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A REVIEW ON EMULGEL - NEW APPROACH FOR TOPICAL DRUG DELIVERY

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ABSTRACT

Topical drug delivery is the delivery of drugs anywhere in the Body via skin, vaginal, ophthalmic and rectal routes. Pills may Be given for localized or systemic results. Topical formulations with varying physicochemical homes, which includes solid, Semisolid, or liquid, may be developed. The topical system is Created by means of preparing a drug emulsion and incorporating it into an emulgel. Emulgel is a Thermodynamically strong method with low interfacial anxiety That is made through combining a surfactant and a co-surfactant and has numerous properties which include multiplied Permeability and accurate thermodynamic stability. Emulgel Has a twin control and a sustained release pattern. Emulgel Improves bioavailability in addition to affected person Compliance. The pH, viscosity, particle size, zeta capacity, drug Content material, stability study, pores and skin inflammation Test, and other properties of the organized formula are Evaluated. Formulating the emulgels was found useful in combating the fungal infection. Scientists Have been trying to develop emulgel of various drugs to treat various kinds of skin diseases.

KEYWORDS: Emulgel, Co-surfactant, Gelling agent, Surfactant, Topical drug delivery.

INTRODUCTION

Topical drug delivery can be defined as the application of a drug containing formulation to the skin to directly treat the cutaneous disorder. The topical drug delivery system is generally

used where other routes (such as oral, sublingual, rectal, and parental) of drug administration fails or in local skin infection like fungal infection.[1] delivery of medications topically is a desirable method of local and systemic therapy. The direct access to the skin as a target organ for diagnosis and treatment is a special feature of dermatological pharmacology.[2,3] Now emulgels have been used for 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 to emulgel have been carried by different scientists to judge its efficacy against the fungal infection such as candidacies. Species causing candidiasis are Candida Tropicalis, Candida albicans, Candida parapsilosis, Candida Glabrata and Candida krusei. Formulating the emulgels was found useful in combating the fungal infection. Scientists have been trying to develop emulgel of various drugs to treat various kinds of skin diseases.[3,4]

The formulations are available in a wide range of forms, including solid, semisolid, and liquid. Topically applied medications are used for their actions at the application site or systemic effects. Drug absorption is enhanced by the skin if the medication is in solution, if its lipid/water partition coefficient is favourable, and if it is non electrolyte.[5] Gel are homogeneous, semisolid preparation usually consisting of solution or dispersion of one or more medicament in suitable hydrophilic or hydrophobic bases.[6] (IP volume 2) Gel formulations typically offer faster medication release than standard ointments and lotions. The polymers used to prepare pharmaceutical gels include the natural gums tragacanth, pectin, synthetic and semisynthetic materials such as methyl cellulose, carpools.[6] (Lochmanns 717). Gels' main drawback is their difficulty in delivering hydrophobic medications. Emulgels are prepared in order to overcome this limitation, and even with a hydrophobic medication that can benefit from the special properties of characteristics of gels when emulsions and gels are utilised. The dosage forms are referred to as emulgel when gels and emulsions are combined. In actual, the water phase's existence of a gelling agent makes an emulgel from a conventional.[7]

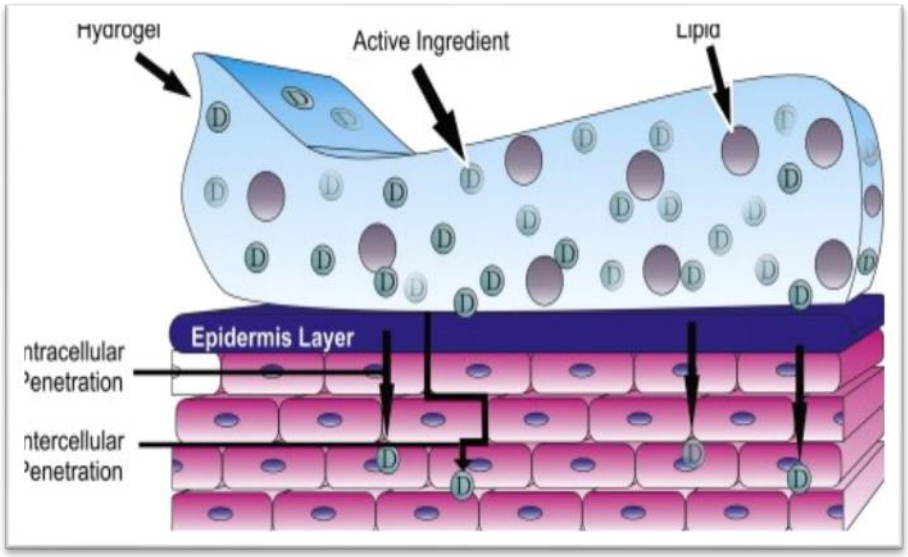

Figure No. 1: Structure of Emulgel.

Topical Drug Delivery System

Topical drug delivery system there are two basic types of topical drug delivery products, externally used topical and internally used topical. The externally used topical are spread, sprayed or otherwise dispersed on the tissue to shield diseased area, while the internally used topical are applied to mucous membrane orally, vaginally or on the rectal tissues for local activity. Main benefit of topical drug delivery system are avoiding first pass metabolism, avoiding gastrointestinal incompatibilities, specific site selective, improving patients compliance, possible and easy self-medication, and drugs with short half-life and narrow therapeutic index are also subjected to be utilized, facility is used to easily terminate medicines whenever required.[8] Disadvantages of topical drug delivery system are skin irritation on contact dermatitis, allergic reactions, poor drug permeability through skin, drugs of large particle size are not absorbed easily through skin. Skin is thick, complex in structure. Molecules moving from the external environs must penetrate the stratum corneum as well as any material of endogenous or exogenous origin on its surface. They must then penetrate the viable epidermis, the papillary dermis and the capillary walls into the blood stream or lymph compartment, where upon they are removed from the skin by flow of blood or lymph. To move across the skin membrane is obviously a complex process and challenge in analysis. Factors affecting the topical drug delivery system can be physiological factors e.g. thickness, hydration, inflammation and pH of skin, lipid content, densities of hair follicles and sweat glands, blood flow etc., and physico-chemical factors like partition coefficient, molecular weight, degree of ionization, effect of vehicle etc.[9] When moiety touches intact skin, it

contacts cellular debris, microorganisms, sebum and the other materials. The diffusion of drug will be done by various routes via hair follicles, sebaceous gland and sweat ducts across the continuous stratum corneum.

Classification of topical drug delivery systems

1. Solid: Powders, Plasters Ointments,
2. Semi solid: Creams, Poultices, Gels, Pastes
3. Liquid: Liniment, Lotions, solution, tinctures, Emulsions, Suspensions, Paints
4. Miscellaneous: Transdermal drug delivery systems, Tapes and Gauzes, Rubbing alcohols, Liquid cleanser, and Topical aerosol.[10]

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.[11]

Factors affecting topical drug absorption

Physiochemical factors Drug substances	1.Molecular weight (<400 dalton) 2. Diffusion coefficient 3. Water/lipid partition coefficient 4. Permeability coefficient 5. Ionization- unionized drug are well absorbed 6. Protein binding capacity.	Physiological Factors	14. Skin thickness 15. Lipid content 16. Density of hair follicles 17. Density of sweat glands 18. Skin pH 19. Blood flow 20. Hydration of skin 21. Inflammation of skin
Vehicle	7.Solubility/polarity 8. Volatility 9. Concentration 10. Distribution in a stratum corneum 11. Excipients 12.Penetration enhancer 13. PH	Site of application	22. Skin area dose (film thickness, concentration) 23. Total skin area in contact with vehicle 24. Duration of exposure

Table No. 1: - Factors affecting topical Absorption of drug.[12,13]

Physiology of Skin

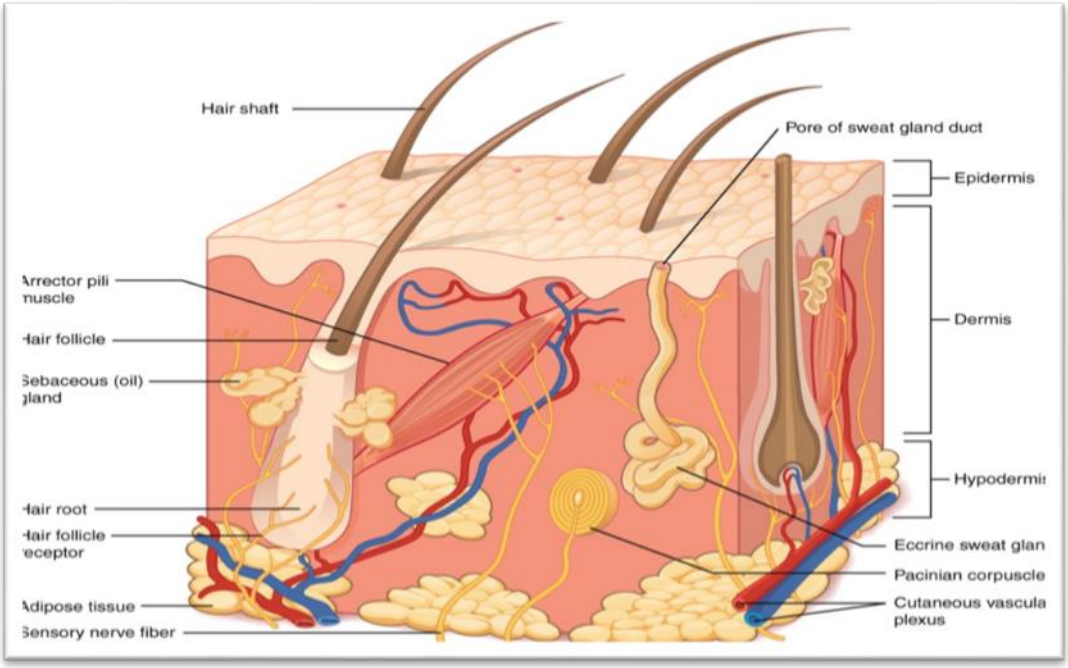

Figure No. 2: Physiology of Skin.

Most of the current preparations are for use on the skin. Therefore, a basic understanding of the skin and its physiological function is essential for the design of the appropriate dosage form. The skin of the adult body covers a surface of about 2 square meters of the epidermis that cannot be reached, and receives one third of the blood flowing through the body. The average human skin surface has 40 to 70 hair follicles and 200 to 300 sweat ducts per square centimetre of skin. The pH of the skin varies from 4 to 5.6. Sweat and fatty acids secreted from sebum affect the surface pH of the skin. The skin can be thought of as having four layers of tissue.[14,15]

Non-viable epidermis

The stratum corneum is the outermost layer of the skin and is the physical barrier to most substances that come into contact with it. The stratum corneum is 10 to 20 cell layers thick in most parts of the body. Each cell has a flat, plate-like structure – 34-44 µm long, 25-36 µm wide, 0.5-0.20 µm thick and a surface of 750-1200 µm, stacked brick-like. The stratum corneum is composed of fat (5-15%) including phospholipids, glycosphingolipid, cholesterol sulfate and neutral lipid, protein (75-85%), mainly keratin.

Viable epidermis

This layer of skin is between the stratum corneum and the dermis and is between 50 and 100 micrometers thick. The cell structure of the living epidermis is similar in body chemistry to other living tissues. Cells are held together by tonofibrils. The density of this area is not significantly different from water. The shape of the water is a shape. 90%.

Dermis

Just below the living epidermis is the dermis. It is a fibrin structure and contains few cells similar to those found in tissue. The skin is between 2000 and 3000 micrometers thick, and is a loose connective tissue tissue containing a protein encased in an amorphous matrix.

Subcutaneous Connective tissues

The subcutaneous tissue or hypodermis is not considered a true part of the formed connective tissue, it contains Connective tissue, white, connective tissue that contains blood and lymphatic vessels. Pores sweat glands and skin veins. Most researchers believe that the drug enters the bloodstream through the skin before reaching the hypodermis, although adipose tissue can act as a drug depot.

Factors to considered when choosing a topical preparation

1. For example, the product of the vehicle will increase the energy consumption and be more efficient. The vehicle itself can be cooled, dehumidified, heated or heated.
2. Compare the prepare type with the garbage type. For example, avoid oils in case of acute dermatitis.
3. Set the configuration type to the location. (eg, sunscreen or lotion for Hairy areas)
4. Irritation or excess. In general, complex oils and creams are less irritating than gels. Oils do not contain preservatives or emulsifiers if sensitivity to these drugs is a concern.[16,17]

Drug delivery across the skin

The skin has two main layers: the epidermis and the dermis. Blood vessels are distributed under the skin and the underlying layer. There are three main methods of drug absorption in the skin: intercellular, transcellular and follicular. The second major route of delivery is via the pilosebaceous route, which results in absorption through the extracellular matrix, but the intracellular route has been found to be a faster route for highly polar molecules. In normal healthy skin, the keratinized corneas and non-polar lipids, mainly the intercellular cement of the stratum corneum, have been shown to be the main factors that contribute to maintaining

an effective resistance to drugs.[18] Drug penetration into the skin is increased by using organic solvents such as propylene glycol, surfactants and DMSO. Penetration enhancers alter the barrier properties of the stratum corneum by a number of mechanisms, including increasing solubility, disintegrating the stratum corneum, and decreasing the crystalline structure of the stratum corneum.[19] Creams and skins have been used for many years to treat ailments and diseases. New technologies Allow other drugs to penetrate the skin. These can be used to treat the affected areas of the skin, but for the whole body through systemic route.[20]

Emulsion

The word emulsion came from "emulgio" meaning to "milk out". An emulsion is a thermodynamically unstable system consisting of at least two immiscible liquids phases one of which is dispersed as globules in the other liquid phase stabilized by a third substance called as emulsifying agent.[11]

Classification of Emulsion

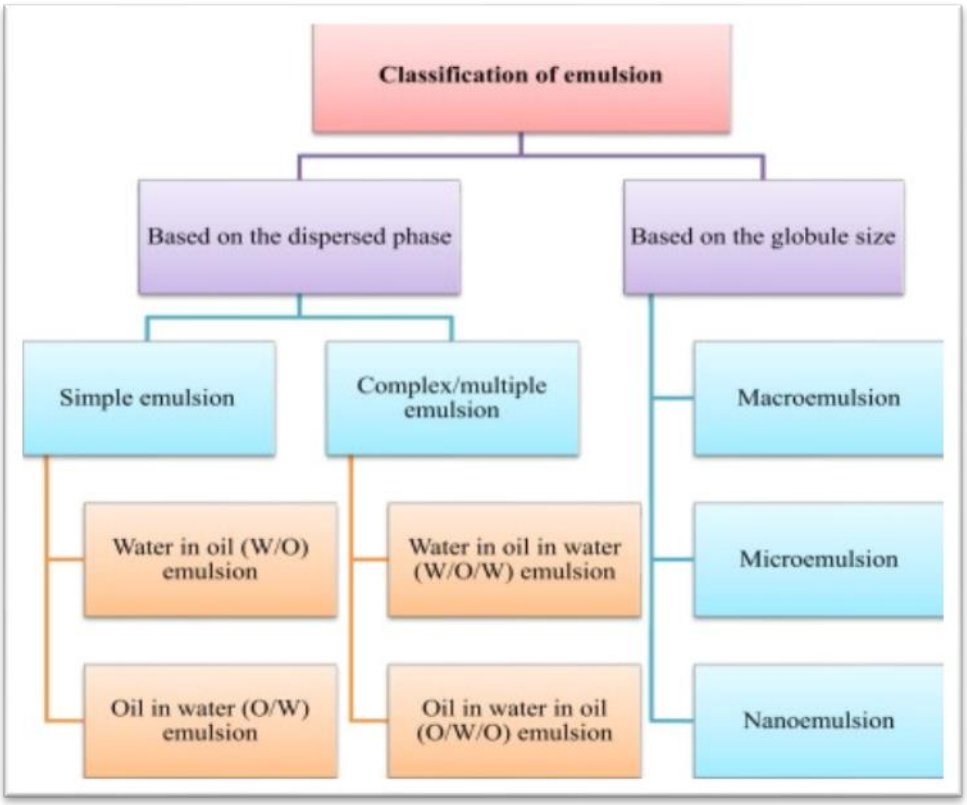

Table No. 2 Classification of Emulgel.

Based on Dispersed phase

1. Oil in Water emulsion (O/W)

Emulsion having an oleaginous internal phase and aqueous external phase are referred as Oil in water emulsion (O/W).

2. Water in Oil emulsion (W/O): -

Emulsion having an aqueous internal phase and oleaginous external phase are referred as Water in oil emulsion (W/O).

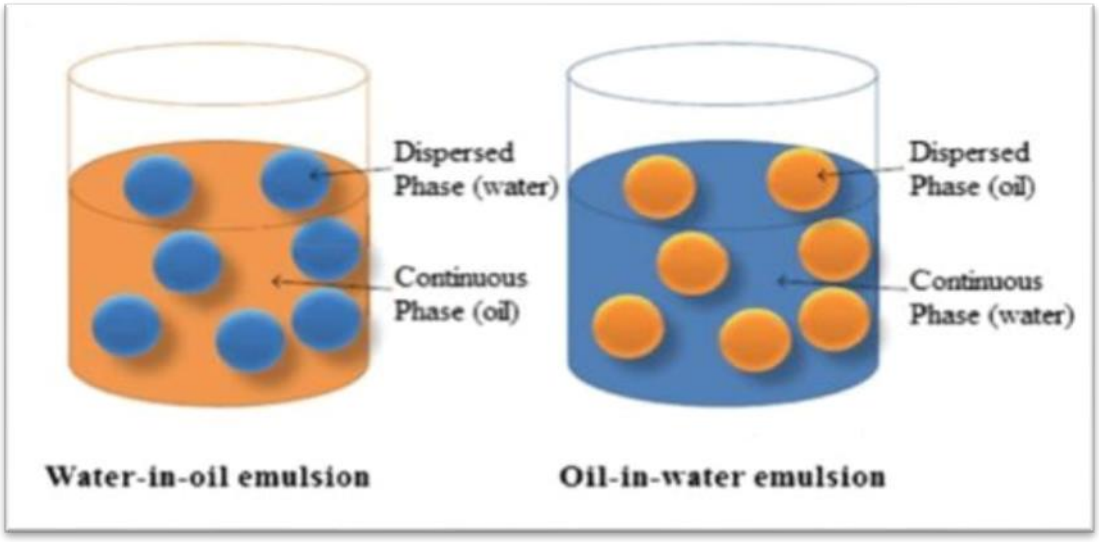

Figure No.3: W/O and O/ W Emulsion.

Based on Size of Liquid Droplet

1. Microemulsion

Micro emulsions are isometric emulsions of a two-component o/w system stabilized with a surfactant that maintains fluidity and transparency. The droplets vary in size from 10 to 100 nm and do not coalesce. It contains a lot of oil, cosurfactant, surfactant and water. Micro emulsions can have unique properties, including very low surface tension, large surface area, and ability to dissolve in water and oil-soluble liquids.

The materials in the micro emulsion can help the drug to penetrate more quickly by reducing the parallel barrier of the stratum corneum. However, due to the low viscosity, the use of micro emulsions in the pharmaceutical industry is limited due to the ability to keep the skin low. To overcome this limitation, gelling agents such as HPMC K100M, Carbopol 940 and guar gum are added to the micro emulsion to create various internal micro emulsions with good viscosity for application purposes.[21,22,23]

2. Macroemulsion

Emulgel with emulsion droplet particles Larger than 400 nm. They are not visible physically, but under the microscope the individual moles are clearly visible. Macro emulsions are stable, but surfactants can help stabilize them.

Advantages of emulgel

1. Improved patient acceptability.
2. Offer targeted drug delivery.
3. Termination of the therapy at any time.
4. Enhance bioavailability as well as the low doses can be effective in comparison with Other conventional semi solid preparation.
5. Became a stable formulation by decreasing surface interfacial tension which leads to Increase the viscosity of aqueous phase, more stable as compare to transdermal Preparations which are comparatively less stable.
6. Hydrophobic drug can be easily incorporated in emulgel form by using emulsion as the Drug barrier which is finally dispersed in to gel.
7. Provide the controlled effect of that helps to prolong the effect of drug with short half-Life.
8. Easy to formulate and cost-effective preparation.
9. Drug loading capacity is better than other novel dosage forms like neosomes and Liposomes
10. Skin penetration is enhanced due to both hydrophilic and hydrophobic nature.[24-26]

Disadvantages of emulgel

1. Skin irritation on contact dermatitis.
2. Bubbles formed during emulgel formulation.
3. Chance of allergenic reactions6
4. Drugs with large particle size (>400 Daltons) are not easily absorb or cross through the skin barrier.
5. Poor permeability of some drugs through the skin.[27]

Essential ingredient

1. Aqueous materials

The aqueous phase of the emulsion is formed using aqueous materials. Alcohol and water are used to prepare the liquid phase.[28]

2. Oils

These elements form the oil phase in the form of an emulsion. For external use, emulsions, mineral oils, alone or combined with soft or hard paraffin, are widely used as carriers for the substance with their occlusive and sensitive properties. The most commonly used oils in food products are non-biodegradable mineral oils and castor oil, which are effective locally, and cod liver oil or other essential oils of vegetable origin (such as in arachis, cotton and wheat) in food supplements.[29,30]

3. Emulsifier

Emulsifying is used to stabilize the emulsion during manufacture and to control shelf life, which can vary from days for home-made emulsions to months or years for formulations. Commercial, such as polyethylene glycol 40-stearate,[31] sorbitan monooleate (open 80),[32] polyoxyethylene sorbitan monooleate (Tween 80),[34] stearic acid,[35] sodium stearate.[36]

4. Gelling agent

These are the agents used to increase the consistency of any dosage form can also be used as thickening agent.[37,38]

5. Permeation Enhancer

These are agents that partition into and interact with skin Constituents to induce a temporary and reversible increase in skin Permeability.[39]

Properties of penetration enhancer

1. It should be non-toxic, non-irritating and non-irritating.
2. It means that the action is fast, and the action and the duration of the effect Must be predictable and repeatable.
3. It should not have any pharmacological activity in the body, ie, it should not be restricted to the receiving areas.
4. Penetration promoters must act independently, that is, they must allow the drug to enter the body and prevent the loss of active substances from the body.
5. Enhancement should be suitable for manufacturing in various requirements for the project, so it should be compatible with pharmaceuticals and drugs.
6. It should really suit your skin tone.

6. Humectants

Humectants are used to prevent loss of moisture from the formulation. They minimize drying of emulgels and thereby enhance qualities such Ease of application and consistency. Examples of humectants include Glycerine, propylene glycol Etc.[28]

Additives/Excipients used in Emulgel Formulation.

1. They should not be harmful, for one.
2. They should be made available for purchase in the proper grade.
3. They should be sensibly estimated.
4. They should be genuinely and synthetically Stable both all alone and in combinations with different substances.
5. They should have matching varieties.[40]

Preparation of Emulgel

Emulgel was prepared by the method reported by[28] with slight modifications.

Stage 1: Formation of Gel

The gel in the formulation was prepared by dispersing Carbopol 934 in purified water with constant stirring at high speed and carbopol 940 in purified water with constant stirring at high speed. Adjust from 6 to 6.5. n Triethanolamine (TEA).

Stage 2: Formation of Oil phase

The oil phase of the emulsion was prepared by dissolving Span 80 in clear liquid paraffin containing the drug in ethanol solution, while the water phase was prepared by dissolving Tween 80 in waste water. Methyl and propyl paraben were dissolved in propylene glycol and mixed with the aqueous phase.

Stage 3: Mixing of both phase

The oil and water phases were heated separately to 70-80°C. Add the oil portion to the water portion and stir continuously until it cools to room temperature. And add glutaraldehyde while mixing the gel and emulsion in a ratio of 1:1 to obtain an emulgel.

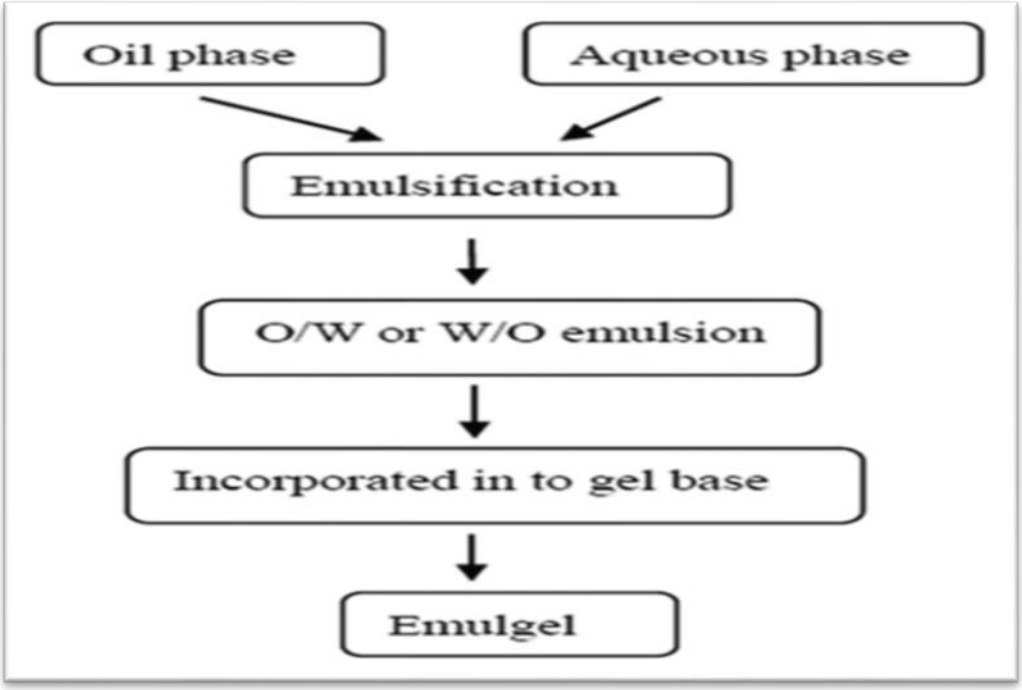

Figure No. 4: Flowchart of Emulgel Preparation.

Evaluation of Emulgel

1. Determination of pH

Numerous topical formulations have a pH range between 5-6, measured with a pH meter. To determine the pH, take 1 gram of the product and dissolve it in 10 ml of Water. The pH of each sample was made in triplicate to minimize error.[32]

2. Swelling Index

1 gm of prepared emulgel is taken on porous aluminium foil which is then dispread in 10 ml of 0.1 N NaOH solutions. Sample removed on various time interval and weight Is noted till no further change in weight:[41]

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

Where, (SW) % = Percentage swelling,

Wo = Original weight of emulgel

Wt. = Weight of swollen emulgel at time t

3. Determination of Rheological properties

20gm of prepared emulgel filled in 25ml beaker was used to measure viscosity by Using Spindle number S64 by Brookfield Viscometer.[33]

4. Physical examination

The prepared emulgel formulations, colour, homogeneity, consistency, and phase separation were all inspected Visually.[42]

5. Drug Content Determination

Emulgel is mixed in a suitable solvent. Filter it to obtain clear solution. Determine its Absorbance using UV spectrophotometer. From the standard equation by putting the Absorbance value concentration and drug content can be obtained.[44]

Drug Content = (Concentration × Dilution Factor × Volume taken) × Conversion Factor.

6. Microbiological assay

Ditch plate technique was used. It is a technique used for evaluation of bacteriostatic or fungi static activity of a compound. It is mainly applied for semisolid formulations. Previously prepared Sabouraud's agar dried Plates were used. Three grams of the Jellified 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.[25]

% inhibition = L2 / L1 × 100

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

L2 =length of inhibition.

7. Spreadibility

The spreadibility 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.[45]

7. 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.[46]

8. Accelerated stability studies of Jellified 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 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.[47]

9. In vitro release study

Franz diffusion cell is used for drug release studies. Jellified emulsion approximately (200 mg) is applied onto the surface of the egg membrane evenly. The Egg membrane is clamped between the donor and the Receptor chamber of the diffusion cell. The receptor Chamber is filled with freshly prepared Phosphate Buffered Saline (PBS) (pH 5.5) solution to solubilize The drug. The receptor chamber is stirred by a magnetic Stirrer. The samples (1.0 ml aliquots) are collected at a Suitable time interval and are analysed for drug content By UV visible Spectrophotometer after appropriate Dilutions. The cumulative amount of drug released Across the egg membrane is determined as a function of time.[48-50]

10. Stability Study

The stability study of emulgel is performed according to International Council on Harmonization (ICH) Guidelines. Briefly, the emulgel formulations are Packed in collapsible tubes made up of aluminium. Then these tubes are stored at different temperatures and relative humidity such as 5°, 25°/60 % RH, 30°/65 % RH and 40°/75 % RH for 3 mo. During the storage, the formulations are withdrawn after a particular time Interval (15, 30, 60 and 90 d) and can be subjected for Evaluation of physical appearance, viscosity, pH, drug Content and in vitro drug release, etc.[51]

11. Globule size and size distribution in 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.[52-54]

12. 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 (AUC0-∞). 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 15 000 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).[55]

Marketed Emu gels

Table No. 3: Various Marketed Emulgel.

Sl No	Brand name	Active ingredient	Manufacturer	Uses
1	Voltarol 1.16% emulgel	Diclofenac Diethylammonium salt	Novartis	Anti-inflammatory
2	Miconaz-H-emulgel	Miconazole nitrate, Hydrocortisone	Medical union pharma ceuticals	Topical corticosteroid & antifungal
3	Denacine Emulgel	Clindamycin phosphate	Beit jala pharmaceutical company	Anti-acne
4	Diclon emulgel	Diclofenac diethylamine	Medpharma	Anti-inflammatory
5	Cataflam emulgel	Diclofenac potassium	Novartis	Anti-inflammatory

Packaging of emulgel is usually done in membrane

Sealed lacquered aluminium tube with an inner coating of a phenoxy-epoxy based lacquer closed with a Propylene screw cap or aluminium laminated tubes Closed by a molded seal, with a propylene screw cap (Public Assessment Report of Voltaren Emulgel). These laminate tubes give the benefit of aluminium Tube properties with the appearance of plastic. The new Generation of laminate tubes uses modern technology to produce the tube with maximum space for graphics. Laminate material prevents the transfer of light, air and moisture. It consists of two layers, an aluminium Layer providing integrity and shelf appealing plastic Tubes. The protective barrier serves various functions as they provide high gloss protective

lacquer, a resistant Barrier for products requiring maximum compatibility Along with the flavours and fragrance protection with the Reduced absorption.[56]

Challenges with emulgel formulations include

1. **Skin irritation**

The drug or excipients in the emulgel can cause skin irritation or allergic reactions in people with contact dermatitis.

2. **Drug permeability**

Some medications have low permeability through the skin, making it difficult for the drug to be absorbed.

3. **Bubble entrapment**

Bubbles can get trapped during the preparation process, but this can be fixed by sonicating the gel for 15 minutes.

4. **pH**

The pH of the emulgel should be compatible with the skin's pH to avoid skin irritation.

5. **Drug particle size**

Larger-particle-size drugs are not easily incorporated into the skin.

6. **Stability**

The stability and efficacy of emulgel can be influenced by the gelling agent, oil agent, and emulsifiers.

CONCLUSION

Emulgel is a novel approach that has been proven to be the most convenient, superior, and efficient delivery 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 the oil 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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