialtension, a broad interfacial region, and the ability to dissolve both aqueous and oil-solublecompounds. 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 toform microemulsion-based gels with a viscosity appropriate for topical application [13,14,15].

Nanoemulgel

Nanoemulsion is transparent (translucent) oil-water dispersions that are thermodynamicallystable due to surfactant and cosurfactant molecules with a globule size range from 1nm to100 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 dermaldelivery properties in vivo as well as in vitro. Because of its high loading capacity and smallglobule size, the drug easily penetrates the skin and provides less therapeutic effect in a short period.

Macroemulsion gel

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 agents can help to stabilize them.

Characterization of emulgel

Physical appearance -The color, consistency and homogeneity of the preparedformulation arevisually inspected for observations of physical properties .

pH measurement- A digital pH meter is used to determine the pH of all prepared emulgel. Calibration of the pH meter is performed before using a standard buffer solution. 1 gm of the formulation is dissolved in distilled water until a uniform
suspension is formed and is kept aside for 2 hours. After 2 hours the glass electrode is dipped inthe suspension and the pH is measured .

- **Rheological study**- The viscosity of the prepared formulation is determined at 37^0C using a coneand plate Brookfield viscometer .
- **Stability study** -Stability studies are carried out by inducing stress at different temperatures and humidity (room temperature of 30^0C±2^0C, RH of 65%±5% and room temperature of 40^0C±2^0C, RH of 75%±5%) using a stability chamber with proper excipient quantity (API-0.1gm, oil- 2.5gm, surfactant-6.665gm co-surfactant- 13.33gm, double-distilled water 27.15ml).The study is done for 1 month and observation is done for physical changes such as a change in clarity, observance of turbidity and detection of particle growth .
- **Skin irritation test**_-Skin irritation test is usually done in skin of human volunteers with proper written consent. The prepared formulation is applied to the skin of the hand and observation is done to check for any undesirable effects.
- **Zeta potential-** The Zeta potential of the emulgel preparation is determined by zetasizer (Malvern Zetasizer) The formulation is placed in a clear, disposable zeta cell, and the result is determined. Before experimenting, cuvettes are washed with methanol and then the sample is placed .
- **Particle size and polydispersity index (PDI)**_-The globule size of emulgel is measured at 25^0C by using a zetasizer (Malvern zetasizer instrument, ZS90). The sample is diluted before the experiment[37].
- **Swelling Index**_-1 mg of gel is placed on porous aluminium foil separately in a 50 ml beaker that contained 10 ml of 0.1 N NaOH. The sample is removed from the beaker at various time intervals and kept in a dry place for some time after it is reweighed [38,39].

- Swelling Index (SW) % = [[Wt-Wo]/Wo]*100

Where (SW) %= Equilibrium percentage swelling.
Wo= Original weight of emulgel at zero time where time t, Wt=Weight of swollen emulgel

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1. **Drug Content determination-** A spectrophotometer is used to determine the drug concentration in the emulsion. The drug content of an emulsion is determined by sonicating a known amount of emulsion in a solvent (methanol). In a UV/VIS spectrophotometer, absorbance is measured after appropriate dilution
2. **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 appliedfor semisolid formulations. Previously prepared Sabouraud‟s agar dried plates were used. Threegrams 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 ang le from the ditch to the edge of the plate. After incubation for 18 to 24 hours at 25°C, the fung algrowth 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.

3.Spreadability: Spreadability is determined by apparatus suggested by Mutimeret al (1956) which is suitably modified in the laboratory and used for the study. It consistsofa wooden block, which is provided by a pulley at one end. By this method, spreadability is measured on the basis of „Slip‟ and „Drag‟ characteristics of emulgels. A ground glass slide is fixed on this block. An excess of emulgel (about 2 gm) understudy is placed on this groundslide. The emulgel is then sandwiched between this slide and another glass slide having thedimension of fixed ground slide and provided withthe hook. A 1 Kg weight is placed on thetop of the two slides for 5 minutes to expelair and to provide a uniform film of the emulgelbetween the slides. Excess of the emulgel is scrapped off from the edges. The top plate is then subjectedto pull of 80 gms.

Spreadability (S) =ML/T Where, M = Weight tied to upper slideL= Length of glass slide
T= Time taken to Cover distance by upper slide

4. Extrudability study - It is a usual empirical test to measure the force required to extrudethe 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 emulgelin 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).

Fig.no.2 Emulgel

Table 2: Marketed formulation of emulgel

Sr. no.	Marketed formulation	API	Manufacturer	Use
1	Diclobaremulgel	Diclofenac diethylamine	Barakat Pharm	Anti-inflammatory, analgesic
2	Voltarenemulgel	Diclofenac diethyl Ammonium	NovartisPharma	Anti-inflammatory

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3	Miconazemulgel	Miconazole nitrate, Hydrocortisone	Medical union Pharmaceuticals	Topical corticosteroid and antifungal
4	Diclomaxemulgel	Diclofenacsodium	Torrent Pharma	Anti-inflammatory
5	Levoragemulgel	Hibiscus, licorice. natural extracts	THD Ltd	Emollient

VI. CONCLUSION:-

Emulgel is a novel approach that has been proven to be the most convenient, superior, and efficientdelivery system. Because of its non-greasy nature and lack of oily bases, it gives gel- like properties and gives excellent drug release when compared to conventional topical delivery systems. Emulgel has a high drug loading capacity and is effective in drug delivery at the target site. Penetration of a drug through the skin is effective due to its small particle size. Emulgel is formed by incorporating emulsion into the gel base and provides a dual control release effect. The emulgel technique helps to solve different problems, such as creaming, phase separation and its stability improves. Hydrophobic drugs can be delivered with the help of emulgel and they can be incorporated into theoil phase of the emulsion and combined with gel. This technique improves patient compliance and increases the bioavailability of the drug in specific areas.

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