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FORMULATION AND EVALUATION OF AN EMULGEL FOR ENHANCED TOPICAL DRUG DELIVERY

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ABSTRACT

Emulgels have gained significant attention as a novel and efficient topical drug delivery system, particularly for the administration of hydrophobic drugs. By combining the structural features of both emulsions and gels, emulgels offer a dual-controlled release mechanism that enhances the therapeutic efficacy and stability of the formulation. These systems are primarily composed of either oil-in-water (O/W) or water-in-oil (W/O) emulsions, which are gelled using appropriate gelling agents to form a stable, semi-solid preparation. The unique architecture of emulgels facilitates improved drug permeability, prolonged release, and increased bioavailability, while also ensuring user-friendly application due to their non- greasy, easily spreadable, and cosmetically appealing nature. Topical drug delivery systems are traditionally used for localized action in dermatological conditions, but recent innovations have expanded their utility to also achieve systemic effects. Conventional topical formulations like ointments, lotions and creams often suffer from drawbacks such as poor stability, limited drug penetration, stickiness and challenges in delivering lipophilic drugs. Emulgels overcome these limitations by offering better solubilization of hydrophobic drugs, increased skin retention time, and enhanced patient compliance. Emulgels are particularly useful for the delivery of drugs used in the treatment of acne, fungal infections, arthritis, inflammation, psoriasis, and other skin-related disorders. The formulation process involves preparing an emulsion containing the active drug and incorporating it into a gel base using surfactants, co-surfactants, and stabilizers. The final product is evaluated for parameters such as pH, viscosity, drug content, zeta potential, particle size, stability, and skin irritation to ensure safety and efficacy. The success and functionality of emulgels largely depend on critical formulation components like gelling

agents, oil phase, and emulsifying agents. Their thixotropic nature, ease of removal, long shelf life, non-staining properties, and eco-friendliness make them superior alternatives to conventional semisolid systems. Given their versatility and therapeutic potential, emulgels are increasingly being explored in pharmaceutical and cosmetic formulations, with a promising scope for future developments.

INTRODUCTION

Over the last decade, scientists and industrial researchers have become more interested in pharmaceutical semisolid dosage forms, particularly emulgels. The skin is a key site for systemic and local drug administration. Though the skin is an easily accessible route of drug administration, some drugs do not penetrate the skin.[1] A variety of topical medicinal products are available from simple solutions and ointments to multiphase nanotechnology-based products.[2] In the forthcoming years, topical drug delivery systems will be used considerably to improve patient compliance.

Topical medication administration is a simple way to treat native and general conditions. The direct accessibility of the skin as an organ for diagnosis and therapy is a novel aspect of dermatological pharmacology. Topical drug delivery systems provide various advantages, including the capacity to administer a large amount of medicine to a specific region, avoidance of gastrointestinal incompatibility, and metabolic degradation associated with oral administration. By avoiding first pass metabolism by the liver and ensuring steady distribution for a long time, many over topical treatments provide improved bioavailability. Dissolution and diffusion of the drug in the delivery of hydrophobic medications, and permeation through the stratum corneum in the administration of hydrophilic pharmaceuticals, are the major drawbacks of topical dosage forms. In emulgel formulation, both oil-in-water and water-in-oil emulsions are widely utilized as carriers to deliver both hydrophilic and hydrophobic medications to the skin. They're also good in dissolving drugs and penetrating skin.[3,4]

Topical medication administration is the simplest and most convenient method of delivering localized drugs to any part of the body via ophthalmic, rectal, vaginal, and cutaneous channels. These are applied to the healthy or diseased skin as a wide range of preparations in both aesthetic and dermatological cases. The formulations come in a variety of forms, ranging from solid to semisolid to liquid. Drugs are applied topically to have an effect at the application site or to have systemic effects. Drug absorption through the skin is improved

when the drug substance is in solution, has a favourable lipid water partition coefficient, and is a non-electrolyte.[3,4]

Many widely used topical agents like ointments, creams, lotions, gel are associated with disadvantages like stability problems, stickiness and lesser spreading coefficient, irritation, allergic reactions, poor permeability, poor absorption and difficulty in absorption of large molecule.[5,6] Cream, ointments and gels are the semisolid formulations which are commonly used for local and regional skin disorders. Semisolids can change their shape, because of plastic behaviour, except gels having viscoelastic effect because of showing liquid and solid properties.[7-9]

EMULGEL

Emulsions are thermodynamically unstable biphasic dosage forms consisting of two immiscible liquids, one of which is uniformly dispersed as globules (internal phase) throughout the second phase (external phase).[13] Emulsions allow the incorporation of hydrophobic medicinal agents into the oil phase which facilitates the dispersion of oil globules in the aqueous phase and produces an oil-in-water (O/W) emulsion.[10-12] Furthermore, emulsions are capable of acting as controlled drug delivery systems where the medicinal agent to be delivered is stored inside the oil phase.

Emulsions are of the oil-in-water or water-in-oil kind the USP defines a gel as a semisolid system containing and interpenetrated by liquid and composed of dispersions of small inorganic particles or large organic molecules. The gel traps small drug particles and maintains regulated drug release by containing a larger amount of aqueous or hydro alcoholic liquid in a cross connected network of colloidal solid particles. The liquid phase forms a three-dimensional polymeric matrix, which is then cross-linked either physically or chemically. The continuous structure produces solid, homogeneous, and transparent behaviour. The controlled drug release from the systems is controlled by both the emulsion and the gel. The organic solvent-based, hydrophobic or organogels and the water-based, hydrophilic or hydrogels are the two forms of gels. The first is a liquid paraffin basis with polyethylene or fatty oils gelled with colloidal silica, aluminium, or zinc soaps, while the second is a water, glycerol, or propylene glycol base. Although gels have many advantages, they have a limitation in the delivery of hydrophobic medications. To overcome this limitation and enjoy delivery of hydrophobic drugs in the form of gel, the concept of emulgel was developed, in which hydrophobic drugs are integrated in an emulsion and then gelled.[14]

Emulgel are seen better choice for the class II of drug as per the BCS classification systems that show poor solubility and high permeability.[17] Emulgel possess the properties as thixotropic, grease less, easily spreadable, easily removable, emollient, nonstaining, water soluble, long shelf life, biofriendly and pleasing appearance that improves the patient acceptability.[5] Emulgel are being used for the treatment of various anti-inflammatory activity and other skin related viral, bacterial and fungal infections.[15, 16]

ADVANTAGES[18-21]

1. Increased patient acceptability.
2. Provide targeted drug delivery.
3. Easy termination of the therapy.
4. Drugs that are hydrophobic are included.
5. Improved loading capacity and stability.
6. Provide the controlled effect of that enhance the prolong effect of the drug with short half life.
7. Easy and cost effective preparation.
8. Keeping gastrointestinal incompatibility to a minimum.
9. Penetration to skin is enhanced due to both hydrophilic and hydrophobic nature.

DISADVANTAGES[5,17]

1. Poor absorption of macromolecules.
2. Entrapment of bubble during formulation.
3. Hydrophobic drugs are the best choice for such delivery systems.
4. Contact dermatitis causes skin irritation.
5. Allergic reactions are a possibility.
6. Some medications have a low permeability through the skin.

TYPES OF EMULGELS[23]

1. Macroemulsions Gel

The most frequent type of emulgel is one in which the particle size of the emulsion droplets is greater than 400mm Macroemulsions are thermodynamically unstable, although surface active substances can help to stabilize them. The gelling oils were utilized. The oil phase was liquid paraffin. agent carbopol 940 was used to make a 19 e.g. emulgel of mefenamic acid. As a penetration enhancer, clove and mentha oils were utilized. The oil phase was liquid paraffin.

2. Nanoemulgel

Nanoemulgel is the term used when nanoemulsion is mixed into a gel. Nanoemulsions are transparent (translucent) dispersions of oil and water that are stabilised by an interfacial coating of surfactant and co-surfactant molecules with droplet sizes smaller than 100 nm. eg. Oleic acid and isopropyl myristate were used to make the oil phase of the carvedilol nanoemulgel (3:1). As a gelling agent, Carbopol 934 was utilized. As a cosurfactant and surfactant, carbitol and tween 20 were utilized.

3. Microemulsion Gel

Because their droplet sizes range from 10 to 100 nm and they do not coalesce, microemulsions are transparent and thermodynamically stable. Using capryol 90 as the oil phase and cremophor El. as the surfactant, a microemulsion-hased clotrimazole vaginal gel was created. As a gelling agent, Carbopol ETD 2020 is utilized.

ANATOMY OF SKIN[24 – 30]

With an area of around 1.7 square metres, the skin is the biggest organ in the body, accounting for 16% of an average person's total weight. Its primary role is to serve as the body's harrier of defence, guarding against a variety of external hazards such as allergens, chemicals, UV radiation, pathogens, and moisture loss. The epidermis, dermis, and hypodermis are the three main layers of skin that operate as a barrier of defence and regulate how the body interacts with its surroundings.

Epidermis

The thickness of the layers that make up the epidermis vuries. The eyelids measure around 0.06 mm while the palms and soles measure 0.8 mm. Curiously, this layer is devoid of blood vessels, thus the epidermal cells must transfer nutrients and remove waste materials across the epidermal-dermal interface in order to reach the dermal cutaneous circulation.

The four layers of the epidermis are:

1. Stratum basale (basal or germinativum cell layer)

The innermost layer of the epidermis consist mainly dividing and non-dividing keratinocytes, which are attached to the basement membrane by hemidesmosomes. It also consists of melanocytes producing melanin pigment. Merkel cells are also found in the basal layer with large numbers in touchsensitive sites as the fingertips and lips.

2. Stratum spinosum (spinous or prickle cell layer)

Basal cells moves towards the outer layer as they reproduce and mature forming the stratum spinosum. Intercellular bridges, the desmosomes, which appear as prickles' at a microscopic level, connect the cells. Langerhans cells are dendritic, immunologically active cells derived from the bone marrow, and are found on all epidermal surfaces but are mainly located in the middle of this layer having significant role in immune reactions of the skin, acting as antigen-presenting cells.

3. Stratum granulosum (granular cell layer)

Continuing their transition to the surface the cells continue to flatten, lose their nuclei and their cytoplasm appears granular at this level.

4. Stratum corneum

Result of keratinocyte maturation is found in the stratum corneum, made up of layes of hexagonal shaped, non-viable cornified cells known as corneocytes. 10±30 layers of stacked corneocytes are found in most area of skin with maximum layers in the palms and soles.

Proteins covera the corneocytes and is filled with water- retaining keratin proteins. Strength is gained due to cellular shape and orientation of keratin proteins. Surrounding the cells in the extracellular space are lipid bilayes. The resulting structure provides the natural physical and water-retaining barrier of the skin. The corneocyte layer is capable to absorb water of about 3 times its weight but it cracks and no longer remains pliable if water content drops below 10%.

Dermis

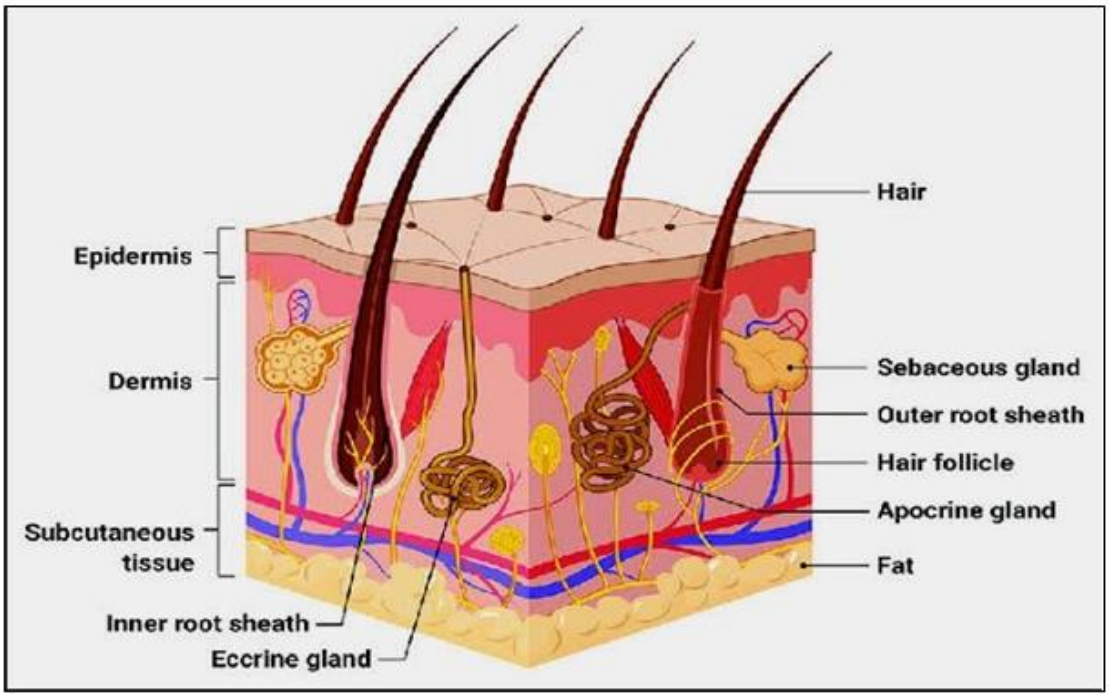
The dermis, which has a thickness of 2-3 mm, is predominantly made up of elastin and collagenous fibres, which make up around 70% of the tissue and give the skin its flexibility and strength. Blood vessels are essential to this layer because they provide nutrition to the dermis and the epidermis. To further improve its performance and responsiveness, the dermis also contains neurons, macrophages, and lymphatic veins.

Structural support and bulk of the skin is provided by the dermis the deeper layer and is responsible for pliability. elasticity, and tensile strength. It is an integrated system of fibrous, filamentous, and amorphous connective tissue that accommodates stimulus-induced entry by nerve and vascular networks, epidermally derived appendages, fibroblasts, macrophages, and mast cells. Blood-borne cells as lymphocytes, plasma cells, and other leukocytes, enter the

dermis in response to various stimuli. It protects the body from mechanical injury, binds water, aids in thermal regulation, and includes receptors of sensory stimuli. The dermis interacts with the epidermis in maintaining the properties of both tissues. The two regions collaborate during development in the morphogenesis of the dermal-epidermal junction and epidermal appendages and interact in repairing and remodeling the skin as wounds are healed. Collagen a fibrous protein representing 70% of the skin's dry weight is the main component of the dermis.

Hypodermis

The word hypodermis, often known as subcutaneous tissue, refers to the layer located under the dermis. The makeup of it consists of elastin and loose connective tissue. The subcutaneous layer contains the vascular plexus, which comprises the arteries and veins responsible for draining the dermis. Dermal arteries infiltrate the papillary dermis layer, producing a complex framework of capillary loops inside the skin. Multiple lymphatic veins pass the hypodermis to reach the specific lymph nodes responsible for emptying the dermis. Interestingly, a significant amount of adipose (fat) tissur is mostly stored in the hypodermis.



DRUG DELIVERY ACROSS SKIN

The epidermis is the most superficial layer of the pores and pores and pores and skin and includes stratified keratinised squamous epithelium which varies in thickness in a single-of-a-type additives of the frame. Its miles thickest on with elastic fibres. The pores and skin forms

a quite water resistant layer that protects the deeper and more sensitive structures. Blood vessels are dispensed profusely underneath the skin. Mainly critical is a non-prevent venous plexus this is provided thru inflow of blood from the pores and skin capillaries. Within the maximum exposed regions of the body the palms, feet, and cars blood is likewise fumished to the plexus straight away from the small arteries through especially muscular arteriovenous anastomoses. A completely unique factor of dermatological pharmacology is the direct accessibility of the skin as a goal organ for assessment and treatment. The pores and pores and skin acts as a way harrier to prevent absorption or loss of water and electrolytes. There are three number one mechanisms of topical drug absorption: transcellular, intercellular, and follicular. Most drugs bypass through the torturous path round comcocytes and through the lipid bilayer to viable layers of the pores and skin. The subsequent most common (and probably below diagnosed inside the scientific placing) path of transport is through the pilosebaceous path. The barrier is living within the outermost layer of the dermis, the stratum corneum, as evidenced by using way of using approximately identical charges of penetration of chemical substances via remored stratum corneum or entire pores and pores and skin. creams and gels which can be rubbed into the pores and skin were used for years to deliver ache remedy and infection stopping capsules to an affected net on-line of the body. Those consist of, among others, gels and creams for vaginal yeast infections, topical creams for pores and pores and skin infections and lotions to assuage arthritis pain. New generation now allow one-of-a-kind tablets to be absorbed via the pores and pores and skin transdermal).

Those can be used to deal with no longer absolutely the affected regions (for example, the pores and skin) however the whole body.

FACTORS INFLUENCING DRUG ABSORPTION TOPICALLY[13,31]

Physiological Elements

1. pH of the skin.
2. Lipid content
3. Skin thickness
4. Blood circulation
5. Skin Hydration
6. Density of hair follicles
7. Density of sweat glands
8. Inflammation of skin

Physicochemical Elements

1. Effect of the vehicle
2. Molecular mass (less than 400 daltons)
3. Permeability coefficient
4. lonization- unionized drug are well absorbed.
5. Protein binding capacity
6. Coefficient of partition.
7. Ionization level

Vehicle

1. Solubility/polarity
2. Volatility
3. Concentration
4. Distribution in a stratum corneum
5. Excipients
6. Penetration enhancer
7. PH

FORMULATION OF EMULGEL[33 – 35]

In the formulation of emulgel, various components, including the drug, are employed, such as:

- **Vehicle:** Enhancing medication absorption via the skin is mostly dependent on the vehicle used in emulget formulation.
- **Aqueous Material:** Commonly used substances like water and alcohols are employed to generate the aqueous phase of the emulsion
- **Oils:** The type and quantity of oil used as one of the emulsion phases is intimately related to the ensulger's intended application. Furthermore, these oil phases have a substantial impact on the emulsion's viscosity, permeability, and stability,
- **Emulsifiers:** The addition of the proper emulsifying agents helps stabilize an emulsion. which is a thermodynamically unstable system. These materials have a major role in decreasing interfacial tension, which boosts the stability of emulsions. For instance, steuric acid. Tween 20. Span 80, Tween 80, esc
- **Gelling Agents:** Gelling agents, also known as cross-linking agents, are essential in the emulgel formaalation because they add thixotropic qualities to the system. Their

principal mile is to thicken the dosage form, improving both the texture and quality. Eg. Carbopol 934, Carbopol 940.HPMC, etc

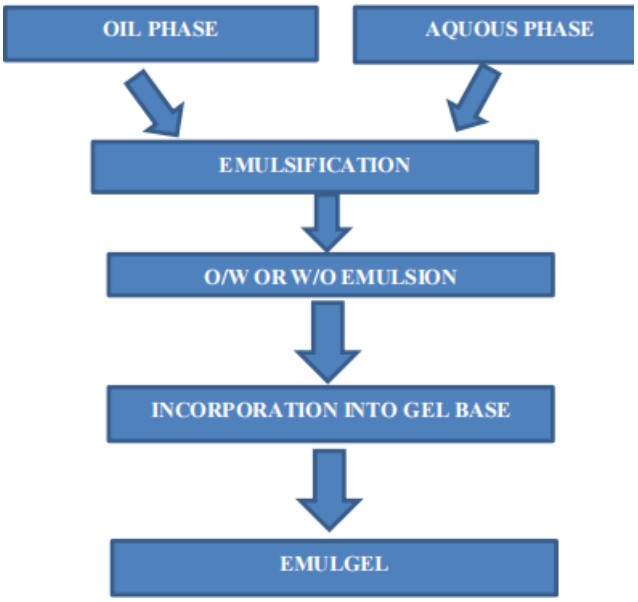
- **Penetration Enhancer:** These chemicals are primarily used to promote medicine transdermal distribution. The penetration enhancers used in the emulgel should be non-aritating, have low toxicity, and promote pmetrability. Eg. Oleic acid, lecithin, clove oil. menthol, eucalyptus oil, etc
- **Humectant:** They are employed to stop the formulation from losing moisture. By reducing ermalgel drying, these ingredients improve consistency, ease of application, and other attributes. Ey. Propylene glycol, glycerine.

Method Of Preparation – Three basic stages that must be followed in order to prepare emulgel are also shown.[36]

Step 1: The preparation of an emulsion can result in either an oil-in-water (O/W) or water-in-oil (W/O) arrangement.

Step 2: Gelling agents and water must be consistently mixed while the pH is being adjusted in order to create a gel base.

Step 3: It takes constant stirring and heating to incorporate the emulsion into the gel base.



EVALUATION OF EMULGEL

1. Physical observation

Physical parameters such as color, appearance, consistency, grittiness on application and other visual factors like clarity and color of formulation are flest thing decides quality of

formulation. Any change in physical observation with time reflects physical instability of formulation and make the product cosmetically unacceptable. Physical instability refers to the change in color, texture, gloss appearance, feel and other visual factors. Generally in dispersion system like emulsion, physical instability is caused by phase separation of emulsion as the effect of temperature, time and other dependent factors which may try to affect the separation immediately after preparation of emulsion. This unwanted separation of phases makes the product cosmetically inelegant and un acceptable Physical parameters such as color, homogeneity, consistency, grittiness, and phase separation were recorded.

2. Determination of pH

The pH value can be considered as an indicator to possible instability as any deterioration of ingredient's due to varied climatic conditions during storage and incompatibility of ingredients can lead to change in viscosity. pH of all formulations was determined by a pH meter (Digital pH meter). The pH meter was calibrated with a standard buffer solution having pH 4 and 7 before use.1 g of the formulation was dissolved in distilled water and stirred until a forms a uniform suspension, kept is aside for 2 h. The volume made up to 100 ml and pH of the suspension was measured with the help of calibrated pH meter.

3. Viscosity

Viscosity is the most important parameter in the evaluation as it governs many properties of the formulation such as spreadability, pourability of the product from the container etc. As there are various factors which can affect the viscosity like change in temperature, change manufacturing conditions, quality of raw materials etc. The viscosity of emulgel was determined by LVT Brookfield viscometer. The sample was placed in a clean and dried container and viscosity was checked as per standard operating procedure of viscometer by using spindle no. 4 at speed 30 rpm. After recording the dial reading viscosity was calculated in the centipoises (cps). Following formula is used for the calculation of the viscosity:

Viscosity in centipoises (cps) Dial reading Factor.

For calculation of viscosity put the factor value corresponding to the speed and the spindle number.

4. Rheological Studies

Rheological properties (study of deformation and flow of matter) are required in various

pharmaceutical areas. Some of the reasons for determining these properties are:

a. It helps in understanding the physicochemical nature of vehicle andquality control of ingredients, test formulations and finalproducts, togetherwiththemanufacturing process such as mixingpumping and filling.
b. It reflects the effects such as temperature and storage time on the products.
c. It helps to assess a topical formulation with respect to the patient usage e.g. removal of preparation from jar or tube withoutspillageorspreadability and adherence to skin.
d. Finally, it helps to monitor the effects of vehicles consistency on therelease of drug from the preparation and its subsequent percutaneous absorption. Rheological techniques may be used to study the conditions operating during the application of preparation to the skin.

5. Determination of spreadability

One of the desired properties of any topical preparation in that they should spread well, uniformly and easily on skin without any drag. Spreadability is a term expressed to denote the extent of area to which the cream readily spreads on application to skin. The therapeutic efficiency of a formulation also depends upon its spreading value. Hence determination of spreadability is very important in evaluating cream characteristics. The spreadability was determined by parallel plate method. Two glass slide of 10- 20 cm were selected. The formulation whose spreadability had to be determined was placed over one slide. The other slide was placed upon the top of the formulation such that the cream was sandwiched between the two slides across a length of 14.5 centimeters along the slide.[71-72] Two slides are fixed to stand so that lower slide was remained fixed to stand so that lower slide was remained fused allowing the upper slide to slip off freely with the help of 50 gm weight. The time required for the upper slide to separate out from lower slide was noted and spreadability was calculated as follows.

$S = WL/T$

Where, S-Spreadability

L-Length of the glass plate W-Weight tied to upper plate

T-Time taken to separate the slide completely from each other

6. Extrudability test

In the present study, the method adopted for evaluating emulgel formslation for extrudability is based upon the quantity in percentage of emulgel and emulgel extruded from lacquered aluminum collapsible tube on application of weight in grams required to extrude at least 0.5

cm ribbon of emulgel in 10 seconds. More quantity extruded better is extrudability. The measurement of extradability of each formulation is in triplicate and the average values are presented. The extrudability is than calculated by using the following formula:

Extrudability Weight applied to extrude Emulgel from tube (in gm)/Area (in cm2).

7. Stability study

Stability may be defined as the ability of the drug to retain its property within specified limits throughout its shelf life. Improper storage of cosmetic product can lead to their physical deterioration & chemical degradation resulting in reduced activity occasionally in the form of toxic degradation product. So stabilky studies are carried out for each product. It was carried out for 3 months and the samples were withdrawn on at a regular interval of 1, 2, and 3 months for evaluation of physical appearance, pH, rheological properties, drug content and drug release. The present stability studies are carried out according to guidelines given by International council of Hormonisation.

8. Skin Irritation Test[39]

Few portion of rats were shaved for the application of emulgel and an area of 4 cm2 was marketed, emulgel was applied (500mg) two times a day for 7 days and the site was observed for any sensitivity and reaction. The sensitivity was graded as 0, 1, 2 and 3 for no reaction, slightly patchy erythema, patchy erythema and severe erythema with or without edema respectively. If the skin irritation symptoms arises then the test was repeated in more than 2 rats.

9. Drug Content Determination[37]

1 gramme of emulgel is required. It should be mixed in a suitable solvent. To get a clear solution, filter it. Using a UV spectrophotometer, determine its absorbance. In the same solvent, a standard drug plot is made. Using the same standard plot, the concentration and drug content can be determined by plugging the absorbance value into the standard plot equation.

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

10. In Vitro release study[38]

The drug release investigations are conducted using the Franz diffusion cell. Emulgel is evenly placed on the surface of the egg membrane. Between the donor and the diffusion cell's

receptor chamber, the egg membrane is secured. To solubilize the medication, the receptor chamber is then filled with newly made PBS (pH 5.5) solution. A magnetic stirrer is used to stir the receptor chamber. The 1.0 ml aliquots of the emulgels must be collected at appropriate time intervals, and the correctly diluted samples must then be analyzed for drug content using a UV visible spectrophotometer. Cumulative adjustments are used to determine the overall amount of medication released at each time period. Time is employed as a function to calculate the total amount of medication released across the egg membrane.

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