



Overview On Emulgel- A Promising Topical Drug Delivery System

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I. INTRODUCTION

Topical drug delivery system is the dosage form which is applied externally to treat skin disorders. These can be prepared in different consistency such as solid, semisolid, and liquid (1,2). Topical formulation like ointment, suppository, creams, gel, emulsions, paste, solutions, liniments, lotion, etc. each have their own drawbacks, but they have the advantage of negotiating the first pass metabolism. They also help to avoid the risk and inconvenience of i.v. route therapy (2). When drug administration through other routes fails for skin infections, topical delivery system is preferred (3). Active ingredients can penetrate the skin by three routes: through intact *stratum corneum*, through sweat ducts or through the sebaceous follicles. The surface of the *stratum corneum* presents more than 99% of the total skin surface available for percutaneous drug absorption (4).

Emulgels are also known as **gelled emulsions** or **creamed gels**. They are the interesting topical drug delivery system for the deliverance of hydrophobic drugs and has dual release control system, like gel and emulsion. It has several merits like easily spreadable, easy to remove, greaseless, emollient and transparent (5). Studies on emulgel promise a better future in delivering more topical medicinal agents. It has merits over other drug delivery systems. It is commonly used for the delivery of analgesics, anti-inflammatory, anti-fungal, anti-acne drugs and various cosmetic agents (6).

Emulgel is prepared both in oil-in-water and water-in-oil type emulsion mixed with gel. Oil-in-water type is used for lipophilic drugs and water-in-oil type is used for hydrophobic drugs delivery (2). It is the best vehicle for hydrophobic drugs and is stable. Patient acceptability is high in case of emulgels as they have the advantages of both gels and emulsions (7). In emulsion, the entrapped drugs slowly release from internal phase through external phase and slowly get absorbed through the skin. Thus, emulgel itself is a controlled release system (8). Sometimes more than one formulations can be combined to enhance the drug delivery resulting into the novel dosage form (9).

Types of Emulgel: There are several types of emulgel depending on the particles size of emulsion droplets (5). The types of emulgel are mentioned below with the suitable example.

Macroemugel:

These are most common type of emulgels where the particle size of droplets of emulsion is more than 400 nm. 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, Khullar R. et al, prepared macroemulgel of mefenamic acid using Carbopol 940 as gelling agent (5,10).

Microemulsion gel:

Microemulsions are transparent and thermo-dynamically stable as their droplet size range from 10 to 100 nm and they do not coalesce. 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, to overcome this disadvantage, gelling agents such as Carbopol 940, xanthan gum etc. have been added into the microemulsion for forming microemulsion based gel in order to increase its viscosity which could be suitable for topical application e.g. Bachhav Y. G et al, prepared clotrimazole microemulsion based vaginal dosage form using Caproyl 90 as oil phase and Cremophor as surfactant(5,11).

Nanoemulgel:

When nanoemulsion is incorporated into gel it is called as nanoemulgel(12). 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 (13). They have improved transdermal permeation of many drugs over the conventional topical formulations such as emulsions and gels. For e.g., Singh B. P et al, prepared Carvedilol nanoemulgel using oleic acid and isopropyl myristate (3:1) as oil phase(5,14).

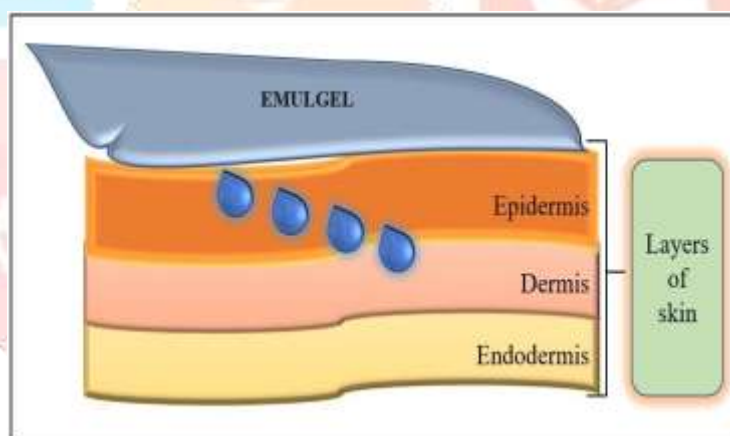


Fig.1. Control release of drug through layers of skin

There are several advantages and disadvantages of Emulgel formulation over conventional dosage form or delivery of hydrophobic drugs are given in following table:

Table.1. Advantages and Disadvantages of Emulgel Formulation

ADVANTAGES	DISADVANTAGES
Hydrophobic medicines can be incorporated. First pass metabolism can be avoided (15).	Skin irritation as a result of contact dermatitis (16).
Loading capacity and Stability is improved. More selective to a specific site (17).	Allergic responses as a result of contact dermatitis (18).
Release under supervision (18).	The inability of some medications to pass through the skin (19).
More focused on a certain location. Convenient and simple to use (20).	The difficulty of absorbing pharmaceuticals with big particle sizes via the skin (15).
Avoiding metabolism's initial pass. Patient compliance has improved (21).	The formation of a bubble during emulgel formulation (9).

II. MATERIALS AND METHODS

A. Materials

The general requirements and properties of ingredients for the preparation of emulgel are as follows:

• Drug

The physicochemical and biological properties of drugs for topical or transdermal delivery is applicable for selecting the drug for emulgel formulation. Even oil can be taken as active drug ingredients.

• Vehicle

The vehicle used for formulation of emulgels must possess properties such as should effectively deposit and evenly distribute the drug, release the drug for free migration of drug to the site of action, effectively deliver the drug to the appropriate target sites and sustain the therapeutic level of drug for a longer duration.

• Aqueous Phase

The aqueous phase of the emulsion is formed by using aqueous materials. Alcohol and water are commonly used to prepare aqueous phase.

• Oil

Castor oils and mineral oils that are non-biodegradable are utilized for local laxative effect. Oils those are extracted from various types of plants having different medicinal values shall be used in preparation of emulgels.

• Emulsifier

The emulsifying agents are used to boost emulsification during manufacturing as well as to maintain the stability during the shelf life e.g., sorbitan mono-oleate, polyethylene glycol 400/600, sodium stearate and stearic acid.

• Humectant

Humectants are used to prevent loss of moisture from the formulation. They minimize drying of emulgels and thereby enhance qualities such ease of application and consistency. Examples of humectants include glycerin, propylene glycol etc. (7).

pH adjusting agent

pH is the most important character must follow by all the type of topical preparation. To adjust the pH of formulation, triethanolamine is mostly used (2).

Gelling agent

The consistency and the gelling property can be increased by using various gelling agents. An inverse relationship between the concentration of the gelling agent and the drug release can be observed. Carbopol, Polyvinyl alcohol and HPMC is often used in emulgel (22).

Penetration Enhancers

Penetration enhancer's increases the drug permeability through the skin. Absorption of the drug through the skin can be promoted by using vehicles like penetration enhancers which for a short period disturbs the extremely ordered structure of the fluidize lipid channels of the stratum corneum that enhances the drug delivery into skin and partitioning of the drug into the skin (23).

Table.2. Example of Gelling agent and Penetration enhancers used in Formulation

Agent	Examples	Quantity	Dosage form	References
Gelling agent	Carbapol-934	1%	Emulgel	Mohamed, M.I. AAPS
	HMPC 2910	2.5%	Emulgel	Mohamed, M.I. AAPS
	Carbapol-940	1%	Emulgel	Jain, Ankur. IJPRD
	HPMC	3.5%	Gel	Gupta, A., Drug I Today
	narmelos Polymer (natural)	1%	Gel	Kumar, L., Int. J. Drug Del.
	Sodium CMC	1%	Gel	Singh, S., Pak J. Pharm. Sci.
	Xanthan Gum	1%	Gel	Singh, S., Pak J. Pharm. Sci.
	Poloxamer 407	1%	Gel	Singh, S., Pak J. Pharm. Sci.
Permeation enhancers	Isopropyl myristate	5%	Gel	Mortazavi, S.A., IJPS
	Urea	10%	Gel	-
	Eucalyptus oil	NA	None	Pathan, I.B., Trop J Pharm Res
	Chenopodium oil	NA	None	Pathan, I.B., Trop J Pharm Res
	Linoleic Acid	5%	Gel	Kasliwal, N., AJPS
	Menthol	4-6%	NA	A.H., European Journal of Pharmaceutics
	Dimethyl sulphoxides	NA	None	Pathan, I.B., Trop J Pharm Res

Method of Preparation:

Emulgel preparation is a straight forward and cost-effective procedure. It provides the main processes described in Figure

3. As necessary, the medication is integrated. The gel base is next prepared, and the emulsion is added while stirring continuously. The aqueous phase is formed by combining filtered water with a solvent fixing component, such as a soluble chemical, and heating it to 70°C for developing or making emulsions. Emulsifying agents, such as tween 20, span 20, cetaryl alcohol, PEG- 20 stearate, carbomer-940/934, stearyl alcohol, etc are also included.

Following the preparation of the aqueous phase, the oil phase is taken into consideration. Surfactants, such as spans 20, cocoamido-propyl hydroxy-sultaine, cetylricinoleate, are dissolved to make it. It is heated at the same temperature with the addition of a hydrophobic medication. The gel is typically made by dispersing the polymer in filtered water and combining it at a moderate speed. At this moment, the pH is balanced at 6–6.5. Preservatives were added in the aqueous phase as the final step. Oil and aqueous phases were heated to 70°–80°C respectively, after heating both phases, the oily phase was introduced to the aqueous phase, followed by continuous stirring. The emulsion is poured into the gel base at a 1:1 ratio for the formation of emulgel (6).

The general procedure for formation of any type of emulgel is depicted in following steps: STEP 1:

Formulation of Emulsion (either O/W or W/O)

STEP 2: Formulation of gel base

STEP 3: Incorporation of emulsion into gel base with continuous stirring (24).

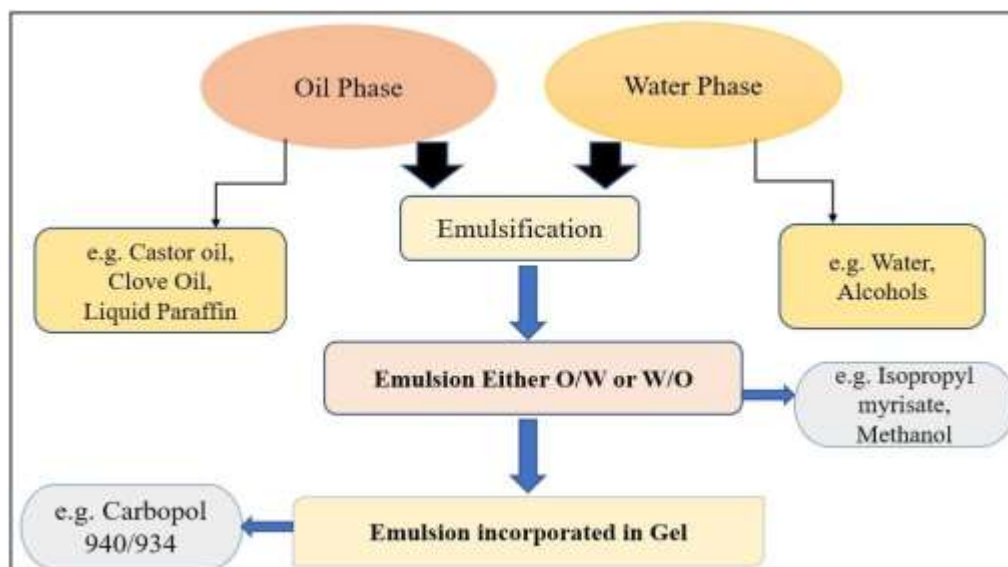


Fig.2. General Method for Preparation of Emulgel

III. EVALUATION OF EMULGEL

Every dosage form shall be evaluated for its quality, purity and safety as per WHO guidelines. Thus, emulgel can be evaluated by following parameters.

- **Physical appearance:** The formulation color should be compared against a white and black background. The emulgel consistency should be tested by putting it to the skin. The odor of emulgel should be determined by dissolving it in water and smelled it (25).

- **pH:** A digital pH meter should be used to determine the pH of the produced gels (1% aqueous solutions). The pH of the semisolid formulations was measured after the electrodes were completely dipped in them (26).

- **Viscosity:** The rheological property of emulgel sample should be determined by using Brookfield viscometer (2).

- **Homogeneity Test:** The homogeneity of a 0.1g emulgel distributed across the surface of the object-glass should be observed. The absence of coarse granules on the object-glass indicates that Emulgel has a similar configuration. The experiment lasted for six weeks. (27).

- **Spreadability:** Mutimeret *et al.*, (1956) proposed a method for determining spreadability, which should be adjusted in the lab and employed in the study. A wooden block is attached to one end by a pulley. The 'Slip' and 'Drag' features of emulgels are used to determine spreadability using this method. This block is equipped to a ground glass slide. This ground slide has an excess of emulgel (about 2 gm) under observation. The emulgel is at that point sandwiched between this slide and other glass slide with the same dimensions as the fixed ground slide provided with hook. For 5 minutes, a 1 kg weight is placed on top of the two slides to release air and provide a consistent emulgel coating between the slides. The excess emulgel is scraped away from the edges. After that, an 80gm pull is applied to the top plate. The time (in seconds) required by the top slide to travel a distance of 7.5 cm should be recorded with the help of string tied to the hook. Spreadability of 5-7 cm revealed the semisolid dosage form's consistency, which is easy to use. Spreadability is better when the interval is shorter(28).

Formula:

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

Where,

S = Spreadability,

M = Weight tied to upper
side, L = Length of glass

slides,



T = Time taken to separate the slides completely from each other (29).

- **Extrudability study:** It is a usual empirical test to measure the force required to extrude the material from tube. The method applied for determination of applied shear in the region of the rheogram corresponding to a 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 aluminium collapsible tube on application of weight in grams required to extrude at least 0.5 cm ribbon of emulgel in 10 seconds. More quantity extruded better is extrudability. The measurement of extrudability of each formulation is in triplicate and the average values are calculated (29).

Formula:

$$\text{Extrudability} = \text{Applied weight to extrude emulgel from tube (gm)} / \text{Area (in cm}^2\text{)}$$

Globule size and its distribution in emulgel: Optical microscope should be used to determine the size and distribution of globules. To achieve homogenous dispersion, a 1 gm sample was dissolved in sterilized water and stirred. The sample was examined under an optical microscope to determine the mean globule diameter and distribution (2).

- **Phase separation Test:** There were two components to this test:

a. **Centrifugation test:** The tubes should be filled with 5g of emulgel and centrifuged for 60 minutes at 3750 rpm. After then, it was determined whether or not phase separation had happened.

b. **Freeze-thaw test:** Emulgel should be held at 4°C for 48 hours in a freeze-thaw test. It was then placed in a 40°C oven for 48 hours (1 cycle). It went on for another five cycles after that. The emulgel could see if there was phase separation when each cycle was finished (27).

- **Swelling index:** For determination of swelling index of formulated emulgel following procedure adopted, 1 gm of gel is taken on porous aluminum foil and then placed separately in a 50 ml beaker containing 10 ml 0.1 N NaOH. After that, samples should be taken from beakers at various time intervals and placed in a dry area for a while before being reweighed. Swelling index is calculated as follows:

$$\text{Swelling index (SW) \%} = [(W_t - W_o) / W_o] \times 100$$

Where,

(SW) % = Equilibrium percentage swelling,

W_o = Original weight of emulgel at zero time after time t W_t = Weight of swollen emulgel.

- **In- vitro drug diffusion study:** A Franz diffusion cell should be used to test the release of the drug emulgel formulation through a typical cellophane membrane. The cellophane membrane was soaked in diffusion solution overnight before being put on the diffusion cell assembly's support screen. The receptor media was ethanolic phosphate buffer (60:40) at pH 6.8, and 1 g of the gel was put on the donor side. 2ml of sample was taken from the receptor compartment at predefined time intervals and refilled with the same volume of ethanolic phosphate buffer (60:40) at pH 6.8. A UV spectrophotometer set at 538 nm was used to examine the samples (25).

Cumulative amount of drug diffused (CADD) was calculated as follow:

$$\% \text{ CADD} = [\text{Concentration (}\mu\text{g/ml)} \times \text{Volume of diffusion medium} \times \text{Dilution factor}] / 1000$$

- **Drug Content Determination:** Drug concentration in emulgel should be measured by spectrophotometer. Drug content in emulgel should be measured by dissolving known quantity of emulgel in solvent (methanol) by Sonication.

Absorbance can be measured after suitable dilution in UV/VIS spectrophotometer (UV-1700 CE,

Shimadzu Corporation, Japan) (29).

- **Drug-excipient compatibility study:** FTIR spectra of the active drug ingredients and other excipients like gelling agent, emulsifying agent should be compared with spectra of prepared emulgel formulation (25).
- **Skin Irritation test:** Because the medication is a topical formulation, the skin irritation test is critical. The test should be done on the skin of the animal. After applying the emulgel to the animals' skin, they are returned to their cages. The animals are evaluated after 24 hours. The emulgel is then washed away from the location using tap water (2).
- **Stability study:** Stability tests should be performed on the emulgel, which was packaged in aluminum collapsible tubes and kept under harsh temperature. Emulgel was packed in aluminum collapsible tubes (5 gm) 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 months as per ICH guidelines. Samples are withdrawn at each month as per ICH guidelines and analyzed for the physical appearance, pH, drug content, drug release profile, etc. (25).
- **Microbiological assay:** The methods for microbial assay can be carried out by various methods for emulgel are as follows:

1. Pour plate technique should be used. It is a technique used for evaluation of bacteriostatic or fungistatic activity of a compound. It is applied for semisolid formulations. Previously prepared Soya casein agar dried plates were used. 3 g of the emulgel are placed in a well of the plate. Freshly prepared culture loops are streaked across the agar at a right angle from the ditch to the edge of the plate. After incubation for 18 to 24 hours at 25°C, the fungal growth was observed and the percentage inhibition was measured as follow (25).

$$\% \text{ Inhibition} = L2 / L1 \times 100$$

Where,

L1 = Total length of the streaked culture L2 = Length of inhibition.

2. Ditch plate technique also should be used. It is a technique used for evaluation of bacteriostatic or fungistatic activity of a compound. It is also applied for semisolid formulations. Previously prepared Nutrient agar dried plates are used. 3 g of the gellified emulsion are placed in a ditch cut in the plate. Freshly prepared culture loops are streaked across the agar at a right angle from the ditch to the edge of the plate. After incubation for 18–24 h at 25°C, the fungal growth is observed and the percentage of inhibition is measured as follows (30,31).

$$\% \text{ Inhibition} = L2 / L1 \times 100$$

Where,

L1 = Total length of the streaked culture L2 = Length of inhibition

IV. MARKETED PRODUCTS AND RESEARCH DONE ON EMULGEL CONTAINING SYNTHETIC AND HERBAL CONSTITUENTS

There are several researches published on emulgel containing synthetic are given in table no. 3.

Table 3. Research Published on Emulgel Containing Synthetic Compounds drugs

Drug	Polymer	Enhancer	Purpose	References
Chlorphenisin	rbopol-934, HPMC	Propylene glycol	f gelling agent on release	Magdy M, 2004(32).
Diclofenac	Carbopol-934,940, HPMC	Propylene glycol, Crodamol GTCC	ct of penetration enhancer	Vijaya Bhanu P, 2011(33).

Flurbiprofen	Carbapol-934,940	Propylene glycol, Polyethylene glycol	Contains Natural Permeation Enhancers	Manmode DP, 2019(23).
Itraconazole	Carbapol-934,940	Propylene glycol	e selective safe	Sawant A, Mohite S, 2015(34).



Tioconazole	Carbopol-934,940	Propylene glycol	Comparative study of polymer and drug release	Sah SK, Badola A,2017(35).
fanamic acid	Carbopol 940	Propylene glycol	Release study and Pharmacological action	lar R, Kumar D, 2012(10).
Miconazole	Carbopol-934,940	Propylene glycol	Controlled delivery	Dalal Y T, 2021(36).

There are few marketed products that are made in the form of emulgel formulation are given in following table no.4.

Table 4. Available Marketed Formulations of Emulgel

Product name	Drug Manufacturer	Manufacturer
Accent gel	Aceclofenac	AlIntra Labs India Pvt. Ltd.
enzolait emulgel (All variety)	Cyclopentasiloxane,Benzoyl peroxide	RoydermalSRL
Diclon emulgel	Diclofenac	Med Pharma
Gbrth Emulgel Advance	Gluthathione, Kojic acid,Niacinamide	Gbrth Advance
Melasure Emulgel	Niacinamide	Talent India
Miconaz- H- Emulgel	Miconazole nitrate,hydrocortisone	Medical unionpharmaceuticals
Oxalgin Nanogel	Diclofenac	Zydus synovial
Pernox gel	Benzoyl peroxide	Cosme remedies Ltd.
Photostable Emulgel	Ethylhexyl Methoxycinnamate	Sun Pharma Lab. Ltd.
Tolagin Gel	Diclofenac	Pharmed Ltd.
Voltaren emulgel	Diclofenac- diethyl- ammonium	Novartis pharma
Voveron Emulgel	Diclofenac	Novartis India Ltd

The researched Emulgel formulation containing the herbal extract or herbal content to delivering the natural products are given in table below:

Table 5. Research work on Herbal Emulgel

Chemical constituent	Plant	Purpose	Reference
Lycopene (Carotenoid)	<i>Solanum lycopersicum</i>	Increased Bioavailability and enhanced stability	Muhmmad Sohail, 2018 (37).
Flavonoid, Carotenoids, Phenolic Acid, Tannins	<i>Vitis vinifera</i> L.	Anti-Aging, Antioxidant	FithKhairaNursal, 2021(27).
Eicosane, Lantalinic Acid	<i>Lanata camara</i>	Itches, Cuts, Ulcers, Swelling	Sk. Shaheda Sultana, 2016(38).
Alkaloids, Lupeol, B-Amyrin	<i>Coccinia grandis</i>	sy, Jaundice, Asthma, Skin Eruption	Gayathri G, Gudeli M, 2019(39).
, Draco Resinolanol, Draco Alban	<i>nonoropsdraco</i> (W illd Blume)	nd Healing, Anti- Diarrhoea	Wulandari M, 2021(40).
Flavones,Schaftoside, Isoschaftoside, Vitexin	<i>Prosopis juliflora</i>	cancer, Antidiabetic, Antimicrobial	Nasser A. Awadh Ali,2016(41).
Azadirachtin, Nimbin, Azadirone, Salannin	<i>Azadirachta indica</i>	Acne, Antipyretic, Anti-Inflammatory, Antimicrobial	Somnath D. Bhinge, 2021(42).

Conclusion: Topical drug delivery system is an effective dosage form for several skin related problems. Cream, lotion, gel etc are the conventional topical dosage form containing the medicinal agents such as antibiotics, enzymes, antioxidants, antimicrobial agents. The modification in dosage forms is required, depending upon several solubility issues of the medicinal agents used in them. Emulgel is the results of such

dosage form for the active pharmaceutical ingredients which are not compatible in gels. Such compounds are made available in the form of emulgel. The phytoconstituents such as flavonoids, phytosterols, terpenoids and volatile oils have the solubility issues in gels. Therefore, emulgel is the better dosage form for such constituents. This review highlights the emulgels containing synthetic and naturally derived compounds. There is a need to develop many herbal emulgels for the better results for skin disorder.

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