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EMULGEL: AN EMERGENT TOOL IN TOPICAL DRUG DELIVERY

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ABSTRACT: In comparison among the other groups of semisolid preparations, the use of gels has been emerged both in cosmetics and in pharmaceutical preparations because of its unique array of features. Despite of providing several benefits the category gel faces limitations in delivering hydrophobic drug molecules via skin. So in order to cover up this lacking a recent emulsion based approach is being used so that even a hydrophobic therapeutic moiety can enjoy the unique properties of gels. The use of gels and emulsions as combined dosage form results into formation of emulgel showing dual release. With this approach the use of polymers with enhanced effect in release pattern has been emerged providing sustained and controlled release. The presence of a gelling agent in the water phase converts a classical emulsion into an emulgel. These emulgels show major advantages on novel vesicular system as well as on conventional systems in various aspects. Emulgels have several favourable properties for dermatological use such as being thixotropic, greaseless, easily spreadable, easily removable, emollient, nonstaining, long shelf life, bio-friendly, transparent and pleasing appearance. So emulgels can be used as better topical drug delivery systems over present systems. The use of emulgels can be expanded in analgesics, anti-inflammatory, anti-fungal, anti-acne drugs and various cosmetic formulations. This review gives knowledge about Emulgel including its properties, advantages, formulation considerations, and its recent advances in research field.

INTRODUCTION: Topical drug administration is simplest and easiest route of localized drug delivery anywhere in the body by routes as ophthalmic, rectal, vaginal and skin. These are applied as wide spectrum of preparations in case of both cosmetic and dermatological, to the healthy or diseased skin¹.

The formulations are available in different forms like from solid through semisolid to liquid. Drugs are administered topically for their action at the site of application or for systemic effects². Drug absorption is enhanced through the skin if the drug substance is in solution, if it has a favorable lipid/water partition coefficient and if it is a non electrolyte.

Mostly, pharmaceutical preparations applied to the skin are expected to serve some local action and are formulated to provide prolonged local contact with minimal systemic drug absorption. Drugs applied to the skin for their local action include antiseptics, antifungal agent, skin emollients and protectants. Topical delivery system proves beneficial by

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bypassing 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 time are other advantages of topical preparations³⁻⁴. The topical drug delivery system allows its usage where the others system of drug administration fails or it is mainly used in fungal infection.

Human skin is a uniquely engineered organ that permits terrestrial life by regulating heat and water loss from the body whilst preventing the ingress of noxious chemicals or microorganisms. It is also the largest organ of the human body, providing around 10% of the body mass of an average person, and it covers an average area of 1.7 m². Whilst such a large and easily accessible organ apparently offers ideal and multiple sites to administer therapeutic agents for both local and systemic actions, human skin is a highly efficient self-repairing barrier designed to keep the insides in and the outside out⁵.

Gels being newer class of dosage form are created by entrapment of large amounts of aqueous or hydro alcoholic 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 origin⁶. The constitution of higher aqueous component permits greater dissolution of drugs, and also permits easy migration of the drug through a vehicle that is essentially a liquid, compared with the ointment or cream base⁷. All these findings make them superior in terms of use and patient acceptability. In spite so advantageous gels show a major limitation in the delivery of hydrophobic drugs. So in order to cover up this lacking, emulgel is prepared and used so that even a hydrophobic therapeutic moiety can enjoy the unique properties of gels. In fact, the presence of a gelling agent in the water phase converts a classical emulsion into an emulgel⁸. Both oil-in-water and water-in-oil emulsions are used as vehicles to deliver various drugs to the skin.

For dermatological use Emulgels show several favorable properties such as being thixotropic, greaseless, easily spreadable, easily removable, emollient, non-staining, long shelf life, bio-friendly, transparent & pleasing appearance⁹. Use of topical agents requires an appreciation of the factors that influence percutaneous absorption

¹⁰. Molecules can basically penetrate into skin by three routes: through intact stratum corneum, through sweat ducts, or through sebaceous follicle. The surface of the stratum corneum presents more than 99% of the total skin surface available for percutaneous drug absorption¹¹. Passage through this outer most layer is the rate limiting step for percutaneous absorption. The major steps involved in percutaneous absorption include the establishment of a concentration gradient, which provides the driving force for drug movement across the skin, release of drug from the vehicle (partition coefficient), and drug diffusion across the layers of the skin (diffusion coefficient).

Preferable characteristics of topical drugs involve molecular mass (600 Da), proper solubility in oil and water, and a high partition coefficient. Except for very small particles, water soluble ions and polar molecules do not penetrate intact stratum corneum. Topical formulation can be used to manipulate the barrier function of the skin, for example, topical antibiotics and anti bacterials help a damaged barrier toward off infection, sun screening agents and the horny layer protect the viable tissues from Ultraviolet radiation and emollient preparations restore pliability to a desiccated horny layer¹². This review represents the overview of emulgels its properties and aspects of the formulation are discussed.

ADVANTAGES OF EMULGEL¹³⁻¹⁴

Incorporation of hydrophobic drugs: The hydrophobic moieties cannot be added directly to the gel bases because of the improper release shown by drug as of lack of solubility. The emulgel allows the addition of such hydrophobic drugs in the oil phase which leads to the dispersion of oil globules in aqueous phase resulting in formation of o/w emulsion. Further this emulsion can be simply added to the gel base, thereby providing good stability and better release of drugs.

Better loading capacity: Gels show greater loading capacity than other novel delivery systems due to the lesser entrapment efficiency shown by them because of their nano size.

Better stability: Majority transdermal preparations are comparatively less stable than emulgels. Like

powders are hygroscopic, creams shows phase inversion or breaking and ointment shows rancidity due to oily base.

Production feasibility and low preparation cost:

Preparation of emulgels comprises of simpler and short steps which increases the feasibility of the production. There are no specialized instruments needed for the production of emulgels. Moreover materials used are easily available and cheaper. Hence, decreases the production cost of emulgels.

Controlled release: Emulgels can be used to prolong the effect of drugs having shorter $t_{1/2}$.

No intensive sonication: Production of vesicular molecules needs intensive sonication which may result in drug degradation and leakage. But this problem is not seen during the production of emulgels as no sonication is needed.

TOPICAL DELIVERY INCLUDES TWO BASIC TYPES OF PRODUCTS 15:

External topical that are spread, sprayed or otherwise dispersed on to cutaneous tissues to cover the affected area.

Internal topical that are applied to the mucous membrane orally, vaginally or on a rectal tissues for local activity.

RATIONALE OF EMULGEL AS A TOPICAL DRUG DELIVERY SYSTEM:

Numbers of medicated products are applied to the skin or mucous membrane that either enhances or restores a fundamental function of skin or pharmacologically alters an action in the underlined tissues. Such products are referred as topical or dermatological products. Many widely used topical agents like ointments, creams lotions have many disadvantages. They are sticky in nature causing uneasiness to the patient when applied, have lesser spreading coefficient so applied by rubbing and they also exhibit the problem of stability. Due to all these factors within the major group of semisolid preparations, the use of transparent gels has expanded both in cosmetics and in pharmaceutical preparations. In spite of many advantages of gels a major limitation is in the delivery of hydrophobic

drugs. So to overcome this limitation an emulsion based approach is being used so that even a hydrophobic therapeutic moiety can be successfully incorporated and delivered through gels.

DRUG DELIVERY ACROSS THE SKIN:

The epidermis is the most superficial layer of the skin and is composed of stratified keratinized squamous epithelium which varies in thickness in different parts of the body. It is thickest on with elastic fibres. The skin forms a relatively water proof 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 neither absorption nor 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 layers of 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 penetration of 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 can be used to treat not just the affected areas (for example, the skin) but the whole body. (systemic)

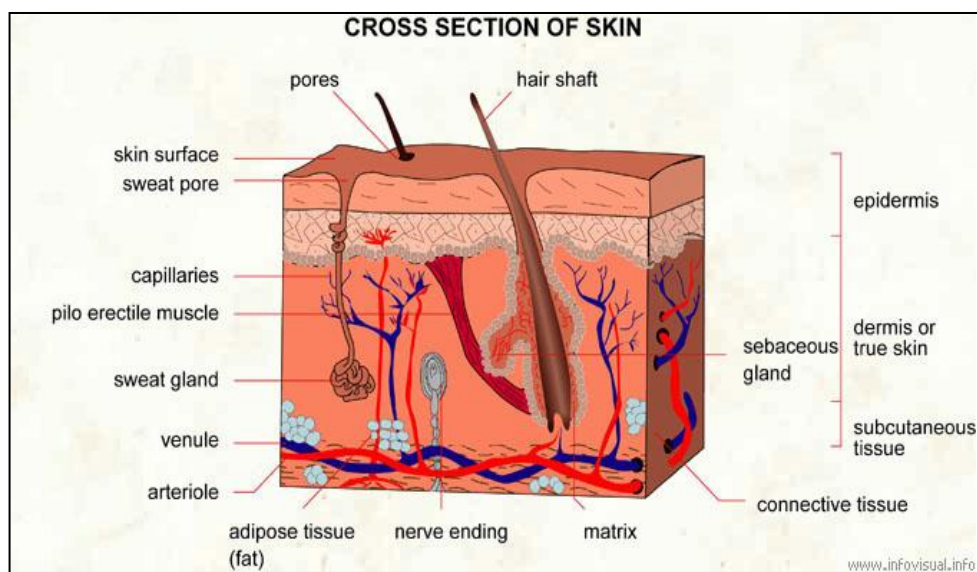


FIGURE 1: PHYSIOLOGY OF SKIN

Factors Affecting Topical Absorption of Drug ¹⁶⁻¹⁷

Physiological Factors

1. Skin thickness.
2. Lipid content.
3. Density of hair follicles.
4. Density of sweat glands.
5. Skin pH.
6. Blood flow.

7. Hydration of skin.

8. Inflammation of skin

Physiochemical Factors

1. Partition coefficient.
2. Molecular weight (<400 dalton).
3. Degree of ionization (only unionized drugs gets absorbed well).
4. Effect of vehicles

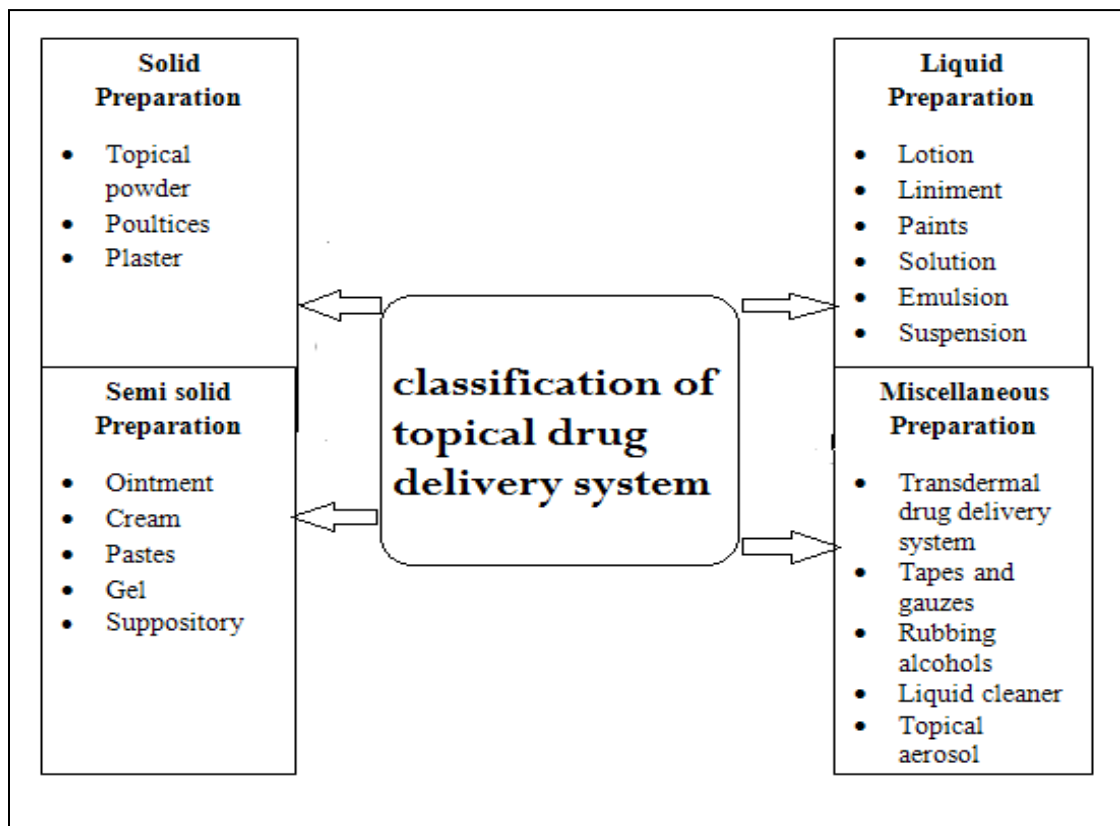


FIGURE 2: CLASSIFICATION OF TOPICAL DRUG DELIVERY

FACTORS TO BE CONSIDERED WHEN CHOOSING A TOPICAL PREPARATION¹⁸⁻¹⁹

1. Effect of the vehicle is to be checked e.g. an occlusive vehicle enhances penetration of the active ingredient and improves efficacy. The vehicle itself may have a cooling, drying, emollient, or protective action.
2. The type of preparation should be matched with the type of lesions. For example, avoid greasy ointments for acute weepy dermatitis.
3. Match the type of preparation with the site (e.g., gel or lotion for hairy areas).
4. Irritation or sensitization potential. Should be notified.

FORMULATION OF EMULGEL:

Vehicle²⁰:

The vehicle has following properties.

- Efficiently deposit the drug on the skin with even distribution.
- Release the drug so it can migrate freely to the site of action.
- Deliver the drug to the target site.
- Sustain a therapeutic drug level in the target tissue for a sufficient duration to provide a pharmacologic effect.
- Appropriately formulated for the anatomical site to be treated.
- Cosmetically acceptable to the patient.
- Due to the efficiency of the epidermal barrier, the amount of topical drug that gets through the stratum corneum is generally low. Rate and extent of absorption vary depending on characteristics of the vehicle but is also influenced by the active agent itself.

Aqueous Material:

This forms the aqueous phase of emulsion. The commonly used agents are water, alcohols etc.

Oils:

These agents from the oily phase of 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 supplements²¹.

Emulsifiers:

Emulsifying agents are used both to promote emulsification at the time of manufacture and to control stability during a shelf life that can vary from days for extemporaneously prepared emulsions to months or years for commercial preparations e.g. Polyethylene glycol 40stearate, Sorbitan mono-oleate (Span 80), Polyoxyethylene sorbitan monooleate (Tween80), Stearic acid and Sodium stearate²².

Gelling Agents:

These are the agents used to increase the consistency of any dosage form can also be used as thickening agent. Carbopol-940 1% HPMC-2910²³.

Penetration Enhancers:

In order to promote absorption of drugs, vehicles often include penetration enhancing ingredients that temporarily disrupts the skin barrier, fluidize the lipid channels between coenocytes, alter the partitioning of the drug into skin structures, or otherwise enhance delivery into skin. E.g. Clove oil 8%, Menthol 5%²⁴.

Properties of penetration enhancers²⁴:

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

They would ideally work rapidly, and the activity and duration of effect should be both predictable and reproducible.

1. They should have no pharmacological activity within the body i.e. should not bind to receptor sites.
2. The penetration enhancers should work unidirectional i.e. should allow therapeutic agents into the body whilst preventing the loss of endogenous material from the body.
3. The penetration enhancers should be appropriate for formulation into diverse topical preparations, thus should be compatible with both excipients and drugs.
4. They should be cosmetically acceptable with an appropriate skin 'feel'.

METHOD OF PREPARATION²⁵⁻²⁶:

STEP1: Formulation of Emulsion either O/W or W/O

STEP2: Formulation of gel base

STEP3: Incorporation of emulsion into gel base with continuous stirring

The flow chart of emulgel preparation is shown in

Figure 3.

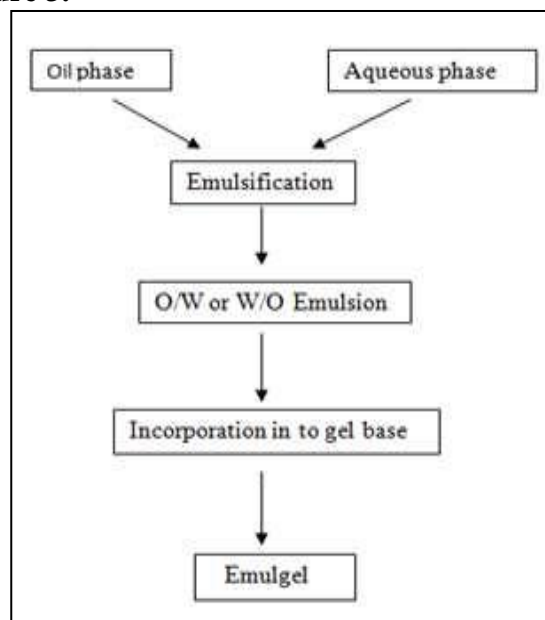


FIGURE 3: FLOWCHART FOR EMULGEL PREPARATION

EVALUATION PARAMETERS^{26,6}

Physical appearance:

The prepared Emulgel formulations are inspected visually for their color, homogeneity, consistency and pH. The pH values of 1% aqueous solutions of the prepared Gellified Emulsion are measured by a pH meter (Digital pH meter DPH 115 pm).

Rheological Studies:

The viscosity of the different emulgel formulations is determined at 25°C using a cone and plate viscometer with spindle 52 (Brookfield Engineering Laboratories,) and connected to a thermostatically controlled circulating water bath.

Spreadability:

Spreadability is determined by apparatus suggested by Mutimer et al (1956) which is suitably modified in the laboratory and used for the study. It consists of a 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) under study is placed on this ground slide. The emulgel is then sandwiched between this slide and another glass slide having the dimension of fixed

ground slide and provided with the hook. A 1Kg weight is placed on the top of the two slides for 5 minutes to expel air and to provide a uniform film of the emulgel between the slides. Excess of the emulgel is scrapped off from the edges. The top plate is then subjected to pull of 80 gms. With the help of string attached to the hook and the time (in seconds) required by the top slide to cover a distance of 7.5 cm be noted. A shorter interval indicates better spreadability. Spreadability was calculated by using the formula,

$$S = M.L/T$$

Where, S = spreadability,

M = Weight tied to upper slide,

L = Length of glass slides

T = Time taken to separate the slides

Completely from each other.

Extrudability study:

It is a usual empirical test to measure the force required to extrude the material from tube. The method applied for determination of applied shear in the region of the rheogram corresponding to a shearrate 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 0.5cm ribbon of emulgel in 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 then calculated by using the following formula.

Extrudability = Applied weight to extrude emulgel from tube (in gm) / Area (in cm²)

Globule size and its distribution in emulgel:

Globule size and distribution is determined by Malvern zeta sizer. A 1.0 gm sample is dissolved in purified water and agitated to get homogeneous dispersion. Sample was injected to photocell of zetasizer. Mean globule diameter and distribution is obtained.

Swelling Index:

To determine the swelling index of prepared topical emulgel, 1 gm of gel is taken on porous aluminum foil and then placed separately in a 50 ml beaker

containing 10 ml 0.1 N NaOH. Then samples are removed from beakers at different time intervals and put on dry place for some time after it reweighed. Swelling index is calculated as follows: Swelling Index (SW) % = $[(W_t - W_o) / W_o] \times 100$. Where, (SW) % = Equilibrium percent swelling, W_o = Original weight of emulgel at zero time After time t, W_t = Weight of swollen emulgel

Ex-vivo Bioadhesive strength measurement of topical emulgel:

(MICE SHAVEN SKIN): The modified method is used for the measurement of bioadhesive strength. The fresh skin is cut into pieces and washed with 0.1 N NaOH. Two pieces of skin are tied to the two glass slide separately from that one glass slide is fixed on the wooden piece and other piece is tied with the balance on right hand side. The right and left pans are balanced by adding extra weight on the left-hand pan. 1 gm of topical emulgel is placed between these two slides containing hairless skin pieces, and extra weight from the left pan is removed to sandwich the two pieces of skin and some pressure is applied to remove the presence of air. The balance is kept in this position for 5 minutes. Weight is added slowly at 200 mg/ min to the left-hand pan until the patch detached from the skin surface. The weight (gram force) required to detach the emulgel from the skin surface gives the measure of bioadhesive strength. The bioadhesive strength is calculated by using following:

$$\text{Bioadhesive Strength} = \frac{\text{Weight required (in gms)}}{\text{Area (cm}^2\text{)}}$$

Drug Content Determination:

Drug concentration in Gellified Emulsion is measured by spectrophotometer. Drug content in Gellified Emulsion is measured by dissolving known quantity of Gellified Emulsion in solvent (methanol) by Sonication. Absorbance is measured after suitable dilution in UV/VIS spectrophotometer (UV-1700 CE, Shimadzu Corporation, Japan).

In Vitro Release Study:

Franz diffusion cell (with effective diffusion area 3.14 cm² and 15.5 ml cell volume) is used for the drug release studies. Gellified Emulsion of approximately (200 mg) is applied onto the surface of egg membrane evenly. The egg membrane is clamped between the donor and the receptor

chamber of diffusion cell. The receptor chamber is filled with freshly prepared PBS (pH 5.5) solution to solubilize the drug. The receptor chamber is stirred by magnetic stirrer. The samples (1.0 ml aliquots) are collected at suitable time interval. Samples are analyzed for drug content by UV visible Spectrophotometer after appropriate dilutions. Cumulative corrections are made to obtain the total amount of drug release at each time interval. The cumulative amount of drug released across the egg membrane is determined as a function of time.

Microbiological assay:

Ditch plate technique is used. It is a technique used for evaluation of bacteriostatic or fungistatic activity of a compound. It is mainly applied for semisolid formulations. Previously prepared Sabouraud's agar dried plates are used. Three grams 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 angle from the ditch to the edge of the plate. After incubation for 18 to 24 hours at 25°C, the fungal growth is observed and the percentage inhibition is measured as follows.

$$\% \text{ inhibition} = \frac{L_2}{L_1} \times 100$$

Where L_1 = total length of the streaked culture, and L_2 = length of inhibition.

Skin Irritation Test (Patch Test):

The emulgel is applied on the properly shaven skin of rat and its adverse effect like change in color, 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.

Accelerated stability studies of Gellified Emulsion:

Stability studies are performed according to ICH guidelines. The formulations should be 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 should be analyzed for drug content every two weeks by UV-Visible spectrophotometer. Stability study is carried out by measuring the change in pH of gel at regular interval of time.

Drug release kinetic study

To analyze the mechanism of drug release from the topical gel, the release data should be fitted to following equations

Zero – order equation:

$$Q = k_0 t$$

Where Q is the amount of drug released at time t, and k₀ is the zero – order release rate.

First – order equation:

$$\ln(100 - Q) = \ln 100 - k_1 t$$

Where Q is the percent of drug release at time t, and k₁ is the first – order release rate constant.

Higuchi's equation:

$Q = k_2 \sqrt{t}$ Where Q is the percent of drug release at time t, and K₂ is the diffusion rate constant.

CONCLUSION: As emulgel promises to be a novel technique for topical drug delivery this proves an effective delivery of hydrophobic drugs in a water soluble gel bases. So, in future trends this dosage form will impart great patient compliance. Since emulgel possesses an edge in terms of spreadibility, adhesion, viscosity and extrusion, they will become a popular drug delivery system.

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