



CODEN [USA]: IAJPBB

ISSN : 2349-7750

**INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES**

SJIF Impact Factor: 7.187

<https://doi.org/10.5281/zenodo.5176099>Online at: <http://www.iajps.com>

Review Article

A REVIEW ON EMULGEL¹Pinky Bisht* and ²G. Gnanarajan^{1,2}Department of Pharmaceutics, School of Pharmaceutical Sciences,
Shri Guru Ram Rai University, Patel Nagar Dehradun.

Article Received: July 2021

Accepted: July 2021

Published: August 2021

Abstract:

Emulgels have emerged as one of the most interesting topical drug delivery systems as it has dual release control i.e. emulsion and gel. The developed emulgels were evaluated for their physicochemical properties like colour, homogeneity, consistency, spreadability, pH value, rheological behaviour, drug content, drug release and stability. They are generally adopted for the purpose as antiseptics, antifungal agents, skin emollients, and protective. The activity of topical preparation reveal the various factors as drug solubility, contact time to skin, its lipophilicity, its permeability. Gels are a quite newer class of dosage form formulated by entrapment of large amounts of aqueous or hydro-alcoholic liquid with in the network of colloidal solid particles. Gel formulations generally provide faster drug release as compared to conventional topical drug delivery formulations. In spite of many advantages of gels, a major limitation is in the difficulty in delivery of hydrophobic drugs. So to overcome these limitations, emulgels are prepared. Emulgel are being used for the delivery of analgesics, anti-inflammatory, anti-fungal, anti-acne drugs and various cosmetic formulations with still wide range to explore.

Keywords: Emulgels, topical drug delivery, emulsion, gel.

Corresponding author:**Pinky Bisht,**

Department of Pharmaceutics,
School of Pharmaceutical Sciences,
Shri Guru Ram Rai University,
Patel Nagar Dehradun.

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Please cite this article in press Pinky Bisht *et al.*, A Review On Emulgel., Indo Am. J. P. Sci, 2021; 08(08).

INTRODUCTION:

Topical drug administration is considered as simplest and easiest route of localized drug delivery anywhere in the body by different routes. These are wide spectrum of preparations in case of cosmetic as well as dermatological, to the healthy or diseased skin.

Gels and emulsions when used in combined form the dosage forms are referred as emulgels^[1]. In order to deliver the drugs to the skin, both oil-in-water and water-in-oil type of emulsions are used as vehicles. They additionally have a high capacity to infiltrate the skin. The nearness of gelling agent in water stage changes over an established emulsion into an emulgel. Emulgel for dermatological utilize have a few great properties, for example, being thixotropic, greaseless, effortlessly spreadable, effectively removable, emollient, nonrecoloring, water dissolvable, longer shelf life of realistic usability, bio agreeable, and satisfying appearance^[2].

Topical gel formulations provide a suitable delivery system for drugs because they are less greasy and can be easily removed from the skin. Percutaneous absorption of drugs from topical formulation involves the release of the drug from the formulation and permeation through skin to reach the target tissue. The release of the drug from topical preparations depends on the physicochemical properties of the vehicle and the drug employed. In order to enhance drug and skin permeation, methods such as the selection of suitable vehicle, coadministration of a chemical enhancer have been studied. Use of topical agents requires an appreciation of the factors that influence percutaneous absorption. Molecules can penetrate the skin by three routes, through intact stratum corneum, through sweat glands, or through the 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 (penetration coefficient); and drug diffusion across the layers of

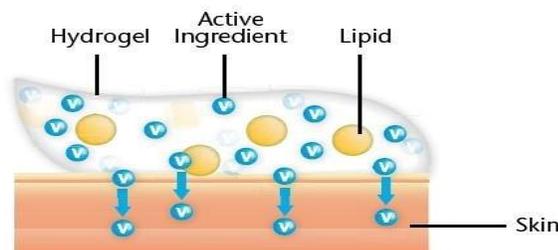
the skin (diffusion co-efficient). Preferable characteristic of topical drugs include low molecular mass (400 Daltons) with adequate solubility in oil & water, and have high partition co-efficient for the topical formulation. Gels are a relatively newer class of dosage form created by entrapment of large amounts of aqueous or hydro alcoholic liquid in a network of colloidal solid particles. Gel formulations generally provide faster drug release compared with ointments and creams. Major drawback of topical dosage form diffusion of drug in the delivery of hydrophobic drugs, and permeation through stratum corneum is for hydrophilic drugs. Therefore, to overcome this limitation emulgels are prepared^[3].

Advantages of Emulgel

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

Disadvantages of Emulgel

1. Poor permeability of some drugs through skin.
2. Occurrence of bubble during formation of emulgel.
3. Drug of large particle size not easy to absorb through the skin.
4. Skin irritation or allergic reaction on contact dermatitis.



Types of Emulgel

Macroemulsions gel:

These are most common type of emulgel where the particle size of droplets of emulsion is more than 400nm. They are visually opaque but the individual droplets can be easily observed under microscope. Macroemulsion are thermodynamically unstable, but can be stabilized using surface active agents. E.g. mefenamic acid emulgel was prepared using Carbopol 940 as gelling agent. Liquid paraffin was used as oil phase. Mentha oil and clove oil was used as penetration enhancer. Then it was evaluated for rheological studies, spreading coefficient studies, skin irritation test, in-vitro release, etc^[6].

Nanoemulgel:

When nanoemulsion is incorporated into gel it is called as nanoemulgel. Nanoemulsions are thermodynamically stable transparent (translucent) dispersions of oil and water stabilized by an interfacial film of surfactant and cosurfactant molecules having a droplet size of less than 100 nm. Nanoemulsion formulations possess improved transdermal and dermal delivery properties in vitro as well as in vivo. Nanoemulsions have improved transdermal permeation of many drugs over the conventional topical formulations such as emulsions and gels .e.g. Carvedilol nanoemulgel was prepared using oleic acid and isopropyl myristate (3:1) as oil phase. Tween 20 and Carbitol were used as surfactant and cosurfactant respectively. Carbopol 934 was used as gelling agent^[7].

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. The ingredients of microemulsion could facilitate the permeation rate of the drug by reducing the diffusion barrier of the stratum corneum. However, due to low viscosity of microemulsion, their less retention capacity in the skin restrains its application in the pharmaceutical industry To overcome this disadvantage, gelling agents such as Carbopol 940, xanthan gum and carrageenan have been added into the microemulsion for forming microemulsion based gel in order to increase its viscosity which could be suitable for topical application. Moreover, microemulsion based gel prevents the absorption of drug in the blood stream and provide higher drug accumulation in the skin for efficient action. E.g. clotrimazole microemulsion based vaginal gel was prepared using Capryol 90 as oil phase and

Cremonophor EL as surfactant. Carbopol ETD 2020 is used as gelling agent^[8].

Rationale

Most of the widely used topical formulations like creams, ointments, lotions have various limitations such as they are sticky in nature, cause uneasiness to the patient on application, need to be rubbed or have lesser spreadability. Also stability of these pose a severe problem, hence to overcome these limitations now a days transparent gels are used widely. Gels are the dosage forms formed by entrapment of large amounts of aqueous or hydroalcoholic liquid in a network of colloidal solid particles. Gels are widely used due to their faster drug release but it also has its limitations in the delivery of hydrophobic drugs and hence to overcome this we combine emulsion and gel to give rise to an emulgel. Emulgel is a novel approach of formulating oil-in-water or water-in-oil gelled with a gelling agent. These are much more stable than the other topical preparations and also serve wide variety of advantages over the other topical formulations.

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. Blood vessels are distributed profusely beneath the skin. The skin acts as a two way barrier to prevent absorption or 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 barrier resides in the outermost layer of the epidermis, the stratum corneum. To overcome this problem various penetration enhances are used to improve the drug absorption through stratum corneum

Factors affecting topical absorption of drug

(A) 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.

(B) Physiochemical Factors

1. Partition coefficient.
2. Molecular weight (< 400 dalton).

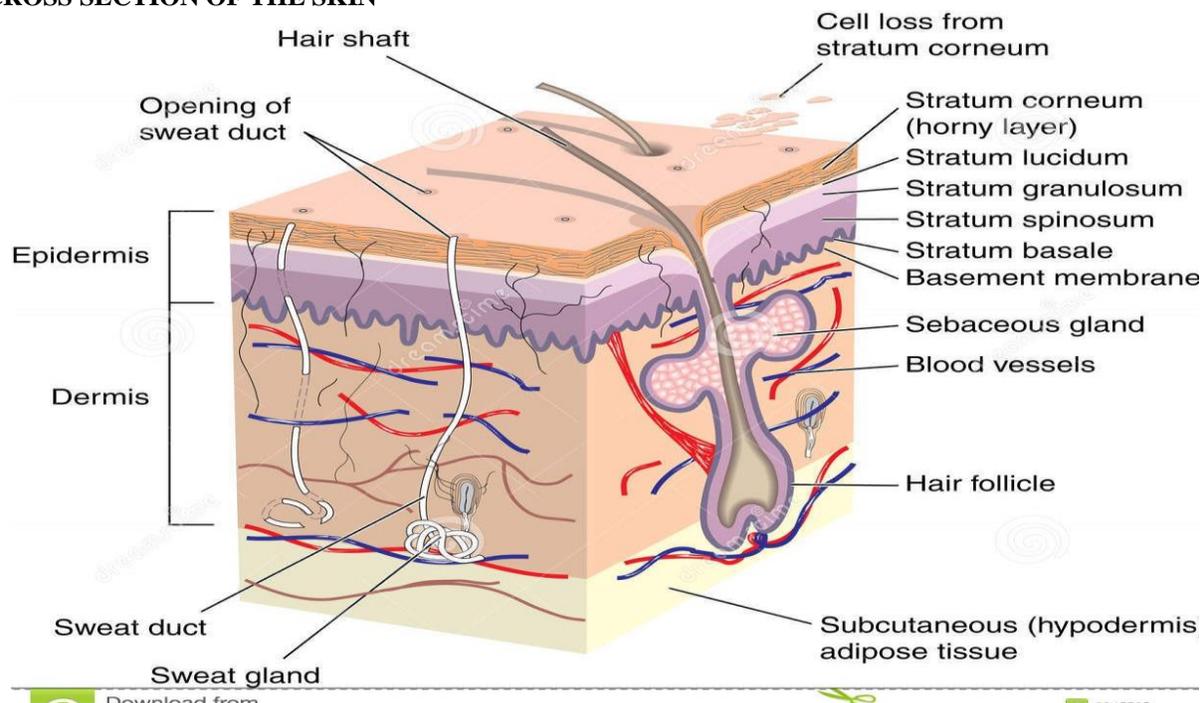
3. Degree of ionization (only unionized drugs gets absorbed well).
4. Effect of vehicles^[9].

Physiology of the skin^[10-11]

The skin consists of several layers. The outer layer is called epidermis, the layer below the epidermis is called dermis. The dermis contain a network of blood

vessels, hair follicle, sweat gland & sebaceous gland. Beneath the dermis are subcutaneous fatty tissues. Bulbs of hair project into these fatty tissues. Human skin surface is known to contain, on 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.

CROSS SECTION OF THE SKIN



Epidermis

It is the outermost layer of the skin, which is approximately 150 micrometers thick. Cell from lower layers of the skin travel upward during their life cycle and become flat dead cell of the corneum. The source of energy for lower portions of epidermis is also glucose, and the end product of metabolism, lactic acid accumulates in skin.

The layers of epidermis are:

- Stratum Germinativum (Growing Layer)
- Malpighion Layer (pigment Layer)
- Stratum Spinosum (Prickly cell Layer)
- Stratum Granulosum (Granular Layer)
- Stratum Lucidum
- Stratum Corneum (Horny Layer)

Stratum germinativum

Basal cells are nucleated, columnar. Cells of this layer have high mitotic index and constantly renew the epidermis and this proliferation in healthy skin balances the loss of dead horny cells from the skin surface.

Malpighion layer

The basal cell also include melanocytes which produce the distribute melanin granules to the keratinocytes required for pigmentation a protective measure against radiation.

Stratum spinosum

The cell of this layer is produced by morphological and histochemical alteration of the cells basal layers as they moved upward. The cells flatten and their nuclei shrink. They are interconnected by fine prickles and form intercellular bridge the desmosomes. These links maintain the integrity of the epidermis.

Stratum Granulosum

This layer is above the keratinocytes. They manufacturing basic staining particle, the keratinohylline granules. This keratogenous or transitional zone is a region of intense biochemical activity and morphological change.

Stratum lucidum

In the palm of the hand and sole of the foot, and zone forms a thin, translucent layer immediately above the granule layer. The cells are nonnuclear.

Stratum corneum

At the final stage of differentiation, epidermal cell constructs the most superficial layer of epidermis, stratum corneum. At friction surface of the body like palms and soles adapt for weight bearing and membranous stratum corneum over the remainder of the body is flexible but impermeable. The horny pads (sole and palm) are at least 40 times thicker than the membranous horny layer.

Dermis

Non-descriptive region lying in between the epidermis and the subcutaneous fatty region. It consist mainly of the dense network of structural protein fibre i.e. collagen, reticulum and elastin, embedded in the semigel matrix of mucopolysaccharidic 'ground substance'. The elasticity of skin is due to the network or gel structure of the cells. Beneath the dermis the fibrous tissue open out and merges with the fat containing subcutaneous tissue. Protein synthesis is a key factor in dermal metabolism.

Subcutaneous tissue

This layer consist of sheet of fat rich areolar tissue, know as superficial fascia, attaching the dermis to the underlying structure. Large arteries and vein are present only in the superficial region.

Constituents of emulgel formulations ^[12-14]

Aqueous materials: These constitute of the aqueous phase of emulsions. The commonly used agents are water, alcohols, etc.

Oils: These constitute of the oil phase of the emulsions. Various externally applied emulsions, mineral oils, either alone or in combination with soft paraffin or hard paraffin, are widely used for their occlusive and sensory characteristics as well as used as vehicle for the drug. The non biodegradable mineral and castor oils are widely used in the oral preparations and these 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.

Emulsifiers: These agents are used to promote emulsification at the time of manufacture and to control the stability during shelf life that can vary from days to months or years for commercial preparations e.g. Polyethylene glycol 40 stearate, Sorbitan mono-oleate (Span 80), Polyoxyethylene

sorbitan monooleate (Tween 80), Stearic acid and Sodium stearate.

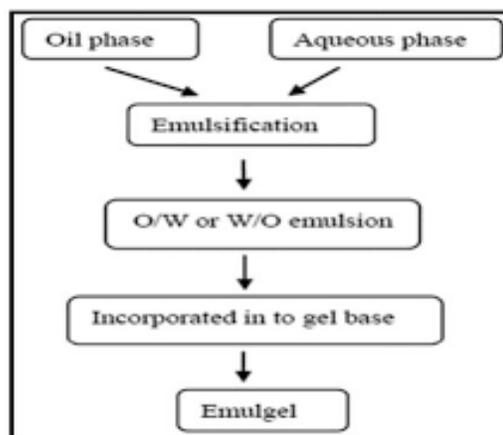
Gelling agents: These are those agents which increase the consistency of any dosage form can also be used as thickening agent. E.g. carbapol 934, carbapol 940, HPMC, HPMC-2910, etc.

Permeation enhancers: These are agents that interact with the skin constituents to induce a temporary and reversible increase in skin permeability.

Preservatives: E.g. methyl paraben, propyl paraben, benzalkonium chloride, benzoic acid, etc.

Antioxidants: E.g. butylated hydroxyl toluene (BHT), ascorbyl palmitate, butylated hydroxyl anisole (BHA), etc.

Humectants: mostly used to prevent loss of moisture. E.g. glycerine, propylene glycol.

Method of Preparation ^[15, 16]:**Flowchart of emulgel preparation**

It consists of three steps:

Step 1: Formulation of Emulsion either O/W or W/O:

- **Preparation of oil phase of emulsion:** Oil phase of the emulsion is prepare by dissolving emulsifier e.g. span 20 in oil phase like light liquid paraffin.
- **Preparation of aqueous phase:** The aqueous phase is prepared by dissolving emulsifier e.g. tween 20 in purified water.
- **Preparation of drug solution:** The drug is dissolved in ethanol. Drug is incorporated into either oil or aqueous phase depending upon its solubility.

Both the oily and aqueous phases were heated separately; then the oily phase were added to the aqueous phase with continuous stirring until cooled to room temperature.

Step 2: Formulation of gel base: The gel phase in the formulations is prepared by dispersing polymer in purified water with constant stirring at a moderate speed using mechanical shaker, then the pH was adjusted to 6–6.5 using tri ethanolamine (TEA).

Step 3: Incorporation of emulsion into gel base: Add glutaraldehyde in during mixing of gel and emulsion in ratio 1:1 to obtain the emulgel.

Characterization of Emulgel:

Physical examination^[17,18]

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

Determination of pH

pH of the formulation was determined 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.

Spreadability^[19-21]

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 g) under study is placed on this ground slide.

The emulgel is then sandwiched between this slide and another glass slide having the dimension of the fixed ground slide and provided with the hook. A 1 kg weight is placed on the top of the two slides for 5

min 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 gm. 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.

Globule size and its distribution in Emulgel^[22,23]

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

Swelling index^[24,25]

To determine the swelling index of prepared topical emulgel, 1 g 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 were removed from beakers at different time intervals and put it on a dry place for some time after it reweighed. Swelling index is calculated as follows:

$$\text{Swelling index (SW) \%} = [(Wt - Wo)/Wo] \times 100,$$

Where, (SW) % = Equilibrium percent swelling, Wt = Weight of swollen Emulgel after time t, Wo = Original weight of Emulgel at zero time.

Drug content determination^[26-28]

Take 1 g of emulgel, mix it in a suitable solvent. Filter it to obtain a clear solution. Determine its absorbance using ultraviolet UV spectrophotometer. Standard plot of the drug is prepared in the same solvent. Concentration and drug content can be determined using the same standard plot by putting the value of absorbance.

$$\text{Drug content} = (\text{Concentration} \times \text{Dilution factor} \times \text{Volume taken}) \times (\text{Conversion factor})$$

Marketed Preparations

Product Name	Drug	Manufacturer
Voltaren emulgel	Diclofenac-diethyl-ammonium	Novartis pharm
Miconaz-H-Emulgel	Miconazole nitrate, hydrocortisone	Medicalunion pharmaceuticals
Excec gel	Clindamycin, adapalene	Zee laboratories
Pernox gel	Benzoyl peroxide	Cosme remedies Ltd
Cloben gel	Clotrimazole, betamethasone	Indoco remedies
Topinate gel	Clobetasol propionate	Systopic pharma
Avindo gel	Azithromycin	Cosme pharma lab

CONCLUSION:

After literature survey it is concluded that emulgels have proven as most convenient, better, and effective delivery system. Due to its non-greasy, gel-like property, it provides and lacks of oily bases, and it provides better release of drugs as compared to other topical drug delivery system. Incorporation of emulsion into gel makes it a dual control release system further problem such as phase separation, creaming associated with emulsion gets resolved, and its stability improves. Emulgel loaded with specific drugs has been found effective in some topical disorders, and it is emerging as potential drug delivery system in the area of dermatology.

Future Prospects: In future, emulgel will provide a solution for topical delivery of hydrophobic drugs. Many of drugs that have utility in the treatment of skin disorders are hydrophobic in nature. Such drugs can be delivered in the form of emulgel where they can be incorporated in the oil phase of the emulsion and combined with gel.

Future work can be taken up with respect to , In vivo safety and efficacy , Stability studies to characterize the delivery system for clinical use.

Emulgels being a recent technique for topical drug delivery is also beneficial in incorporating hydrophobic drugs as well as a good choice for combination of both hydrophilic and hydrophobic drugs. In next few years, topical drug delivery will be used extensively in order to impart patient compliance and since emulgels have non greasy, gel like property along with relatively good drug release rates they may be used popularly as novel topical drug delivery formulations in future.

ACKNOWLEDGEMENT:

It gives me an immense pleasure to acknowledge a debt of gratitude to my guide Dr.G.Gnanarajan, M. Pharm, Ph.D, Associate Professor, Department of Pharmaceutics, School of Pharmaceutical Sciences, SGRR University, Patel Nagar, Dehradun for his constant encouragement, suggestions, supervision and support.

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