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Emulgel: Novel Drug Delivery System

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ABSTRACT

The important component of dermatological therapeutic armamentarium are the topical therapies in cream, ointment and gel formulation. On the other hand, emulgel, mixture of gel and mixture has many advantages as compared to other formulations. Topical delivery of drug is the direct effect of drug containing medicament of drug most of the time to cure disorders.

The rationale for the use of the emulgel is to deliver more topical drugs. It is defined as the dual control release of drug. Emulgel is defined as the emulsion which is gelled by using gelling agent. The main limitation which was encountered were the delivery of hydrophobic drugs. The emulgel provides the properties such as greaseless, thixotropic, emollient, long shelf life, and bio friendly.

It is defined as the recent technology in NDDS. It is used to treat It is used for the delivery of analgesics, anti-inflammatory anti-fungal, anti-acne drugs. In order to understand the potential of emulgel as drug vehicles, these review gives the idea about the properties, formation and characterization emulgel.

KEYWORDS: *Emulgel, Emulsion, Gel, Topical drug delivery system*

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INTRODUCTION

The skin is the largest sense organ of the body and the pH of the skin is 4.0 to 5.6. The skin contains four layers namely non-viable epidermis, viable epidermis, viable dermis, and subcutaneous connective tissue. The topical drug absorption is done by three different mechanisms transcellular, intracellular and follicular.

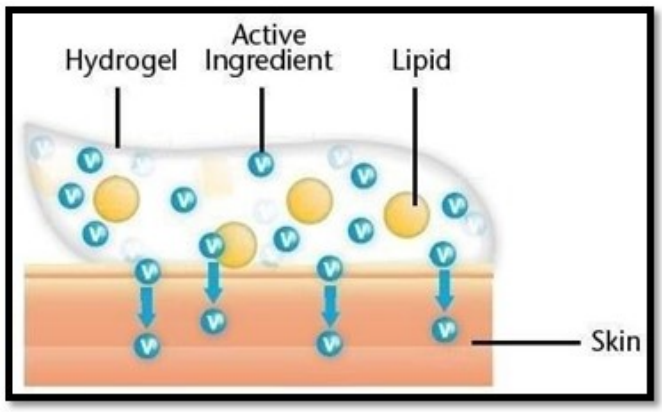
Transcellular are the shortest and direct route. Intercellular mechanism is the common route and follicular mechanism is the mechanism through hair follicles and sweat glands. Topical formulations are the formulations which are administered through the skin. It has the main advantage to avoid first pass metabolism. Topical formulations are prepared in different consistency such as solid, semisolid and liquid. In the preparation of each formulation with the active ingredient the use of the excipients is necessary.

It is also used to avoid the risk and inconvenience of I.V route therapy. At some instances the use of both the formulation is formulated to enhance the delivery of drugs. Emulgel is such type of the formulation. The emulsion and gel have both specific properties. As the gel shows limitations for the hydrophobic drugs, this limitation is overcome by emulgel. There are two types of topical delivery are internal and external products. Externals products are applied by spraying and spreading method and the internal products are applied using orally, vaginally or rectally.

Emulgel is mostly prepared by the incorporation method. Emulgel prepared both in Oil-in-water which is used for lipophilic drugs and water-in-oil emulsions which is used for hydrophobic drugs.

SR no	Brand name	Active Ingredient	Manufacturer	Uses
1	Voltarol 1.16% emulgel	Diclofenac Diethyl Ammonium nitrate	Novartis	Anti- inflammatory
2	Miconaz – H-emulgel	Miconazole nitrate Hydrocortisone	Medical union pharmaceuticals	Topical corticosteroid, Antifungal
3	Denacine emulgel	Clindamycin Phosphate	Beit Jala pharmaceutical company	
4	Diclon emulgel	Diclofenac Diethylamide	Med pharma	Anti-inflammatory
5	Catalan emulgel	Diclofenac potassium	Novartis	Anti- inflammatory

It is used to treat acne, pains colds, headaches, muscles, backaches, and arthritis

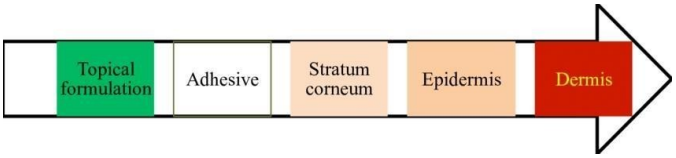


EMULSION

Emulsion are the phases of two or more immiscible liquids and the one phase is dispersed into dispersed medium. The various types of emulsions are prepared for stability of the formulation and emulsifier is necessary.

The different types for emulsion are oil in water emulsion, water in oil emulsion, oil in oil emulsion, multiple emulsion and microemulsion. There are the various factors which affect the

process of emulsion such as concentration of emulsifier, temperature, nature of oil and emulsifier.



Emulsion is defined as the biphasic system consisting of two immiscible liquids, is the dispersed phase is finely and uniformly distributed as globules throughout the continuous phase. The emulsion is thermodynamically stable and it is stabilized by the emulsifier. Emulsifier stabilizes the system by forming a thin film around the globules of dispersed phase. The dispersed phase or continuous phase may vary in consistency. The pharmaceutical emulsion may range from low viscosity to high viscosity. The particle size range of dispersed phase may range from 0.1 to 100 micrometer.

TYPES OF EMULSION:

- Oil in water emulsion
- Water in oil emulsion
- Multiple emulsion
- Microemulsion
- Pickering emulsion

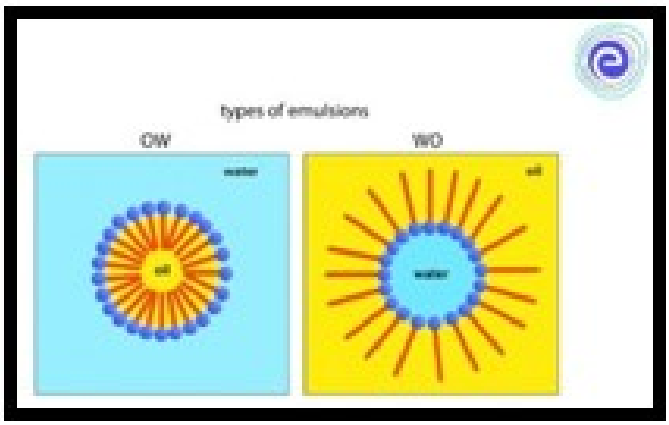
Oil in water emulsion:

The pharmaceutical emulsions generally consist of the aqueous phase with various oil phase and waxes. If the oil phase is dispersed throughout the aqueous phase, the emulsion is termed as oil in water emulsion (O/W) emulsion. They are non greasy and easily removable from the skin surface. They are used externally for cooling effect and internally to mask the bitter taste of drug.

Water soluble drugs are most commonly released from O/W emulsion. They show positive conductivity.

Water in oil emulsion:

This is a system in which the water globules are dispersed in a oil continous phase and it is termed as W/O emulsion. They normally show occusive effect by hydrating the stratum corneum. It is also used for the cleansing of skin of oil soluble dirt. They are greasy and water washable and generally used to avoid evaporation of moisture from the surface of the skin. Oil in external phase is a poor conductor of the electricity.



Multiple emulsions:
They are the complex systems. They are generally the Emulsion of emulsions. It is a complex type of system in which the o/w or w/o emulsion are dispersed in another liquid medium. The application for multiple emulsion generally consists of the taste masking, adjuvant vaccines, sorbent resorvoir of overdose treatments, and also the augmentation of skin. It can be formulated as the cosmetics such as skin moisturizer. Prolonged release can be formulated using the multiple emulsions.

Microemulsion:

These are the systems consisting of water oil and surfactant. These types of emulsions are suggested by Hoar and Schulman. There are mainly two types of emulsions: O/W and W/O microemulsion. This process is generally emulsion-gel-emulsion.

Pickering emulsion:
These are the type of emulsion in which solid phase are the emulsion stabilizers. It has recently applications in cosmetics, food, pharmaceuticals, oil recovery and waste water treatment.

General method for emulsion:
- General method
- Phase inversion method
- Continental and dry gum method
- Wet gum method
- Membrane emulsification method

General method: These are the O/W emulsions which are prepared by dividing the oily phase in minute globules with the use of the envelope of emulsifying agent and finally suspends

globules in the aqueous phase. The W/O emulsion process is converse process. The W/ O emulsion is generally prepared by dividing the aqeous phase completely in the minute globules surrounding each by emulsifying agent envelope and finally suspending in the oily phase.

Phase inversion method: In the following method, the aqeous phase is first added to the oil phase so as to form a W/O emulsion. At the inversion point, the addition of more water results in inversion of emulsion that is the formation of O/W emulsion.

Continental and dry gum method: This method is generally used for the preparation of extemporaneously emulsion. The preparation of emulsion is generally by mixing the emulsifying agent usually acacia with the oil and then the mixing with the aqueous phase. Continental and dry gum method generally differentiate in the proportion of constituents.

Wet gum method: In this method, the proportion of constituents remain same as dry gum method, the difference is just in the method of preparation. Mucilage of acacia is used as a emulsifying agent. The oil is added to the mucilage drop by drop with continuous trituation

Membrane emulsification method: It is based on the novel concept of the generating droplets

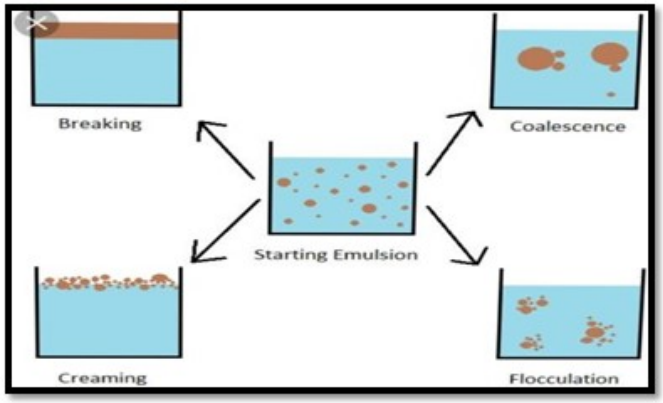
"drop by drop" to produce emulsion. The pressure is directly applied to the dispersed phase.

Stability of emulsion
Coalescence
Flocculation
Creaming
Breaking

Flocculation: It is the association of the small emulsion particles to form large aggregate which is redispersible upon shaking. It is a reversible process in which the droplets remain intact. The flocculation and emulsion droplets by excess surfactant occur because of the **depletion effect.** Flocculation is also called as the precursor of the coalescence.

Creaming: It is the phenomenon in which the dispersed phase separated out, forming a layer on the top of th continuous phase. The conclusion is that the dispersed phase remains in globule state and it can be redispersed on shaking. It is generally reduced by increase in viscosity

Coalescence: A more subtle type of emulsion instability occurs when the mechanical or electrical barrier is insufficient to prevent the formation of the large droplets. These can be prevented by addition of high boiling point or the high molecular weight to the continuous phase.



EVALUATION OF EMULSION
- **Viscosity:** Cone and rotational viscometer can be used with spindle fibers can be used to measure the viscosity.
- **PH:** pH could be measured using digital pH meter.

- **Drug Content:** suitable dilution of drug loaded emulsion is made and concentration could be measured by UV visible spectroscopic method in nm by keeping the reagent blank.
- **Centrifugation:** This is used to measure the physical stability. The emulsion is generally evaluated at the ambient temperature and 5000 rpm to observe the creaming or the phase separation.
- **Dilution Test:** In these method continuous phase is added to the emulsion, it could not be separated into So repeated dilution is done 50 – 100 times to check the phase separation or creaming.
- **Zeta Potential & Micelle Size Analysis:** micelle size, size distribution and Zeta potential can be measured using particle size analyzer
- **Diffusion:** By D – cell at 37 degree Celsius using rate skin as membrane
- **Microbial Study Of Emultion:** Ditch plate technique is used for bacteriostatic and fungistatic activity
- %**Inhibition:** Length of inhibition / whole length ×10

GELS

It is mainly constituted of the entrapment of large amounts of hydroalcoholic or aqueous in the network of the colloidal particles with the use of polymers. Gels are defined as the semi rigid system in which the movement of the dispersing medium is restricted by an interlacing three - dimensional network The polymers may be natural, synthetic, inorganic or organic. The higher aqueous content permits greater dissolution of drug these makes gel poor vehicle for hydrophobic drugs. The limitations of gel can be overcomed by emulgel.

TYPES OF GELS:

- **Based on the colloidal phases:**
- Inorganic Gels
- Organic Gels

Inorganic Gels: It is a two phase system. The partition size of the dispersed phase is relatively large and form a three dimensional structure throughout the gel. It consists of floccules of small particles rather than the larger molecules and gel structure. They are the thixotropic forming semisolid on standing and become liquid on agitation.

Organic Gels: It is a single phase system. These system consists of large organic molecules existing on twisted strands dissolved in a continuous phase. The large polymers are generally referred as the gel formers, they tend to entangle with each other or bound by Vander waals force

Based on the nature of solvent:

- **Hydrogels:** A hydrogels is a network of polymer chains that are hydrophilic, infrequently found in the colloidal gel in which water is a dispersion medium. They are highly absorbent natural or synthetic polymeric networks.
- **Organogels:** An organogels is a non – crystalline, non- glassy thermo reversible solid material composed of liquid organic phases trapped in the 3D cross- link network. The liquid used can be vegetable oil, an organic solvent, mineral oil.
- **Xerogels:** It is a solid formed from a gel by drying with unrestricted shrinkage. It is frequently retains high porosity and huge surface area and along with small pore size. When the solvent is removed in supercritical conditions, the network doesn't shrink and a highly porous, low density material known as aerogel is produced. The high treatment of xerogel at higher temperature produces viscous sintering and transforms the porous gel into thick glass.

Based on rheological properties

- **Plastic gels:** flocculated suspension of Aluminum hydroxide exhibit a plastic flow and the plot of rheogram gives the yield value of gels above which the elastic gel disorts and begins to flow
- **Pseudo-plastic gels:** Liquid dispersion of Tragacanth, sodium alginate, Na CMC, exhibit pseudo-plastic flow. The viscosity of gels decreases with the increasing rate of shear,with no yield value
- **Thixotropic gels:** The bonds between the particles in these gels are very weak and broken down by shaking. The resulting solution will reverse back to gel due to particles colloiding and linking together again. These is also called as reversible isothermal gel- sol-gel formation. It forms scaffold like structure.

Based on physical nature:

- **Elastic gels:** Gels of agar, pectin, Guar gum and alginates exhibit an elastic behaviour. The fibrous molecules being linked at the point of junction by hydrogen bonds. E g Alginate and Carbapol
- **Rigid gels:** This can be formed from macromolecule in which the framework is linked by primary valence bonds.

Preparation of Gels:

Thermal changes: Solvated polymers when subjected to thermal change cause gelatin. Many hydrogen

formers are more soluble in hot water than cold water. Cooling of a concentrated hot solution will produce a gel. Some materials like cellulose have their water solubility in water.

Hence these method is not used to prepare gel as a general method.

Flocculation: In these method, gelatin is produced just by adding sufficient quantity of salt to produce age state, but it is not able to produce complete precitipitation. It is important to ensure that there is a quick mixing to avoid high precitipitation. The gels formed by flocculation method are thixotropic in nature. Hydrophilic colloids such as gelatin, proteins and acacia are affected by high concentration of electrolytes. In salt out effect, the gelatin and colloidal doesn't occur.

Chemical reaction: In these method, gel is produced by chemical interaction between the solute a and solvent. E.g Aluminum hydroxide gel can be prepared by chemical interaction between the aluminum salt and sodium carbonate. An increased concentration of reactants will produce a gel structure

Evaluation of parameters for Formulated Gels:

- **Measurement of pH:** The measurement of pH is done by digital pH meter. Dissolve 1 gm of gel with 100 ml of distilled water and store for 2 hours. The measurement of pH is in triplicate values.
- **Drug content:** Mix 1g of gel with 100; ml of suitable solvent. Filter the stock solution
- The different concentrations by suitable dilutions and measure the absorbance. Drug content was calculated by equation which is obtained by linear regression of calibration curve.
- **Viscosity study:** It is carried using Brookfield viscometer.
- **Spreadability:** It indicates the extent of area to which gel readily spreads on application to the skin or affected part. The therapeutic potency also depend upon the spreading value. S= M×L/T

  M= weight tied to the upper side

  L= length of glass slides.

  T= Time taken to separate the glass
- **Extrudability study::** The formulations are filled in the collapsible tube, after it was set in a container. It is determined in terms of weight in gm required to extrude a 0.5 cm ribbon of gel in 10 second.
- **Skin irritation study:** The gel was applied twice a day for seven days and the site was absorbed for any sensitivity and the reaction if any.
- **In- vitro Diffusion studies:** It can be carried out at Franz diffusion cell, for studying the dissolution release of gels through a cellophane membrane.
- **In- Vivo studies:** Inhibition of carrageenan induced rat paw edema: 3 groups of 6 male Wistar albino rats were used.
- **Stability:** It was carried out at a freeze- thaw cycling. The product is subjected to temperature of 4 degree Celsius for 1 month, 25 degree Celsius for 1 month and then 40 degree Celsius for 1 month, Syneresis were observed.
- **Homogeneity:** Set the gel in container and then it is tested for homogeneity for visual inspection. The presence of their appearance and presence of aggregates were tested.
- **Grittiness:** The formulations were evaluated microscopically to check the presence of any visible particulate matter which is observed under light microscope.

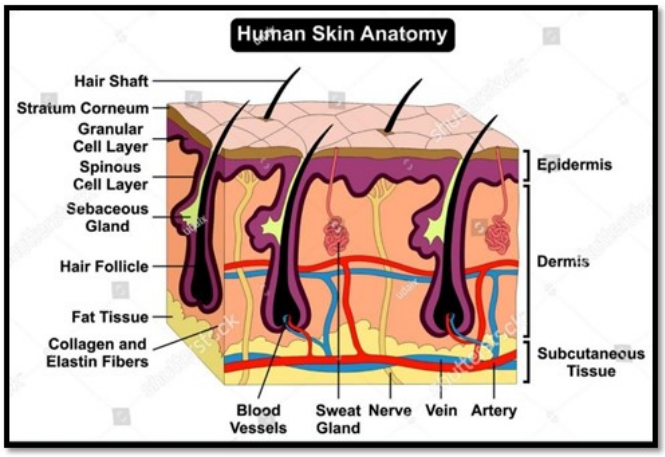
Rheology

Solutions of the gelling agents and dispersion of flocculated solids are pseudoplastic. They exhibit Non – Newtonian behaviour. These are formed by the decrease in viscosity and increase in shear rate. The tennous structure of inorganic particles dispersed in water is disrupted by applied shear stress due to breaking down of interparticulate association, showing great tendency to flow. For the macromolecules, the applied shear stress aligns the molecules in direction of stress straightening them, and showing less tendency to flow.

Emulgel:

In comparison to other groups of semisolid preparations, the use of gels is used mostly in the cosmetics and pharmaceuticals. Despite of providing several benefits the gel category has limitations of delivering hydrophobic drugs. With these approach, there is enhanced effect in release pattern of sustain and control release. The presence of gelling agent converts the classical emulsion into the Emulgel. The use of emulgels can be expanded in analgesics, anti-fungal, anti – acne drugs and various formulations.

Topical drug administration is simpliest and easiest route of delivery by various routes in the body. Topical delivery proves beneficial as it bypass the first pass metabolism. Topical drug mainly is used for the fungal infection. Molecules van basically penetrate into the skin through three routes: the surface of the stratum corneum, through sweat glands, through sebaceous follicle.



Drug Delivery Across the skin:

The epidermis is the most superficial layer of the skin and composed of stratified keratinized squamous epithelium which varies in thickness in dfferent parts of the body. It Is thickest which contains elastic fibres. The skin forms a water proof layer which protects the superficial layer. Blood vessels are distributed beneath the skin. In most exposed areas, the blood vessels are also distributed into small arteries through highly muscular arteriovenous anastomoses. The dermatological pharmacology is direct accessibility to the skin as a target organ for diagnosis and treatment. The skin acts as a two way barrier system to prevent absorption to prevent neither absorption nor loss of water and electrolytes.

There are three primary mechanisms of topical drug absorption: transcellular, intercellular and follicular. The most common path is the path through the corneocytes through lipid bilayer to viable layers through the skin. The next most common route is through the pilosebaceous route

RATIONAL OF EMULGEL

Topical preparation generally has limitations of less spreading, less penetration through stratum corneum, less patient compliance due to stickiness and need to apply with rubbing etc while the gels have the limitations of delivering hydrophobic drugs. On the other hand, emulgel is prepared by using emulsifier and they are prepared by using selected oils so the problem of the solubility is nearly overcomed. Less dose of drug is required to obtain the pharmacological action. Number of medicated products are applied to the skin membrane that either restores the fundamental function of skin or pharmacological alters an action in the underlined tissues. These products are referred as topical or dermatological products. Many other topical formulations have disadvantages such as they are sticky in nature causing uneasiness to patient. With these disadvantages, the use of novel approach as a transparent gel is expanded both in cosmetics and in pharmaceutical preparations.

EVALUTION OF EMULGEL:

- **Physical Examination:** The prepared Emulgel is inspected visually for their color, homogeneity and consistency and pH. The pH values of Gellified emulsion is measured by pH meter.
- **pH:** 1% solution in water of emulgel is subjected to measure pH by digital pH meter.
- **Spreadability Measurement:** 0.5 gm of emulgel is placed on a glass slide and circle made around it. Then the second slide is placed over it and predetermined weight is kept for specific time periods and then the increase diameter is to be noted. It is measured by apparatus called Multimer which his suitably modified in the laboratory and used for study. It consists of the wooden block, which is provided by a pulley at one end. By this method, Spreadability is based on the "Slip" and "Drag" method.

S= M. L×T

S= spreadability

M= Weight tied to the upper side L= length of glass slides

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

- **Syneresis Measurement:** On rest gel shrinks and little liquid is pressed out called syneresis. these is measured by using centrifuge tube.
  Syneresis %= liquid separated from emulgel / Total weight of emulgel before centrifugation ×100
- **Rheology Study:** Viscosity can be measured using rheometer. It is determined at 25 degree Celsius using a cone and plate viscometer with spindle 52 and connected to a thermostatically controlled circulating water bath.
- **Drug Content Determination:** Drug content can be measured using official method in pharmacopoeia.
- **Tube Test:** It determines force necessary for removal of emulgel from tube and is necessary for extrudability.
- **Diffusion Study:** By D cell at 37 degree Celsius at rate skin.
- **Drug Release Kinetic Study**: It can be studied using Higuchi model and various other models.
- **Microbial Assay Of Emulgel:** Ditch plate technique is preferred for microbial assay and zone of inhibition is calculated
- **Optimization & Development Of Emulgel** by

suitable statistical development of design of the experiment.

- **Skin Irritation Test:** By Draize patch test in rabbit.
- **Microbial Assay Of Optimized Batch:** by Ditch plate technique.
- **Accelerated Stability Study Of Optimized Batch:** Batch Sample emulgel is sealed in ampoules and then put in ambient temperature. Chemical stability could be expressed as a content of drug.
- **Globule size and distribution in emulgel:** Globule size and distribution is determined by Malvern Zeta sizer. A 1.0 gm of drug is dissolved in n purified water and agitated to get a homogeneous mixture. Sample is filled in photocell of zetasizer. Mean globule size and distribution is obtained.
- **Swelling index:** To determine the swelling index of prepared topical Emulgel, 1 gm of gel is taken in porous aluminium foil and then placed in 50 ml separate beaker containing 10 ml 0.1 N NAOH.

ADVANTAGES & DISADVANTAGES OF EMULGEL

Advantages:

- Incorporation of hydrophobic drugs
- Better loading capacity.
- Avoidance of first pass metabolism.
- Avoidance of gastrointestinal incompatibility.
- Controlled release of the drug
- More selective for specific site.
- Production feasibility and low preparation.

Disadvantages:

- Skin irritation on contact dermatitis
- The poor permeability of some drugs through skin.
- The occurrence of bubble during formulation of the emulgel.
- Drug size of large particles is not easy to absorb through the skin.
- There is possibility of allergic reactions.

PREPARATION OF EMULGEL

- Formulation of O/W or W/ O emulsions:

The initial step of formulation involves the dissolution of oil – soluble substances in the oil vehicle. E.g dissolving span 20 in liquid paraffin and dissolution of the water soluble substances in n aqueous vehicle.(e.g dissolving tween 80 in purified water)both the phase were mixed at turbulent stirring to ensure the dispersion of the two phase into droplets.

- Formulation of gel base: The water soluble substances are dissolved in aqueous vehicle using mechanical stirring. To avoid aggregation, the hydrophilic polymer is added to stirred mixture and stirring is continued until the polymer has dissolved and the pH remains in the desired range.
- Addition of base into gel base with steady blending: The gel stage is mixed into emulsion stage to the extent of 1: 1 to get emulgel.

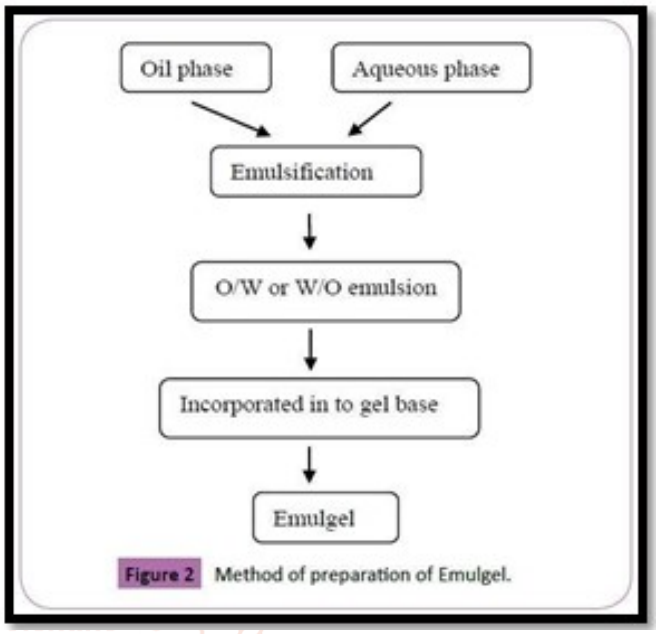


Figure 2 Method of preparation of Emulgel.

FORMULATION OF EMULGEL

For the preparation of emulgel, some of the following constituents are used:

- **Vehicle:** They should follow the ideal characteristics
- **Aqueous Vehicle:** The aqueous vehicles used are water, alcohol etc
- **Oil:** Oil used are mineral oils, paraffin or they are used in combination.
- **Emulsifiers:** Span 80, tween 80, stearic acid, sodium stearate.
- **Gelling Agents:** They enhance the consistency of the preparation.
- **Penetration Enhancers:** It helps to absorb the drug through the skin.
- pH adjusting agent

IDEAL PROPERTIES OF ADDITIVES:

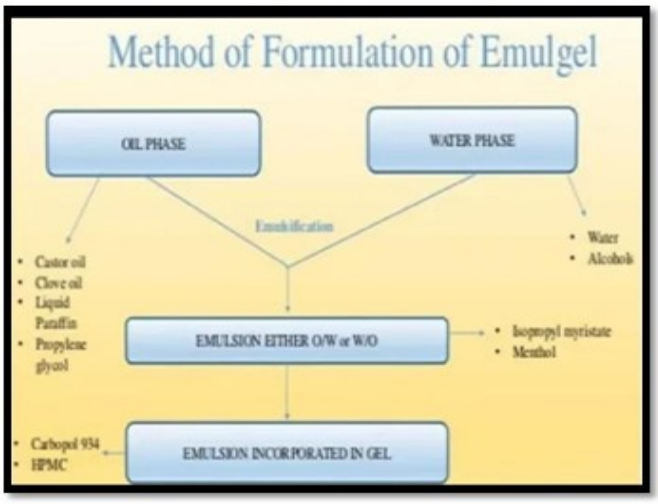
- They should be non- toxic.
- They should be easily available.
- They should be cheap.
- They should not be contraindicated.
- They should be physically and chemically stable.

GENERAL METHOD FOR PREPARATION OF EMULGEL:

Emulgel is prepared by incorporating gel and emulsion. The emulsion and gel are prepared

separately and mixed together. The gel is prepared by using gelling agent. After the preparation of both the formulation

The chemicals used are the oil phase such as castor oil, clove oil, liquid paraffin etc. Water and alcohol are used as a aqueous phase. The aqueous phase is prepared by mixing the tween 80 and water and the oil phase is prepared by using the paraben and propylene glycol. The drug is dissolved in ethanol and two phases are mixed with the continuous stirring and then the polymers are mixed with pH of 6.0 to 6.5. After preparation of gel and emulsion separately, they are mixed to form emulgel



APPLICATION OF EMULGEL

The emulgels are generally used for the delivery of analgesic, anti- inflammatory, anti- acne and antifungal drugs.

They show generally favourable formulation of hydrophobic drugs over the gel formulation.

It show control and better release of drug to be incorporated in gel base to obtain a gelfilled emulsion.

Emulgels shows control and better release by used of combined effect of gel and emulsions.

Emulgel have certain advantages over gel and emulsions such as thixotropic, greaseless, easily spreadable, easily removable, emollient, long shelf life, biofriendly transparent, and pleasant appearance.

FUTURE PROSPECTS:

The nano emulgel drug delivery system is a formulation to improve the systemic delivery and therapeutic profile of lipophilic drugs. Nanoemulgel is a mixture of two different systems in which nanoemulsions drugs are incorporated into the gel ase. Lipophilic drugs can be easily formula d and enhancement of skin permeability by several folds of droplets due to nthe anoemulsions phase. Also the pharmacokinetics apharmacodynamicsmic are significantly increased.

PATENT ABILITY:

An increasing trend in topical nanoemulgel use in recent years has been noticed due to their better acceptability due to their invasive delivery, avoidance of gastrointestinal side effects, easier applicability, and good therapeutic profile. Nanoemulgel has considered a promising formulation and has great potential for drug delivery. The hydrophobic drugs are also formulated using emulated as novel drug delivery.

CONCLUSION

The topical drug delivery system will be extensively used due to better patient compliance. Emulgel possesses an edge in terms of spread ability, adhesion, viscosity, and extrusion. They contain a solution to deliver hydrophobic drugs in water-soluble gel bases. Emulsion topical dosage form is generally used in addition to dermatology pharmacotherapy. Many researchers have concluded that the emulgels area novel drug delivery system fthe or local and systemic site of action.

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