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Review Article

Review On Emulgel for Topical Drug Delivery System

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ABSTRACT

The aim of the review is to detail the emulgel formulations for Topical drug delivery system. Emulgel is a new dosage form that can be used topically to deliver a wide range of medications. It is applied to the skin as a semi-solid preparation and comes into contact with the skin's epidermis. The main advantages of topical administration compared to other delivery methods include avoiding first-pass metabolism, taking medications on a continuous basis, improving patient adherence, greater localization, absorption of hydrophobic drugs, higher loading capacity, greater stability, lower manufacturing costs, and controlled release. The oil phase, the aqueous phase, the emulsifiers, polymers, and permeation enhancers used in the formulations all influence how the emulgel is formed. The types, benefits, disadvantages, ingredients, manufacturing processes, and various studies to characterize emulgels, as well as the mechanism of the antifungal agent, various marketed antifungal emulgel formulations, and recent research on antifungal emulsifiers were the main topics of the review.

INTRODUCTION

Through the ages, Diseases affect the health of human beings by various types of diseases. The efforts have taken to give newer drug molecules by various administration methods for different routes. The route of administration selected depending upon the severity of the disease, type of disease, emergency of treatment and location of the disease. Each type of drug delivery and route of administration has the merits and demerits. The drug molecule in either cream or gel or lotion or

emulsion or suspension or form, when administered through the skin for local actions, called a topical route¹.

The human skin is known as the largest part of the body which contributes around 10- 15% w/w of the human body. The human skin is made up of four different layers with different cell structure and composition. The drug molecule in formulation, when applied on skin for local action called a topical route. But when the drug molecule in formulations applied on skin for systemic

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actions then it is called transdermal route. the human skin is easily available for administration of formulation. Once the drug in formulation applied to the skin and depending on its permeability, the drug permeates through the skin. The drug permeates through the skin layers by three routes such as stratum corneum, sweat ducts and sebaceous glands².

TOPICAL DRUG DELIVERY SYSTEM

The pharmaceutical product along with active molecule applied on the diseased surface of skin for treatment of the local cutaneous disorders or the cutaneous manifestation of general disease with the intent of confining the pharmacological or other effects of the drug to the surface of skin or within the skin called as Topical drug delivery system. Topical formulations are used for localized effects at the site of their application by application of preparation on the mucosal surface or by virtue of drug penetration into the underlying layers of skin or mucous membrane for systemic effect^{3,4}.

Emulgel:

Emulgel are emulsions, either oil phase dispersed in water/aqueous as continuous phase or water/aqueous phase dispersed in oil as continuous phase, which is converted to gel by mixing with a suitable polymer. Emulgel is a most promising vehicle for the delivery of hydrophobic drugs. The Emulgel in other words is a combination of Emulsion and Gel⁵.

Emulsion:

Emulsions are dispersion system which composed of two immiscible fluids is dispersed into one in another. Because this is the biphasic system it led to increase unstability of emulsion. The stability of emulsion is increased by using the surfactants/emulsifiers. Emulsion usually consists

of a mixture of an aqueous phase which includes water or aqueous solvents such as propylene glycol, glycerin, polymethylene glycol etc. with oil phases such as various oils and/or waxes.

If the oil globules/droplets are distributed in every part of the aqueous/water phase, the emulsion is known as oil-in-water(o/w) emulsion. A biphasic system in which water/aqueous phase is distributed in every part the oil phase is known as water-in-oil (w/o) emulsion⁶.

Types of Emulsions:

- Macro emulsions or Coarse emulsions
- Micro emulsions
- Nano emulsions
- Double/ Multiple emulsions

GEL:

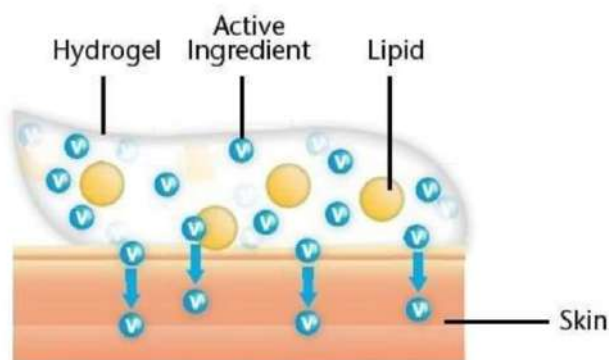
Gel is a high to low viscous semisolid formulation consisting of dispersion formulated of either large organic molecule or small inorganic particles or enclosing and interpenetrated by liquid phase. The gels exhibit no flow when in steady state due to dilute cross-linked polymer system. The gel is a system which is rich in liquids. The presence of continuous structure provides a solid like properties⁷.

EMULGEL:

In pharmaceutical topical semisolid dosage forms, emulgel has been becoming more and more significant since the mid-1980s. Formulation in which emulsion containing oil and Aqueous phase is entrapped in gel phase called as emulgel. First primary emulsion is formed with suitable composition of oil and aqueous phase and then this emulsion is incorporated in thick gel phase. Emulgel formulation contains aqueous phase, oils, gelling agents, penetration enhancers, and emulsifiers for formulation of emulsion. Emulgel



contains an emulsion that act as a vehicle for dissolving drugs. Most of the generally used topical formulations such as lotion, emulsion, suspension, ointment, cream has various demerits. Conventional topical formulations are greasy and provoking unpleasant to the patient when formulation spreaded on the skin. Conventional topical formulation has lesser spreading coefficient and needs to apply on the skin with rubbing. Because of disadvantages of all the conventional semisolid formulations, the utilization of transparent gel formulation has extended to pharmaceutical formulation as well as in cosmetic formulations. A gel formulation is highly wet thick semisolid liquid rigid structure, which is immobilized by surface tension between it and chain of a macro- molecular network of fibers. Although gel formulation has better advantages than the conventional topical formulation, but gel formulation has a prime demerit in the carrying of hydrophobic actives. So, to mitigate the demerit of carrying for hydrophobic drug molecule, an emulsion entrapped in gel base approach is being used. Hydrophobic drug molecules can be incorporated in emulgel formulation and can be delivered more efficiently through the skin. Emulgel can effectively deliver BCS class I, II and III drugs, enhancing their bioavailability^{8,9}.



Advantages of emulgel:¹⁰⁻¹²

- Increased patient acceptability.
- Provide targeted drug delivery.
- Easy termination of the therapy.
- Improve bioavailability and even the low doses can be effective in comparison with other conventional semi solid preparation.
- Stable formulation by decreasing surface interfacial tension resulting in increase in viscosity of aqueous phase, more stable than Transdermal preparations that are comparatively less stable, powders are hygroscopic, creams show phase inversion or breaking and ointment shows rancidity due to oily base.
- Hydrophobic drug can be incorporated in emulgel using emulsion as the drug carrier that is finally dispersed in the gel.
- Provide the controlled effect of that enhance the prolong effect of the drug with short half-life.
- Easy and cost-effective preparation.
- Drug loading capacity is better than other novel approaches like niosomes and liposomes.
- Penetration to skin is enhanced due to both hydrophilic and hydrophobic nature.

Disadvantages of emulgel:^{13,14}

- Poorly soluble and poorly permeable drugs cannot be given through skin.
- Air entrapment may happen during manufacturing which leads to foam generation in the formulation.
- Drug molecule with high molecular cannot be given through Emulgel.
- Drug molecule with large particle size not easily permeable through the skin.
- Skin irritation or allergic reaction may develop on contact dermatitis.

IMPORTANT CONSTITUENTS OF EMULGEL:

i. Vehicle:

Vehicle should deposit the active moiety efficiently and evenly dispersed on the surface of the skin. Vehicles or solvents should deliver the active moiety to the target site. Vehicle should sustain the therapeutic effect of the active moiety to provide a better pharmacological effect. The stratum corneum is the barrier for the topical delivery of the drug; the vehicle influences the rate and extent of absorption¹⁵.

a. Aqueous Materials:

These are the hydrophilic vehicles and it belongs to the aqueous phase of the formulation. The often-employed aqueous agents are water, polyethylene glycols, propylene glycols, alcohols, glycerin etc¹⁶.

b. Oils:

It forms the oily phase of the emulsion. Mineral oils either alone or in combination with soft and hard paraffin is used mostly in the externally applied emulsion. Non- biodegradable minerals and castor oils or various fixed oils like arachis, cottonseed and maize oils are used mostly in oral preparations¹⁷.

ii. Emulsifier:

Emulsifying agents used to promote both emulsification time at the time of manufacture and to control the stability during shelf life. e.g. Polyethylene glycol 40 stearates, Sorbitan monooleate (Span 80), Polyoxyethylene sorbitan monooleate (Tween 80), Stearic acid and Sodium stearate¹⁸.

iii. Gelling Agents :

These are the agents used to increase the consistency and as thickening agent E.g. Carbomer homopolymer Type A, B and C, Hydroxypropyl methylcellulose, Xanthan gum, Poloxamer, Hydroxyethyl cellulose, Hydroxypropyl cellulose, Acrylamide / Sodium Acryloyl dimethyl taurate copolymer, etc¹⁹.

iv. Permeation Enhancers:

Permeation enhancers are the chemical substances, which are used to increase the permeation of drug molecule through skin. Permeation enhancer interacts with the skin components to alter the skin chemical structure. This alteration in skin chemical structure increases the temporary and reversible increase change in the skin permeation²⁰.

Properties of penetration enhancer:

- Permeation enhancers should be non-irritating, non-allergenic and non-toxic.
- Permeation enhancers should have rapid activity.
- Permeation enhancers should have the longer duration of action with both predictable and reproducible action.
- Permeation enhancers should not have pharmacodynamic activity.
- Permeation enhancers should not have affinity to receptor sites.

Mechanism of penetration enhancer:

There are three types of the mechanism by which Permeation enhancers may act:

- Structural disruption of the lipid structure.
- Modification or alteration of intercellular proteins.
- Increased partitioning of the active with co-enhancer or solvent.



Examples: Dimethyl sulfoxide, Diethylene glycol monoethyl ether, N-methyl pyrrolidone, laurocapram, ethanol, menthol, propylene glycols, etc.

Preservatives:

These are those agents which prevent or retard microbial growth and thus protect formulation from spoilage. The commonly used preservatives are Propyl paraben, methyl paraben, Benzalkonium chloride, Benzoic acid, Benzyl alcohol etc²¹.

i. Antioxidants:

Antioxidants are the synthetic or non-synthetic chemical substance which retards the oxidation of active substances and excipient in final formulation and increases the shelf- life of the formulation.

Examples: Butylated hydroxyl toluene (BHT), Ascorbyl palmitate, butylated hydroxyl anisole (BHA), Ascorbic acid, Vitamin E, etc²².

i. Humectants:

The humectant is a substance added in the formulation to retain or hold the water or moisture in the formulation. Humectants are the group of hydrophilic compounds which are frequently used in skin care formulations with the purpose to diminish the clinical symptoms of skin dryness. Hydration of skin has an impact on the permeation of drug through the skin. Humectants are used especially in a skin lotion or a food additive, to reduce the loss of moisture. Humectant helps the skin to retain the moisture in the skin.

Examples: Glycerin, Propylene glycol, Urea, hyaluronic acid etc²³⁻²⁵.

PREPARATION OF EMULGEL:

The methodology for preparation of emulgel includes three steps:

Step 1:

Formulation of gel base: The gel phase is set up by dissolving the polymer in the purified water with enduring mixing at moderate speed using mechanical shaker and the pH was adjusted to 6-6.5 using triethanolamine or NaOH.

Step 2:

Formulation of o/w or w/o kind of emulsion: Oil phase of the emulsion is set up by dissolving emulsifier, while the water phase is set up by dissolving hydrophilic emulsifier. Preservative is dissolved in humectants like propylene glycol and drug is dissolved in ethanol and both the prepared solutions are mixed with watery phase with consistent blending. Both the oily and aqueous phase are freely warmed to 70°C to 80°C, then the oily phase is added to aqueous phase with constant blending. This mix is allowed to cool to room temperature to shape an emulsion.

Step 3:

Incorporation of emulsion into gel base with steady blending: the gel stage is mixed into the emulsion stage in the extent of 1:1 to procure emulgel^{26,27}.

CHARACTERIZATION AND EVALUATION OF EMULGEL:

Physical Examination:

The prepared emulgel formulations are inspected visually for their color, homogeneity, consistency and phase separation^{28,29}.

Rheological Studies:

The rheological properties of emulgels are determined by using cone and plate Brookfield viscometer³⁰.

Measurement of pH:

The pH measurements were done using a digital pH meter which was calibrated with standard buffer solutions. The measurements of pH of each system were replicated three times³¹.

Drug Content Determination:

Take sufficient quantity of emulgel. Mix it in suitable solvent. Filter it to obtain clear solution. Determine its absorbance using UV spectrophotometer. Standard plot of drug is prepared in same solvent. Concentration and drug content can be determined by using the same standard plot by putting the value of absorbance³².

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

Swelling index:

To determine the swelling index of prepared topical emulgel, sample 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 reweighed³³.

Swelling index is calculated as follows: Swelling index (SW) % = $[(W_t - W_o)/W_o] \times 100$,

Where, (SW) % = Equilibrium percent swelling,

W_t = Weight of swollen Emulgel after time t ,

W_o = Original weight of Emulgel at zero time

Globule size and its distribution in emulgel:

Globule size and distribution was determined by Malvern zetasizer. A sample was dissolved in

purified water and agitated to get homogeneous dispersion. Sample was injected to photocell of zetasizer. Mean globule diameter and distribution was obtained³⁴.

Skin Irritation Test:

The preparation is applied on the properly shaven skin of rat and its adverse like change in color, change in skin morphology should be checked up to 24 h. 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 repeated³⁵.

Extrudability Study of Topical Emulgel (Tube Test):

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 Rheograms corresponding to a shear rate 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 0.5 cm ribbon of emulgel in 10s. More quantity extruded better is extrudability. The measurement of extrudability of each formulation is in triplicate and the average values are presented^{36,37}.

The extrudability is then calculated by using the following formula:

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

Spreadability:

Spreadability is determined by apparatus 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 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^{38,39}.

$$S = W \times L/T$$

where,

S= spreadability

L=length of the glass plate

W= weight tied to upper plate

T=time taken to separate the slide completely from each other

The *in-vitro* drug diffusion study:

The *in-vitro* drug diffusion study of emulgel was performed. The Franz Diffusion Apparatus was used for the study of the *in-vitro* drug diffusion. By using the Franz diffusion cell with dialysis membrane as a barrier. The Franz diffusion cell has two compartments, donor and receptor

compartment. Assembly was set and the temperature was maintained at $37 \pm 0.5^\circ\text{C}$ and the stirring speed of the magnetic stirrer was 300 rpm. The 1 gm of emulgel of econazole nitrate was filled in the donor compartment, which was separated from the receptor compartment with the semi permeable membrane. The receptor compartment was filled with the potassium dihydrogen orthophosphate buffer of pH 7.4. At indicated time intervals 1 ml of sample was drawn from the receptor chamber with the help of syringe. Fresh buffer was added in the receptor as the equal value of the drawn sample. The sample were appropriately diluted with the buffer of pH 7.4 and analyzed under spectrophotometer at 200-400 nm. The percent drug content of emulgel was analyzed in percentage drug release at the time interval in hours^{40,41}.

Stability studies:

The prepared emulgels were packed in aluminum collapsible tubes (5 g) and subjected to stability studies at 5°C , $25^\circ\text{C}/60\% \text{ RH}$, $30^\circ\text{C}/65\% \text{ RH}$, and $40^\circ\text{C}/75\% \text{ RH}$ for a period of 3 months. Samples were withdrawn at 15-day time intervals and evaluated for physical appearance, pH, rheological properties, drug content, and drug release profiles^{42,43}.

MARKETED PREPARATIONS:

The different formulations of emulgels available on the market are listed in the table below.⁴⁴⁻⁵³

PRODUCT NAME	API	MANUFACTURER
Cloben Gel	Clotrimazole, Beclomethasone	Indoco Remedies
Topinate Gel	Clobetasol Propionate	Systopic Pharma
Lupigyl Gel	Metronidazole	Lupin Pharma
Miconaz-H-Emulgel	Miconazole Nitrate, Hydrocortisone	Medical union Pharmaceutical
Nadicin Cream	Nadifloxacin	Psycho Remedies
Acent Gel	Acelofenac	Intra Labs India Pvt. Ltd
Diclomax Emulgel	Diclofenac Sodium	Torrent Pharma
Cataflam emulgel	Diclofenac potassium	Novartis



Denacine emulgel	Clindamycin phosphate	Beit jala pharmaceutical company
Avindo gel	Azithromycin	Cosme pharma lab
Pernox gel	Benzoyl peroxide	Cosme remedies Ltd.
Zorotene gel	Tazarotene	Elder pharmaceuticals
Clinagel	Clindamycin phosphate, allantoin	Stiefel pharma
Excex gel	Clindamycin, adapalene	Zee laboratories
Voltaren emulgel	Diclofenac-diethyl-ammonium	Novartis pharma
Kojivit gel	Kojic acid, dipalmitate arbuti	Micro gratia pharma
Diclone emulgel	Diclofenac diethylamine	Medpharma

Various Marketed Preparation of Emulgel with their Manufacturers

FUTURE PERSPECTIVE

Many drugs are naturally hydrophobic. Delivering them to the biological system was a challenge. Various delivery systems, such as ointments, lotions, creams, and pastes, are applied for topical administration of drugs. These topical formulations generally contain a large number of oily raw materials, such as petrolatum, beeswax or vegetable oils, which are themselves hydrophobic and do not allow the absorption of water or aqueous phase. It makes them an excellent emollient, but delays the release pattern of drugs and makes the product thick and greasy. While gel provides the drug with an aqueous environment, it favors its dissolution and ensures faster drug release compared to other topical delivery systems. An emulsion-based gel provides a suitable medium for administering such hydrophobic drugs, wherein these drugs can be incorporated into the fat phase and delivered to the skin.

CONCLUSION

Emulgel is the recently developed technique for topical administration of drugs. It is best suited for hydrophobic drugs and is obviously a better technique for drug delivery of a combination of hydrophilic and lipophilic drugs. The hydrophobic drug formulation can be produced using

emulsifying technology as it consists of both an oil phase and an aqueous phase, while hydrogels are not suitable for hydrophobic drugs. In the future, topical administration of drugs will be used extensively to improve patients' adherence to treatment. Since Emulgel is helpful in improving spreadability, adhesion, viscosity, and extrusion, this novel drug delivery will become a popular formulation in the future.

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