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Review Article

EMULGEL: A NEW APPROACH FOR ENHANCED TOPICAL DRUG DELIVERY

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ABSTRACT

Emulgel is used to treat aches and pains caused by colds, headaches, muscle aches, backaches, arthritis and other conditions and injuries. The patient adherence to topical formulations is significant in relation to chronic skin diseases, like fungal infections, acne, psoriasis. Emulgel is one of the recent technology in NDDS used topically having characteristics of dual control release i.e. emulsion as well as gel. Emulgels have emerged as one of the most interesting topical delivery systems as it has dual release control system i.e. gel and emulsion. When gel and emulsion are used in combined form, the dosage form are referred as emulgel.

Keywords: Emulgel, Gelling agents, Topical drug delivery, Skin diseases

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INTRODUCTION

Topical drug delivery can be defined as the application of a drug containing formulation to the skin to treat cutaneous disorder directly. The topical drug delivery system is generally used where other routes (like oral, sublingual, rectal, parental) of drug administration fails or in local skin infection like a fungal infection [1]. The main advantage of the topical delivery system is to bypass first pass metabolism. Avoidance of the risks and inconveniences of intravenous therapy and of the varied conditions of absorption, like pH changes, the presence of enzymes, gastric emptying time are another advantage of The topical drug delivery system is generally used where the others system of drug administration fails. The study is also carried out for the avoidance of the risks and inconvenience of intravenous therapy and of the varied conditions of absorption, like pH changes, the presence of enzymes, and gastric emptying time.

Topical drug administration is simplest and easiest route of localised drug delivery anywhere in the body by routes as ophthalmic, rectal, vaginal and skin. These are applied as a wide spectrum of preparations in case of both cosmetic and dermatological, to the healthy or diseased skin [2]. 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 effects. Drug absorption is enhanced through the skin if the drug substance is in solution, if it has a favourable lipid/water partition coefficient and if it is a non-electrolyte.

Skin is one of the most readily accessible parts of human body for topical administration and molecules penetrate in the skin mainly by three routes: through intact stratum corneum, through sweat ducts, and through the sebaceous follicle. Topical drug delivery is used for localised action on the body through ophthalmic, rectal, vaginal and skin as topical routes. The topical drug delivery system such as emulgel (gellified emulsion) generally used where the other systems of drug administration fail to directly treat cutaneous disorders such as fungal infections, acne, psoriasis etc [3]. Since the mid-1980's, emulsion gels have been of growing importance in the field of pharmaceutical semisolid dosage forms.



Fig. 1: An emulgel marketed product

Emulgel [1-4]

As the name suggest, they are the combination of gel and emulsion. Both oil-in-water and water-in-oil type of emulsion used as a vehicle to deliver various drugs to the skin. They also have a high ability to penetrate the skin. The presence of the gelling agent in water phase converts a classical emulsion into an emulgel. Emulgel for dermatological use has several favourable properties such as being thixotropic, greaseless, easily spreadable, easily removable, emollient, non-staining, water-soluble, longer shelf life, bio-friendly, transparent and pleasing appearance.

Molecules can basically penetrate into the skin by three routes: through intact stratum corneum, sweat ducts, or sebaceous follicle. The surface of the stratum corneum presents more than 99% of the total skin surface available for percutaneous drug absorption. Passage through this outermost 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).

Advantages [5, 6]

- 1. Avoidance of first pass metabolism.
- 2. Avoidance of gastrointestinal incompatibility.
- 3. More selective to a specific site.
- 4. Improve patient compliance.
- 5. Suitability for self-medication.

6. Providing utilisation of drug with short biological half-life and narrow therapeutic window.

- 7. Ability to easily terminate medication when needed.
- 8. Convenient and easy to apply.
- 9. Incorporation of hydrophobic drugs
- 10. Better loading capacity
- 11. Better stability
- 12. Production feasibility and low preparation cost
- 13. Controlled release
- 14. No intensive sonication

Disadvantages

1. Skin irritation on contact dermatitis.

- 2. The possibility of allergenic reactions.
- 3. The poor permeability of some drug through the skin.
- 4. Drug of large particle size not easy to absorb through the skin.
- 5. The occurrence of the bubble during formation of emulgel.

Rationale of emulgel as a topical drug delivery system

Many widely used topical agents like ointment, cream, lotion have many disadvantages. They have very sticky causing uneasiness to the patient when applied. Moreover, they also have lesser spreading coefficient and need to apply with rubbing. And they exhibit the problem of stability also. Due to all these factors within the major group of semisolid preparation, the use of transparent gels has expanded both in cosmetics and in a pharmaceutical preparation.

A gel is a colloid that is typically 99% wt. liquid, which is immobilised by surface tension between it and a macromolecular network of fibres built from a small amount of a gelatin substance present. 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 deliver through gels [7].

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.

Factors affecting topical absorption of drug [8, 9]

Physiological factors

- 1. Skin thickness.
- 2. Lipid content.
- 3. The density of hair follicles.
- 4. The density of sweat glands.
- 5. Skin pH.
- 6. Blood flow.
- 7. Hydration of skin.

8. Inflammation of skin.

Physicochemical factors

- 1. Partition coefficient.
- 2. The molecular weight (<400 Dalton).
- 3. The degree of ionisation (only unionised drugs gets absorbed well).
- 4. Effect of vehicles.

Physiology of skin [10, 11]

Most of the topical preparations are meant to be applied to the skin. So a basic knowledge of the skin and its physiology function are very important for designing topical dosage form. The skin of an average adult body covers a surface area approximately $2m^2$ and receives about one-third of the blood circulating through the body. An average human skin surface is known to contain, on the average 40-70 hair follicles and 200-300 sweat ducts on every square

centimetre of the skin. The pH of the skin varies from 4 to 5.6. Sweat and fatty acid secreted from sebum influence the pH of the skin surface. The skin can be considered to have four distinct layers of tissue.

Non-viable epidermis

Stratum corneum is the outermost layer of skin, which is the actual physical barrier to the most substance that comes in contact with the skin. The stratum corneum is 10 to 20 cell layer thick over most of the body. Each cell is a flat, plate-like structure- 34.44μ m long, 25-36 μ m wide, 0.5 to 0.20 μ m thick with a surface area of 750 to 1200 μ m stocked up to each other in brick-like fashion. Stratum corneum consists of lipid (5-15%) including phospholipids, glycosphingolipid, cholesterol sulphate and a neutral lipid, protein (75-85%) which is mainly keratin.

Viable epidermis

This layer of the skin resides between the stratum corneum and the dermis and has a thickness ranging from $50\text{-}100 \ \mu\text{m}$. The structures of the cells in the viable epidermis are physicochemically similar to other living tissues. Cells are held together by tonofibrils. The density of this region is not much different than water. The water content is about 90%.

Dermis

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

Subcutaneous connective tissue

The subcutaneous tissue or hypodermis is not actually considered a true part of the structured connective tissue which is composed of loose textured, white, fibrous connective tissue containing blood and lymph vessels, secretary pores of the sweat gland and cutaneous nerves. Most investigators consider drug is permeating through the skin enter the circulatory system before reaching the hypodermis, although the fatty tissue could serve as a depot of the drug.



Fig. 2: Physiology of skin

Factors to be considered when choosing a topical preparation [12, 13]

1. Effect of the vehicle 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. Match the type of preparation 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. Generally, ointments and w/o creams are less irritating, while gels are irritating. Ointments do not contain preservatives or emulsifiers if allergy to these agents is a concern.

Drug delivery across the skin

There are two important layers in the skin: the epidermis and dermis. Blood vessels are distributed profusely beneath the skin in the subcutaneous layer. There are three primary mechanisms for drug absorption through the skin: intercellular, trans cellular and follicular. The next most common route of delivery is through the pilosebaceous route permeation tends to occur through the intercellular matrix, but through the transcellular pathway, it has been shown to provide a faster alternative route of highly polar molecules. In normal intact skin, it has been established that the keratinized corneocytes and the largely non-polar lipid intercellular cement of the horny layer are the major factors involved in the maintenance of efficient barrier for drugs [14]. The drug penetration for skin can be enhanced by using organic solvents such as propylene glycol, surfactants and DMSO. The permeation enhancers are altered the barrier properties of the stratum corneum by types of a mechanism including enhancing solubility, partitioning the stratum corneum, fluidising the crystalline structure of the stratum corneum [15]. Creams and gels that are rubbed onto the skin have been used for years for effective treatment against infections and pain by medication. New technologies now allow other drugs to be absorbed through the skin. These can be used to treat not just the affected areas of the skin but the whole body by systemic route [16].



Fig. 3: Drug delivery cross of section

Emulgel preparation

Aqueous material

This forms the aqueous phase of the emulsion. Commonly used agents are water, alcohols [17].

Oils

These agents form the oily phase if the emulsion. For externally applied emulsions, mineral oils, either alone or combined with soft or hard paraffin, are widely used both as the vehicle for the drug and for their occlusive and sensory characteristics. Widely used oils in oral preparations are non-biodegradable mineral and castor oils that provide a local laxative effect, and fish liver oils or various fixed oils of vegetable origin (e. g., Arachis, cottonseed, and maize oils) as nutritional supplements [18, 19].

Table 1: Use of oils

Chemical	Quantity	Dosage form
Light Liquid Paraffin	7.5%	Emulsion and Emulgel
Isopropylmyristate	7-7.5%	Emulsion
Isopropyl stearate	7-7.5%	Emulsion
Isopropyl palmitate	7-7.5%	Emulsion
Propylene glycol	3-5%	Gel

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 40 stearate [20], sorbitan monooleate (span 80) [21], polyoxyethylene sorbitan monooleate (tween 80) [22], stearic acid [23], sodium stearate [24].

Gelling agent

These are the agents used to increase the consistency of any dosage form can also be used as thickening agent [25, 26].

Permeation enhancers

These are agents that partition into and interact with skin constituents to induce a temporary and reversible increase in skin permeability [27].

Table 2:	Use	of gell	ing	agents
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Gelling agent	Quantity	Dosage form
Carbopol-934	0.5%-2%	Emulgel
Carbopol-940	0.5%-2%	Emulgel
HPMC-2910	2.5%	Emulgel
НРМС	3.5%	Gel
Sodium CMC	1%	Gel

Table 3: Use of penetration enhancers

Penetration enhancer	Quantity	Dosage form	
Oleic acid	1%	Gel	
Lecithine	5%	Gel	
Urea	10%	Gel	
Isopropyl myristate	5%	Gel	
Linoleic acid	5%	Gel	
Clove oil	8%	Emulgel	
Menthol	5%	Emulgel	
Cinnamon	8%	Emulgel	

Properties of penetration enhancers

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

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

3. They should have no pharmacological activity within the body i.e. should not bind to receptor sites.

4. The penetration enhancers should work unidirectional i.e. should allow therapeutic agents into the body whilst preventing the loss of endogenous material from the body.

5. The penetration enhancers should be appropriate for formulation into diverse topical 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 is to 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. Enhancers can increase the drug diffusivity through skin proteins. The type of enhancer employed has a significant impact on the design and development of the product.

Preparation of emulgel

Emulgel was prepared by the method reported by [28] with minor modification. The Gel in formulations were prepared by dispersing Carbopol 934 in purified water with constant stirring at a moderate speed and carbopol 940 in purified water with constant stirring at a moderate speed then the pH are adjusted to 6 to 6.5 using triethanolamine (TEA). The oil phase of the emulsion was prepared by dissolving Span 80 in light liquid paraffin having the drug in ethanol solution while the aqueous phase was prepared by dissolved in propylene glycol and was mixed with the aqueous phase. Both the oily and aqueous phases were separately heated to 70 ° to 80 °C; then the oily phase was added to the aqueous phase with continuous stirring until cooled to room temperature. And add glutaraldehyde in during of mixing of gel and emulsion in ratio 1:1 to obtain the emulgel.

Evaluation of emulgel [29-31]

Fourier transforms infrared spectroscopy (FTIR)

The primary objective of this investigation was to identify a stable storage condition for the drug in solid state and identification of compatible excipients for formulation.

Physical examination

The Prepared emulgel formulations were inspected visually for their colour, homogeneity, consistency and phase separation.

Determination of pH

pH of the formulation was determined by using digital pH meter. pH meter electrode was washed by distilled water and then dipped into the formulation to measure pH and this process was repeated 3 times.

Measurement of viscosity

The viscosity of the formulated batches was determined using a Brookfield Viscometer (RVDV-I Prime, Brookfield Engineering

Laboratories, USA) with spindle 63. The formulation whose viscosity was to be determined was added to the beaker and was allowed to settle down for 30 min at the assay temperature $(25\pm1 \text{ °C})$ before the measurement was taken. Spindle was lowered perpendicularly into the centre of emulgel taking care that spindle does not touch the bottom of the jar and rotated at a speed of 50 rpm for 10 min. The viscosity reading was noted.

Spreadability

To determine spreadability of the gel formulations, two glass slides of standard dimensions were selected. Formulation whose spreadability was to be determined was placed over one slide and the other slide was placed over its top such that the gel is sandwiched between the two slides. The slides were pressed upon each other so as to displace any air present and the adhering gel was wiped off. The two slides were placed onto a stand such that only the lower slide is held firm by the opposite fangs of the clamp allowing the upper slide to slip off freely by the force of weight tied to it. 20 g weight was tied to the upper slide carefully. The time taken by the upper slide to completely detach from the lower slide was noted.

Globule size and its distribution in emulgel

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

Swelling index

To determine the swelling index of prepared topical emulgel, 1 g of gel is taken on porous aluminium foil and then placed separately in a 50 ml beaker containing 10 ml 0.1 N NaoH. Then samples were removed from beakers at different time intervals and put it on a dry place for some time after it reweighed.

In vitro drug release study

The *in vitro* drug release studies of the Emulgel were carried out on Diffusion cell using egg membrane. This was clamped carefully to one end of the hollow glass tube of dial y sis cell. Emulgel (1g) was applied onto the surface of egg membrane dialysis membrane. The receptor chamber was filled with freshly prepared PBS (pH 7.4) solution to solubilize the drug. The receptor chamber was stirred by a magnetic stirrer. The samples (1 ml aliquots) were collected at suitable time interval sample were analysed for drug content by UV-visible spectrophotometer after appropriate dilutions. Cumulative corrections were made to obtain the total amount of drug release at each time interval. The cumulative amount of drug release across the egg membrane was determined as a function of time. The cumulative % drug release was calculated using standard calibration curve.

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 grammes 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.

Skin irritation test

A 0.5 g sample of the test article was then applied to each site (two sites per rabbit) by introduction under a double gauze layer to an area of skin approximately $1" \times 1"$ (2.54 x 2.54 cm²). The Gellified Emulsion was applied on the skin of a rabbit. Animals were returned to their cages. After a 24 h exposure, the Gellified emulsion is removed. The test sites were wiped with tap water to remove any remaining test article residue [32].

Stability studies

The prepared emulgels were packed in aluminium collapsible tubes (5 g) and subjected to stability studies at 5 °C, 25 °C/60% RH, 30 °C/65% RH, and 40 °C/75% RH for a period of 3 mo. Samples were withdrawn at 15-day time intervals and evaluated for physical

appearance, pH, rheological properties, drug content, and drug release profiles [33].

CONCLUSION

The topical drug delivery system will be used extensively due to better patient compliance. Since emulgel possesses an edge in terms of spreadibilty, adhesion, viscosity and extrusion, they will become a popular drug delivery system. Moreover, they will become a solution for loading hydrophobic drugs in a water soluble gel bases.

CONFLICT OF INTERESTS

Declared none

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