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A Review Article

EMULGEL – NOVEL TOPICAL DRUG DELIVERY SYSTEM: A REVIEW

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Abstract:

Emulgel systems are currently of attention to the pharmaceutical scientists because of their substantial potential to act as drug delivery vehicle by incorporating a broad range of drug molecules. These are either emulsion of water in oil type or oil in water, which is gelled by mixing it with a gelling agent. Incorporation of emulsion into gel makes it a dual control release system & also increases its stability. Due to lack of insoluble excipients and excess oily bases, it demonstrates better drug release as compared to other topical drug delivery system. Due to nongreasy because of the presence of gel phase which favors good patient compliance. In order to understand the potential of emulgel as delivery vehicles, this review gives an overview of the ideal properties, formation, and characterization of emulgels. The use of emulgel -based systems as drug delivery vehicles is reviewed, with particular emphasis being placed on recent developments and future directions. In comparison with the other semisolid formulations, the use of gels seems to be more advantageous both in cosmetics and pharmaceutical preparations. When gel and emulsion are used in the combined form, they are referred as emulgel. Emulgel is the promising drug delivery system for the delivery of hydrophobic drugs. Emulgel, an interesting topical drug delivery system, has dual release control system, i.e., gel and emulsion. Emulgel have several merits like greaseless, easily spreadable, easily removable, emollient and transparency. Preparation of emulgel is done by incorporation method. Emulgel are commonly used for the delivery of analysics, anti-inflammatory, anti-fungal, anti-acne drugs and various cosmetic formulations. Studies on emulgel promises a better future in delivering more numbers of topical drugs as emulgel by their merits over other drug delivery systems.

Keywords: Emulgel, Gelling agent, Emulsion, Topical agents

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INTRODUCTION:

Topical drug delivery systems skin serves as one of the most easily accessible routes for drug administration. Topical drug delivery system has been used for centuries for the treatment of local skin disorders and is localised drug delivery system anywhere in the body through ophthalmic, rectal, vaginal and skin as a topical route. 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 the other routes (like oral, sublingual, rectal, parenteral) of drug administration fail or in local skin infection like fungal infection. The topical drug delivery provides a direct accessibility to the skin as a target organ for diagnosis and treatment without fear of undergoing first pass metabolism [1].

The main advantage of topical delivery system is to by 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 preparations. Emulgel is one of the novel technologies widely used for fungal infections, acne, psoriasis, and the other topical disorders. Emulgel is the emulsion, either of o/w or w/o type, which are gelled by mixing with a gelling agent such as carbapol, HPMC etc. Major objective behind emulgel is to deliver hydrophobic drugs to systemic circulation via skin.it has the benefit dual release control system i.e, emulsion and gel [2].

1.1 Emulgel

When emulsion and gel both are used in combined form the dosage form prepared is named as Emulgel. As the name suggests it is the combination of emulsion and gel. Therefore, they have been recently used as vehicle to deliver various drugs to the skin for topical as well as systemic actions. In fact, presence of gelling agent in water phase converts an ancient emulsion into emulgel. Direct (oil-in-water) system is used to entrap lipophilic drugs, while hydrophilic drugs are encapsulated in the reverse (water-in-oil) system. Emulsions have certain degree of elegance and are easily washable whenever required. It also has high ability to penetrate the skin. Topically used emulgels have several desirable properties like being thixotropic. greaseless, easily spreadable as well as removable, emollient, non-staining, water soluble, longer shelflife, bio-friendly, transparent, pleasant appearance etc.

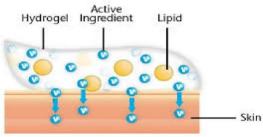


Fig 1.1: Structure of emulgel

Hydrophobic drugs can be easily incorporated into gels using w/o/w emulsions. The major advantage of emulgel is avoidance of first pass metabolism. It is more selective to a specific site. They have better stability, better loading capacity, Production feasibility, low preparation and no intensive sonication. Avoidance gastrointestinal of incompatibility. They improve patient compliance and suitability for self-medication. It isProviding utilization of drug with short biological half-life and narrow therapeutic window. They have ability to easily terminate medication when needed.

The main disadvantage of emulgel is skin irritation of contact dermatitis may occur due to the drug and/or excipients. Poor permeability of some drugs through the skin. Possibility of allergenic reactions. Drugs of larger particle size not easy to absorb through the skin [3].

1.2 Skin as a Site for Topical Drug Administration

The skin is one of the most extensive and readily accessible organs of the human body. The skin of an average adult body covers a surface area of approximately two square meters and receives about one third of the blood circulating through the body. With a thickness of only a few millimetres (2.97 ± 0.28 mm), skin separates the underlying blood circulation network from the outside environment and serves as a barrier against physical and chemical attacks. It acts as a thermostat in maintaining body temperature and shields the body from invasion by microorganisms [4].

Skin is a well-known route of drug administration but its applications have earlier been restricted to local effect. Nowadays delivery of drugs or targeting of drugs to specific sites by topical application for systemic effects has been taken as a challenge by number of researchers. The delivery of drug via transdermal route has been recognized as one of the potential routes for both local and systemic delivery of drugs, due to several advantages. Topical delivery of bioactive substances is indeed a powerful strategy toreduce their systemic toxicity and at the same time restricts the therapeutic effect to specific tissues targeting to a specific site. However, the major limitation of transdermal delivery of drugs is that the skin layers provide high resistance to the penetrate molecules. Consequently, many substances are topically and systemically ineffective when applied onto the skin, due to their complete failure to penetrate. Different strategies including the use of skin penetration enhancers, iontophoresis and sonophoresis, have been developed[5].

1.3 Anatomy and physiology of skin

The skin or cutaneous membrane covers the external surface of the body. It is the largest organ of the body in surface area and weight. Skin consists of two main parts, the superficial, thinner portion, which is composed, of epithelial tissue is the epidermis and dipper thicker layer dermis.

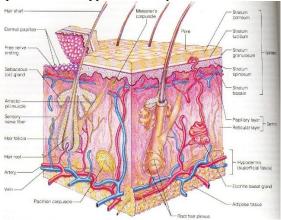


Fig 1.2: Anatomy of skin

Epidermis is composed of keratinised of stratified squamous epithelium. There are several layers of cells in the epidermis, which is extending from the dippiest germinative layer to surface. Stratum corneum cells are formed and continuously replenished by the slow upward migration of the cells produced by the basal cell layer. Keratinocytes comprise 90% epithelial cells. There are several distinct layers of keratocyte in various stages of development. Stratum corneum is underlined with three layers, stratum spinosem (prickly layer), stratum granulosum (granular layer) and stratum lucidum.

The dermis is vascular and supports the epidermis structurally and nutritionally. The second dipper part of the skin, the dermis is composed of mainly connective tissue containing collagen and elastic fibers. It varies in thickness from just over 1mm on the inner forearm to 4mm on the back. The structures in dermis are Blood vessels, Lymph vessels, Sensory nerve ending, Sweat gland and their ducts, Hair roots, hair follicles and Sebaceous glands.

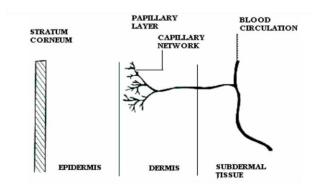
The hypodermis or subcutaneous fat tissue supports the dermis and epidermis. It serves as a fat storage area. For transdermal drug delivery, drug has to penetrate through all these three layers and reach into systemic circulation. In case of topical drug delivery penetration through stratum corneum is essential and then retention of drug in skin layers is desired [6].

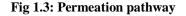
1.4 Fundamentals of skin permeation

The phenomenon of percutaneous absorption can be visualized as a series of steps in sequence, sorption of a molecule onto the surface layer of stratum cornium, diffusion through it and various layers of epidermis. Finally, at the papillary layer of dermis, the molecule is taken up in to microcirculation for subsequent systemic distribution. The viable tissue layers and capillaries are relatively permeable and peripheral circulation is sufficiently rapid.

1.5 Permeation pathways

A molecule may use two diffusional routes to penetrate through skin, the appendageal route and the epidermal route.





1.5.1 Appandagel route

Skin Appendages have fractional area available for absorption is small (about 0.1%) and this route usually does not contribute appreciably to steadystate flux of a drug. However, the route may be important for ions and large polar molecule that cross intact stratum cornium with difficulty.

1.5.2 Epidermal route

The stratum cornium is muilticellular membrane and electron microscopic evidence implies that the

Rohini L M et al

intercellular regions are filled with a lipid-rich amorphous material. Although the intercellular volume is small, it is still sufficiently large to provide a significant route in theory provided that the diffusion coefficient for this pathway is large enough. For drugs which mainly cross the intact horny layer, two potential micro routes of entry exists, the transcellular (or intracellular) and intercellular pathways. The principal pathway taken by a permeant is decided mainly by the partition coefficient (log K). Hydrophilic drugs partition preferentially into the intracellular domains, whereas lipophilic permeates traverse the stratum corneum via the intercellular route. Most permeates permeate the stratum corneum by both routes. However, the tortuous intercellular pathway is widely considered to provide the principal route and major barrier to the permeation of most drugs.

1.6 Routes of Skin Permeation

The structure of skin shows number of diffusional pores like hair follicles, sweat glands, and intracellular spaces etc. which help in the absorption [7].

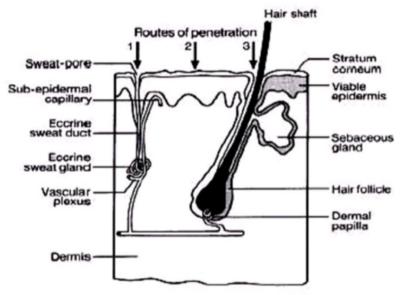
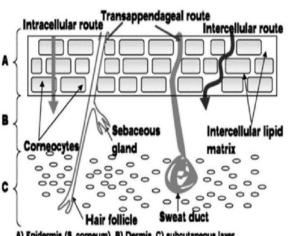


Fig 1.4: Possible routes of penetration of drugs through skin

Route	Relative Surface Area	Diffusional path length
Transcellular	99	25
Intercellular	0.7	350
Trans appendageal	0.1	200

1.7 Drug entry through skin

Drug mostly penetrate the stratum corneum by passive diffusion whereas limited active transport follows these steps: drug dissolution in its vehicle than drug diffusion form the vehicle to surface of the skin and finally the actual penetration of the drug through the different layers of the skin. Active pass through the stratum corneum (lipophilic) into the viable epidermis and continue passively through to the dermis (hydrophilic) to the dermal-epidermal junction where the blood vessels carry it to the systemic circulation. Topical drugs are generally applied for three different functions. First, active for the surface of the skin e.g. for disinfection, insect repellents and cosmetics, so called epidermal formulations. Second functions when formulations are designed to penetrate into the deeper regions of the skin such as the viable epidermis and the dermis, so called endodermal or diadermal formulations. Thirdly, for the systemic action of drugs by transdermal application can be the aim of the topical therapy. Drug penetrates the stratum corneum by two options: the transepidermal route and the route via pores. The transepidermal route can be divided into the transcellular and the intercellular route. Transcellular route is the direct and the shortest route where the drug directly passes through both the lipid structures of the stratum corneum and the cytoplasm of the dead keratinocytes, but encounter significant resistance to permeation because they have to cross both lipophilic and hydrophilic structures. Intercellular is the common route where the drug passes between the corneocytes. Since the skin appendages (glands and hair follicles) occupy only 0.1% of the total human skin surface, the contribution to the pore route was primarily considered to be small. However, for very lipophilic and large molecules (and some electrolytes) the appendages and other diffusion shunts may also play an important role. The follicular apparatus of hair follicles, the sweat glands and microlesions in the interfollicular horny layer were introduced as theoretical vertical pathways for percutaneous penetration. The lipophilic drug that easily crosses the stratum corneum, show slow diffusion when it reaches the hydrophilic epidermis that causes the temporaray deposition, so called reservoir effect. Small molecular size Substances having both lipid and aqueous solubility are capable of best permeation effect. Electrolytes are difficult to absorb when they are applied in aqueous solutions because they create a field of stable hydration that increases the size of the diffusing component. The permeability coefficient of the drugs depends on the solute size, lipophilicity and the diffusion path length. Although Fick's law describes that penetration depends on the thickness of the skin, later works show its dependency more on the lipid composition of the skin [8].



A) Epidermis (S. corneum), B) Dermis, C) subcutaneous layer

Fig1.5: Drug entry through the skin 1.8 Method to enhance drug penetration and absorption

- 1. Chemical enhancement
- 2. Physical enhancement
- 3. Biochemical enhancement
- 4. Super saturation enhancement

1.9 Factors to be considered when choosing a topical preparation

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, but gels are irritating.

5. Ointments do not contain preservatives or emulsifiers if allergy to these agents is a concern.

The various physiological factors affecting topical administration areLipid content. Density of hair follicles, Density of sweat glands, Skin pH, Blood flow, Hydration of skin, Inflammation of skin.

1.9.1 Physiochemical factors

1. Partition coefficient.

2. Molecular weight (<400 Dalton).

3. Degree of ionization (only unionized drugs gets absorbed well).

4. Effect of vehicles

1.9.2 Advantages of topical drug delivery system

1. Avoids hepatic first pass effect (metabolism) and also gastrointestinal incompatibility of drugs, thus reducing the total drug administered.

2. Avoids gastrointestinal irritation caused by various types of agents like NSAIDs. It also avoids the degradation of drug due to pH, enzymatic activity, and drug-food interaction etc.

3. Minimizes inter- and intra- patient variation.

4. Reduces the dosing interval of drug and thus improves patient compliance.

5. Enhances therapeutic efficacy

6. Can be substituted for oral drug administration in cases where patient is unable to swallow the drug or in cases of vomiting and diarrhoea.

7. Avoids risks and inconvenience of parenteral therapy and hence, suitable for self-administration.8. Extends the activity of drug with short biological

half-life, thus reducing the frequency of dosing. 9. The drug effect can be rapidly terminated by

washing out the application or removing the system. This is not possible or is difficult either parenteral or oral therapy.

1.9.3 Disadvantages of topical drug delivery system

1. Drugs with high blood concentration levels cannot be administered.

2. It can be difficult for drugs to permeate through skin. (This is so because the skin, in addition to

being a physical barrier, also acts as a chemical barrier)

3. Drugs incorporated in transdermal formulation should be checked for skin irritation. (As the formulation also contains various adjuvants which may produce irritation or contact dermatitis.)

4. In transdermal gel preparation, it may stain clothes.

5. Drugs with low molecular size are only suitable for formulation.

6. Drugs have limited permeability through skin.

7. Drugs cannot be delivered in pulsatile fashion transdermally[9].

1.10 Emulgel is composed of two parts

1. Emulsion

2. Gel

A. Emulsion

Emulsions are biphasic system in which one immiscible liquid is dispersed into other; due to this the system becomes unstable which is stabilized by emulsifying agents. Emulsion can be either o/w or w/o these are used as vehicles to deliver drug. Emulsions are stabilized by use of emulsifying agents. They can be easily washed off from skin and have good penetration capability. Several types as oil in water (O/W), water in oil (W/O), oil in oil (O/O), micro-emulsions, double and multiple emulsions, mixed emulsions etc. for preparation and stability of emulsion the emulsifier is necessary. Various factors could affect the process of emulsification, such as the nature of oil, emulsifier, the emulsifier concentration used, rpm as well as the temperature.

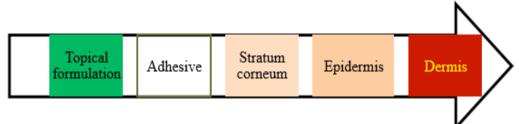


Fig 1.6: Path of drug penetration in topical dosage

1.10.1 Different types of emulsions depending on the size of droplets or nature of distribution macroemulsions

These are most common type of emulsions where the particle size of droplets is more than 400nm. They are visually opaque but the individual droplets can be easily observed under microscope. Macro emulsions are thermodynamically unstable, but can be stabilized using surface active agents.

Microemulsion

Microemulsions are transparent and thermodynamically stable as their droplet size range from 10 to 100 nm and they do not coalesce. Microemulsions are composed of oil, surfactant, cosurfactant and water in specific proportions.

Multiple Emulsion

Small droplets of one phase (e.g. oil) dispersed in larger droplets of second phase (e.g. Water) with the latter further dispersed in the former (i.e. oil) as the continuous medium.

B. Gel

The term "gel" represents a physical state with properties intermediate between those of solids and liquids. However, it is often wrongly used to describe any fluid system that exhibits some degree of rigidity. A gel consists of a polymer which swells

in the presence of fluid and perhaps it within its structure. The rigidity of the gel is determined by the amount of fluid it entraps. These gels are wet and soft and look like a solid material. These are capable of undergoing large deformation in their physical state i.e. from solid to liquid. Gels are constituted by entrapment of large amounts of aqueous or hydroalcoholic liquid in a network of colloidal solid particles, which may be inorganic or organic polymers of natural or synthetic origin. The higher aqueous component permits greater dissolution of drugs, and permits easy migration of the drug as compared to the ointment or cream base. However, this makes gels poor vehicle for hydrophobic drugs. This limitation of gels can be overcome by making emulgel.

1.11 Important constituents of emulgel preparation

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

Oils

These agents form the oily phase if the emulsion. For externally applied emulsions, mineral oils, either alone or combined with soft or hard paraffins, 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.

Table 1.2: List of oils

Chemical	Quantity	Dosage form
Light liquid paraffin	7-7.5%	Emulsion & Emulgel
Isopropyl stearate	7-7.5%	Emulsion
Isopropyl myristate	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.eg Polyethylene glycol 40 stearate, Sorbitanmonooleate (Span 80), Polyoxyethylenesorbitanmonooleate (Tween 80), Sodium stearate.

Table 1.3: List of emulsifiers.

Chemical	Quantity	Dosage form
Polyethylene glycol 40	q.s	Emulsion
Polyethylene stearate	q.s	Emulsion
Sorbitanmonoleate (Span 80)	q.s	Emulsion
Polyoxy ethylenesorbitanmonoleate	q.s	Emulsion
(Tween 80)		
Sodium stearate	q.s	Emulsion

Gelling Agent

These are the agents used to increase the consistency of any dosage form which can also be used as thickening agent gelling agent are Carbopol-934, Carbopol-940.

 Table 1.3: List of Gelling agents

Gelling agent	Quantity	Dosage form
Carbopol 934	0.5-2%	Emulgel
Carbopol 940	0.5-2%	Emulgel
HPMC 2910	2.5%	Emulgel
HPMC	3.5%	Gel
Sodium CMC	1%	Gel

Permeation Enhancers

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

Table 1.4: List of various Penetration enhancers used in Emulgel

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

6. Preservatives e.g. Propyl paraben, methyl paraben, Benzalkonium chloride, Benzoic acid, Benzyl alcohol etc.

7. Antioxidants e.g. ButylatedHydroxyToluene (BHT), Ascorbylpalmitate, DutylatedHydroxyToluene

Butylatedhydroxyanisole (BHA), etc.

8.Humectant e.g. Glycerin, Propylene gylcol, etc[10].

APPLICATIONS OF EMULGEL;

- **Treatment of microbial and viral skin infections**- Emulgel systems containing antibiotic drugs have been investigated in the treatment of skin infections.
- Anti-Inflammatory Emulgel systems-Emulgel systems have been investigated transdermal delivery of anti-inflamatory drugs.
- Emulgel systems of menopausal syndromes-Emulgelcompositions have been tested for their efficiency in the treatment of androgen deficiency associated with menopause in men and menopausal syndromes in women. A testosterone emulgel patch system, Testosome, was designed for the treatment of androgen deficiency in men.
- Analgesic and Antipyretic Emulgel systems-- Emulgel systems have been investigated transdermal delivery of analgesic and antipyretic drugs.

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