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EMULGEL : A NOVEL TOPICAL DUAL CONTROL RELEASE SYSTEM

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ABSTRACT

Topical drug administration is the simplest and easiest route for delivering the drug anywhere in the body, through routes such as opthalmics, rectal, vaginal, and skin. Topical dosage form, which includes spray powders, semi-solids, and liquid formulations. Emulsions and gels are combined to form emulgels. The oil-in-water type is used for lipophilic medications, and the water-in-oil type is used for hydrophobic medications. Emulgel is a dual-control release method that has both gel and emulsion qualities. Emulgel has several advantageous qualities, including good durability, thixotropic, greaseless, good shelf life, and odorlessness. The incorporation method is used to prepare the emulgel. Emulgels are commonly used for the delivery of analgesics, anti-inflammatory, anti-fungal, anti-acne drugs, and various cosmetic formulations. The physical assessment, measurement of pH, rheological properties, spreadability, swelling index, stability studies, skin irritation test, and other properties of the prepared formulations are evaluated. So emulgel can be used as a better topical drug delivery system than the present systems. The review gives knowledge about emulgel, including its properties, advantages, and formulation considerations.

Keywords: Topical drug delivery system, Emulgel, Emulsion, Gel, Incorporation method

INTRODUCTION

The term "topical drug delivery system" (TDDS) refers to a pharmaceutical dosage form that is topically applied to the skin to treat skin conditions. These are meant to limit the drug's pharmacological impact on the skin's surface. [1]

The TDDS comprises a wide range of dosage forms for pharmaceuticals, including spray powders, semi-solids, and liquid formulations. But the most popular semi-solid medication delivery method for topical usage is the use of gels, creams, and ointments. [1]

Administration of a topical drug is the simplest and easiest route for localized drug delivery anywhere in the body through routes such as opthalmics, rectal, vaginal, and skin. [2]

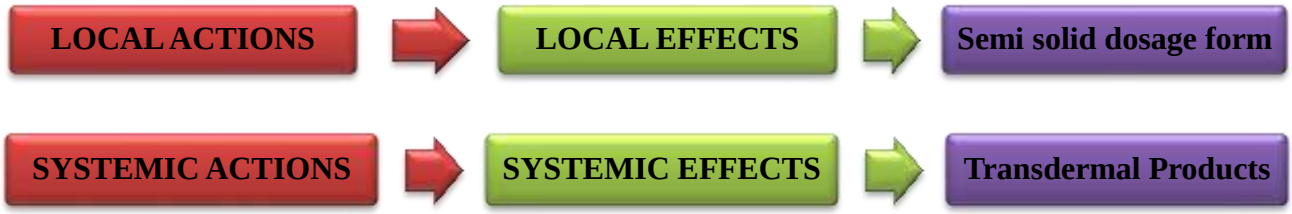


Figure 1:- Local and Systemic Actions

Types of products for topical administration include: [3]

- External topicals are applied topically to the affected region by spreading, spraying, or otherwise dispersing them onto the cutaneous tissues.
- Internal topicals that are given orally, vaginally, or to the tissues of the rectal area for local action.

Advantages of Topical Drug Delivery System [4]

- Avoiding the first pass metabolism.
- Easily applied and convenient.
- Avoidance of the risks and difficulties associated with intravenous therapy as well as the various absorption circumstances, such as changes in pH, the presence of enzymes, and the duration of stomach emptying.
- Easily terminate the medication when needed.
- Deliver medication to a targeted location more precisely.
- Preventing gastrointestinal incompatibilities.
- Enhance patient compliance.
- Self medication.
- Providing utilization of medication with a brief biological half-life and a limited therapeutic range.

Disadvantages of Topical Drug Delivery System [5]

- The medication or excipient may cause skin irritation or contact dermatitis.
- Certain medicines have poor skin permeability.
- An allergic response might occur.
- Large-particle-size drugs are more difficult to absorb through the skin.

Topical Drug Classification System (TCS) [6]

Depending on qualitative (Q1), quantitative (Q2), and semi-solid goods (Q3). TCS offers a classification system for topical medication items. There are four classifications for topical medication products.

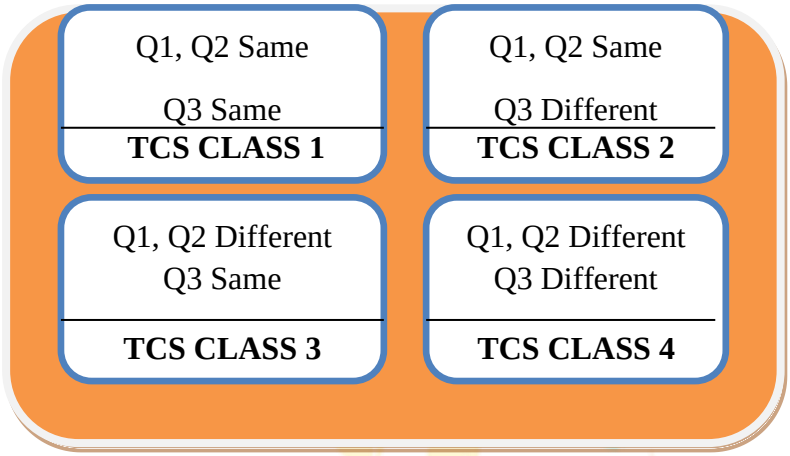


Figure 2:- Classification of topical drug products based on qualitative & quantitative composition

Classification of Topical formulation [7]

1. **Solid: -** Powders, Plasters, Ointments**.**
2. **Semi-solid:-** Creams, Poulticers, Gels, Paster
3. **Liquid: -** Liniment, Lotions, Solution, Tinctures, Emulsions, Suspension, Paints.
4. **Miscellaneous: -** Transdermal drug delivery system, Tapes and Gauzes, Rubbing alcohols, Liquid Cleanser and Topical aerosols.

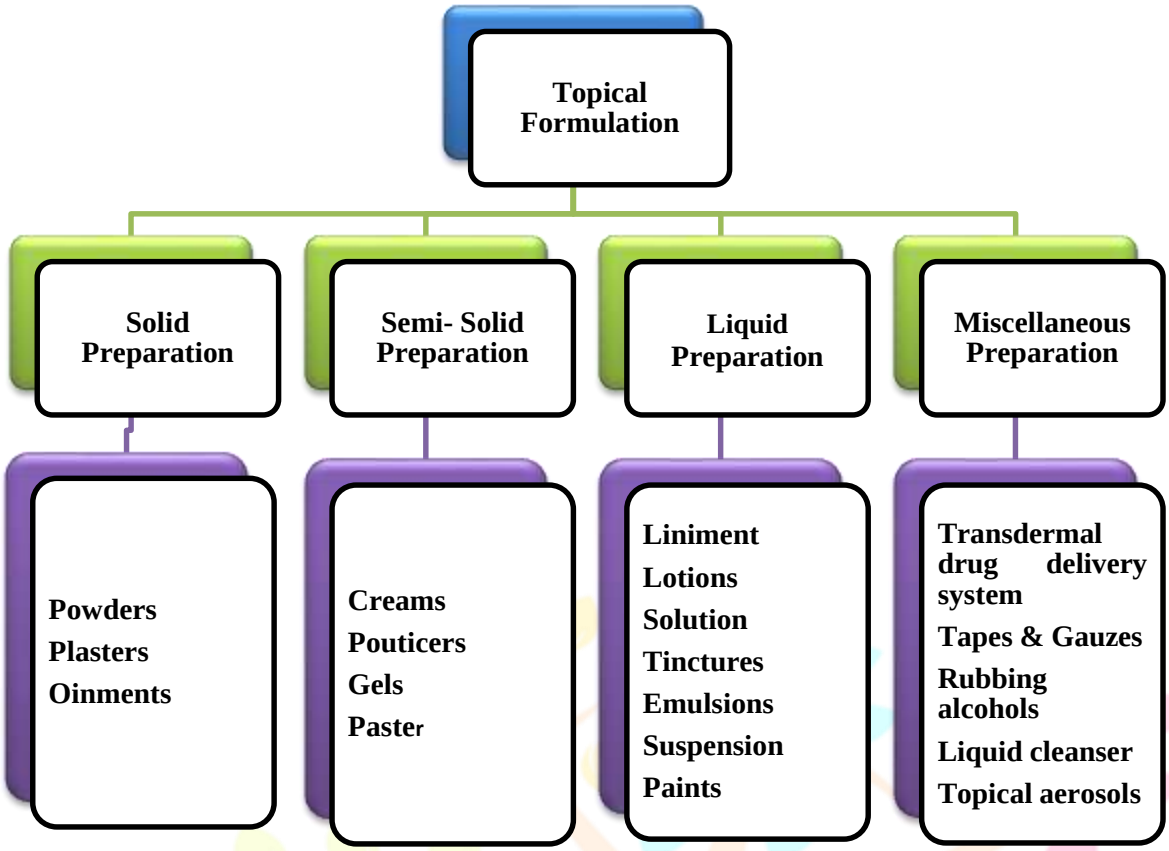


Figure 3:- Classification of Topical Formulations

Factors Affecting Topical Absorption of Drug [8]

A. Physiochemical factors

1. Skin thickness.
2. Lipid content.
3. Skin pH.
4. Hair follicle density.
5. Sweat gland density.
6. Blood circulation.
7. Skin hydration.
8. Skin inflammation

B. Physiochemical factors

1. Molecular weight (<400 Dalton)
2. Diffusion coefficient
3. Partition coefficient
4. Permeability coefficient
5. Degree of ionization (absorbed only ionized drug)
6. Effect of vehicles

Method to Enhance Drug Penetration and Absorption [9]

1. Chemical enhancement
2. Physical enhancement
3. Biochemical enhancement
4. Supersaturation enhancement

PHYSIOLOGY OF SKIN [10]

The skin is made up of several layers. The layer above is termed the epidermis. While the layer under the epidermis is referred to as the dermis. Blood vessels, sebaceous glands, sweat glands, and hair follicles are all found in the dermis. Subcutaneous fatty tissues are located beneath the dermis. The hair bulb protrudes into this adipose tissue. Each square centimeter of human skin is known to have between 40 and 70 hair follicles and 200 to 300 sweat ducts. Skin pH ranges from 4 to 5.6.

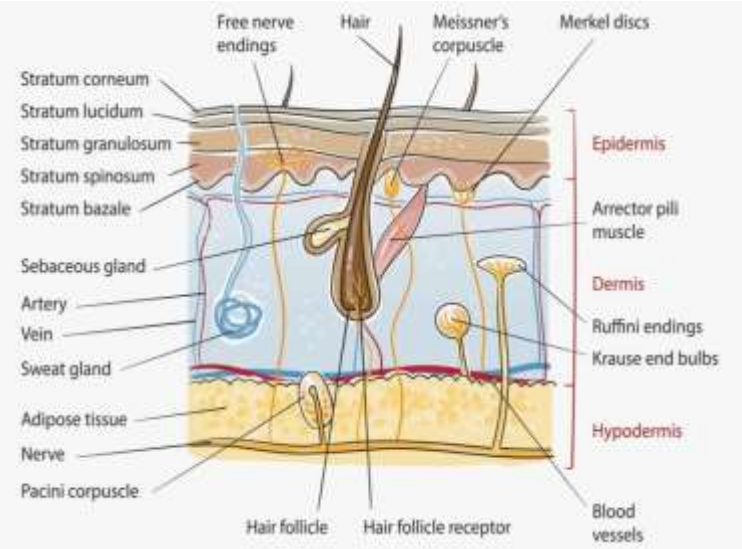


Figure 4:- Structure of Skin

1. Epidermis [11,12]

The stratified, squamous epithelial layer is known as the epidermis. The epidermis is mostly made up of keratinoytes and dendritic cells. Keratinocytes have a lot of stainable cytoplasm and intercellular bridges, which differentiate them from translucent dendritic cells.

In the epidermis, there are three primary cell types.

a. Keratinocytes Cells(K)
b. Langerhons Cells (L) in the malighian layer
c. Melanocytes Cells(M) in the basal layer

The layers that comprise the epidermis are as follows:

a. Stratum Germinativum **(Growing layer**)
b. Malpighion layer **(Pigment layer)**
c. Stratum spinosum **(Prickly cell layer)**
d. Stratum granulosum **(Granular layer)**
e. Stratum lucidum **(False layer**)
f. Stratum corneum **(Horny layer)**

2. Dermis [11]

The dermis is a cohesive structure of fibrous, filamentous, and amorphous connective tissue that allows fibroblasts, mast cells, macrophages, and nerve and vascular networks to enter the body in response to stimuli.

The dermis consists of the following sub layers:

a. Papillary layer
b. Reticular layer

3. Hypodermis [12]

The muscle's dermis, aponeurosis, and fascial are positioned between the layer of adipose tissue known as the hypodermis. Subcutaneous adipose tissue is fundamentally and practically strongly linked with the dermis through the nervous and circulatory systems. The skin hypodermis layer is made up of loose connective tissues, and the body's surface shows differences in its thickness.

4. Subcutaneous tissue [12]

The superfacial fascia, a film of fat-rich aerolar tissue that connects the dermis to the underlying anatomy, makes up this layer. Only the surface area has large arteries and veins.

EMULGEL

Emulsions and gels are combined to create emulgels. Emulgels are emulsions that have been mixed with a gelling agent to create gel, either from water in oil or oil in water. Emulsified gel is a stable and effective carrier for hydrophobic or weakly water-soluble medicine. [13]

The oil-in-water type is used for lipophilic medications. Whereas the water-in-oil type is used for hydrophobic pharmaceuticals. [14]Emulgel is capable of delivering both hydrophilic and lipophilic medicines due to the coexistence of aqueous and non-aqueous phases. In recent years, they have been employed as control release formulations. These are biphasic systems with higher drug loading, capacity, and stability. [15]

Emulgel has several advantages, including good spreadability, thixotropic, greaseless, good shelf life, and odourlessness, and offers a more pleasing look than typical topical formulations. Emulgel is a dual-control release method with both gel and emulsion qualities.[16]

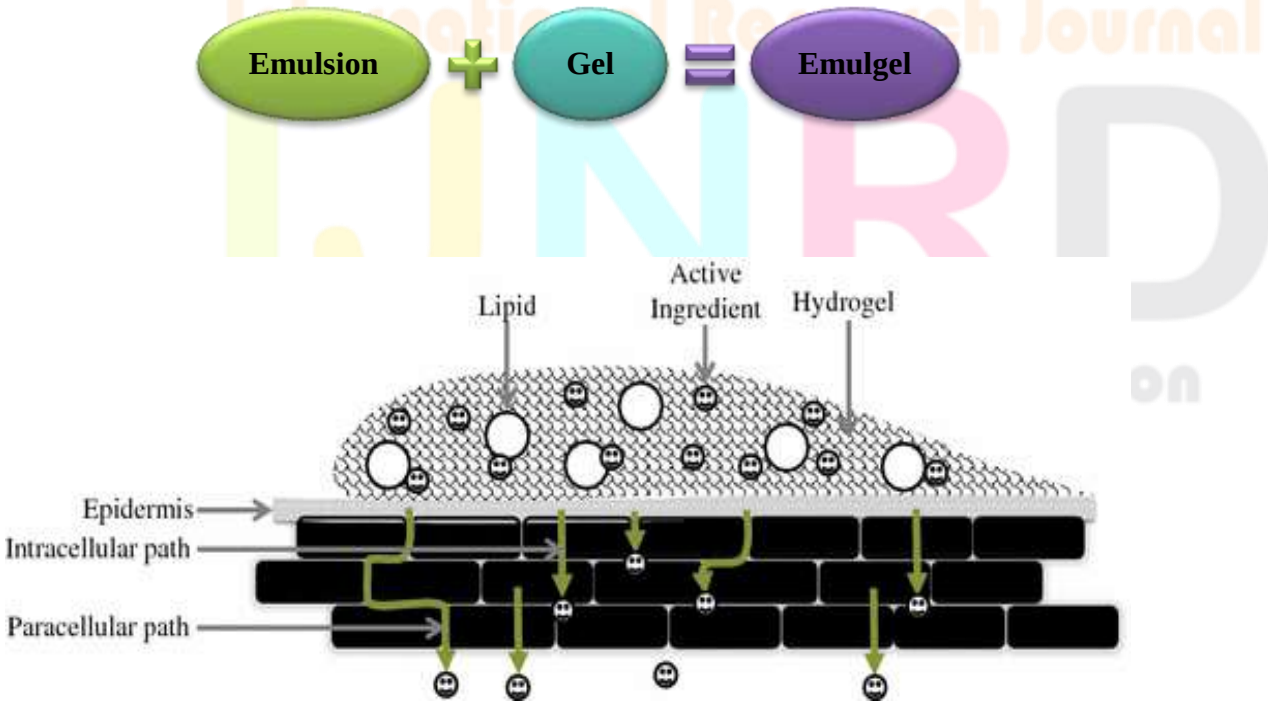


Figure 5:- Structure of Emulgel

Emulgel Ideal Properties [17]

- Being oil free.
- Spreads easily.
- Simple to remove.
- Greater durability and biocompatibility.
- Pleasing appearance**.**

Advantages of Emulgel [18]

- Avoiding first pass metabolism.
- Preventing gastric intolerance.
- Improve patient compliance.
- Easily applied and convenient.
- Ease of quitting medication, when required.
- Hydrophobic drug incorporation.
- Increased loading capacity.
- Increased stability.
- Production viability and inexpensive preparation
- Controlled release.
- No intensive sonication.
- Self medication

Disadvantages of Emulgel [19]

- Large particles of drugs are difficult to absorb or cross through the epidermal barrier.
- Some medications don't pass through the skin well.
- Allergy or skin irritation might occur.
- Bubbles may appear as the emulgel is forming.

Types of Emulgels

Depending on the Emulsion type [20]

1. Macro emulsion gel

Emulgel in which emulsion droplets have a particle size of more than 400nm. Despite being optically opaque, the individual droplets are clearly visible under a microscope. It is thermodynamically unstable for macro emulsions.

2. Nanoemulgel

The term "nanoemulgel" refers to the combination of nanoemulsion and gel. The transparent dispersions of oil and water with a droplet size of less than 100 nm, known as nanoemulsion. Nanoemulsions are thermodynamically stable and sustained by an interfacial coating of molecules of co-surfactant and surfactant. Both in vitro and in vivo nanoemulsion formulations have better transdermal and dermal distribution capabilities.

3. Microemulgel

Microemulsions, whose droplet sizes vary from 10 to 100nm, are transparent and thermodynamically stable, and they do not unite. Water, oil, surfactant, and co-surfactant are combined in precise amounts to form microemulsions.

Depending on the kind of API [21]

1. Herbal / Poly herbal

- Cosmetic emulgel made from field pumkin for skin treatment.
- Babchi oil and gum guggle combined to create an anti-psoriatic emulgel.

2. Allopathic

- Voltaren (Diclofenac Diethyl Ammonium Emulgel) manufactured by Novartis pharma.

Emulgel consists of two components

1. **Emulsion**
2. **Gel**

1. Emulsion [22]

A two-phase system called an emulsion. An emulsion is made up of two fully immiscible liquids, one of which is distributed into the other as tiny globules. Emulgels are a biphasic system that is made by mixing two immiscible liquids is

a. **Dispersed phase:** -Dispersed phase, alternatively called the discontinuous phase. The term "dispersed phase" or "internal phase" refers to the phase that disperses into the dispersion medium**.**
b. **Dispersion Medium:** -Dispersion medium, alternatively called the continuous phase. The term "dispersion medium" or "external phase" refers to the manner in which the dispersion medium is distributed**.**

When an emulsifying agent (emulsifier) is present, the thermodynamic instability of the emulsion system can be stabilized. Preparations used for internal use are denoted by the pharmaceutical word "emulsion." Lotions or creams are considered emulsions for external usage. The globule size, which ranges from 0.1 to 100 micrometers.

Classification of Emulsion [23]

Based on Dispersed phase

- Oil in water (o/w)
- Water in oil (w/o)
- Multiple emulsion (w/o/w) or (o/w/o)

Based on Size of Liquid droplets

- 0.2 to 50 Micrometer (Macro Emulsion)
- 0.01 to 0.21 Micrometer (Micro Emulsion)
- 50 to 1000 Nanometer (Nano Emulsion)

2. Gel [24]

A physical condition whose characteristics lie between those of solids and liquids is referred to as a "gel." However, it is frequently used incorrectly for any fluid system displaying some degree of rigidity. A gel is made up of a polymer that expands when fluid is present, sometimes even inside the polymer itself. The volume of liquid that the gel traps determines the rigidity of the gel. These gels have a solid appearance and are moist and soft. These have the capacity to undergo significant physical state deformation, such as changing from a solid to a liquid.

Classification of Gels [25]

Based on Colloidal Phases

i. Inorganic (Two phase system)
ii. Organic (Single phase system)

Based on Nature of Solvent

i. Hydrogels
ii. Organogels
iii. Xerogels

Based on Rheological Properties

i. Plastic gels
ii. Pseudo plastic gels
iii. Thixotropic gels

Based on Physical Nature

i. Elastic gels
ii. Rigid gels

ESSENTIAL INGREDIENT IN THE FORMULATION OF EMULGEL

Aqueous Material [26]

This creates the emulsion-aqueous phase. Commonly utilized agents include alcohol, water, and so on.

Oils [27]

To prepare an emulsion, oils are utilized. The oil phase plays a crucial role in the emulsion, micro emulsion, and nanoemulsion formulation processes. Balsam, birch, castor, isopropyl myristate, myrrh, rose hip, and wheat germ oils are among the oil phases employed in the production of emulgel.

Table 1: Oils used in emulgel formulations and their properties [28]

Name of Oils	Properties
Olive oil	Antioxidant, Antimicrobial
Castor oil	Topical NSAIDs, Antioxidant
Balsam oil	Antifungal, Topical antibiotics

Isopropyl myristate	Drugs for acne, Topical steroids
Light liquid paraffin	Emollient

Emulsifier [26, 29]

Emulsifiers are compounds that control the emulsifier and stability processes. The main ingredients of emulgel are polyoxyethylene sorbitain monooleate (tween 20), sorbiton manooleate (span 80), and stearic acid as emulsifying agents.

Table 2: Emulsifier used in Emulgel Formulations [30]

Chemical	Formulation
Polyethylene glycol 40 stearate	Emulsion and Emulgel
Sorbitan monooleate (span 40)	Emulgel and Emulsion
Polyoxyethylene sorbitan monooleate (tween80)	Emulgel and Emulsion
Stearic acid	Emulsion
Sodium sterate	Emulsion

Gelling Agents [31]

These are added to any dosage form to improve its consistency and act as thickening agents.

Table 3: Concentrations and type of Gelling Agents used in Emulgel [32, 33]

Gelling agents	Concentrations (%w/w)	Type	Uses
Carbapol 934	1%	Synthetic	Emulgel
Carbapol 940	1%	Synthetic	Emulgel
HPMC-2910	2.5%	Semi-Synthetic	Emulgel
HPMC	3.5%	Semi-Synthetic	Gel
Sodium CMC	1%	Semi-Synthetic	Gel
Guar Gum	0.5%	Natural	Gel
Xanthan Gum	1%	Natural	Gel

Penetration Enhancers [34]

These are substances that interact and partition into skin components to cause a brief reversible increase in skin permeability.

Table 4: Concentrations of Penetration Enhancers used in Emulgel Formulations [35]

Penetration Enhancer	Concentrations (%w/w)	Formulations
Oleic acid	1%	Emulgel
Lecithine	5%	Gel
Urea	10%	Gel
Isopropyl Myristate	5%	Gel
Linoleic acid	5%	Gel
Clove oil	8%	Emulgel
Menthol	5%	Emulgel

Preservatives [28]

These are the compounds that stop or slow down microbial development and preserve formulations from spoiling. The generally used preservatives are propyl paraben, methyl paraben, benzoic acid, benzalkonium chloride, benzoyl alcohol, and other preservatives.

Table 5: Concentration of Preservatives commonly used in Emulgel Formulations [32]

Preservatives	Concentration (%w/w)
Methyl paraben	0.03-0.15
Combination of Methyl and Propyl paraben	0.03-0.05
Phenoxy ethanol	0.2
Benzolkonium chloride	0.01

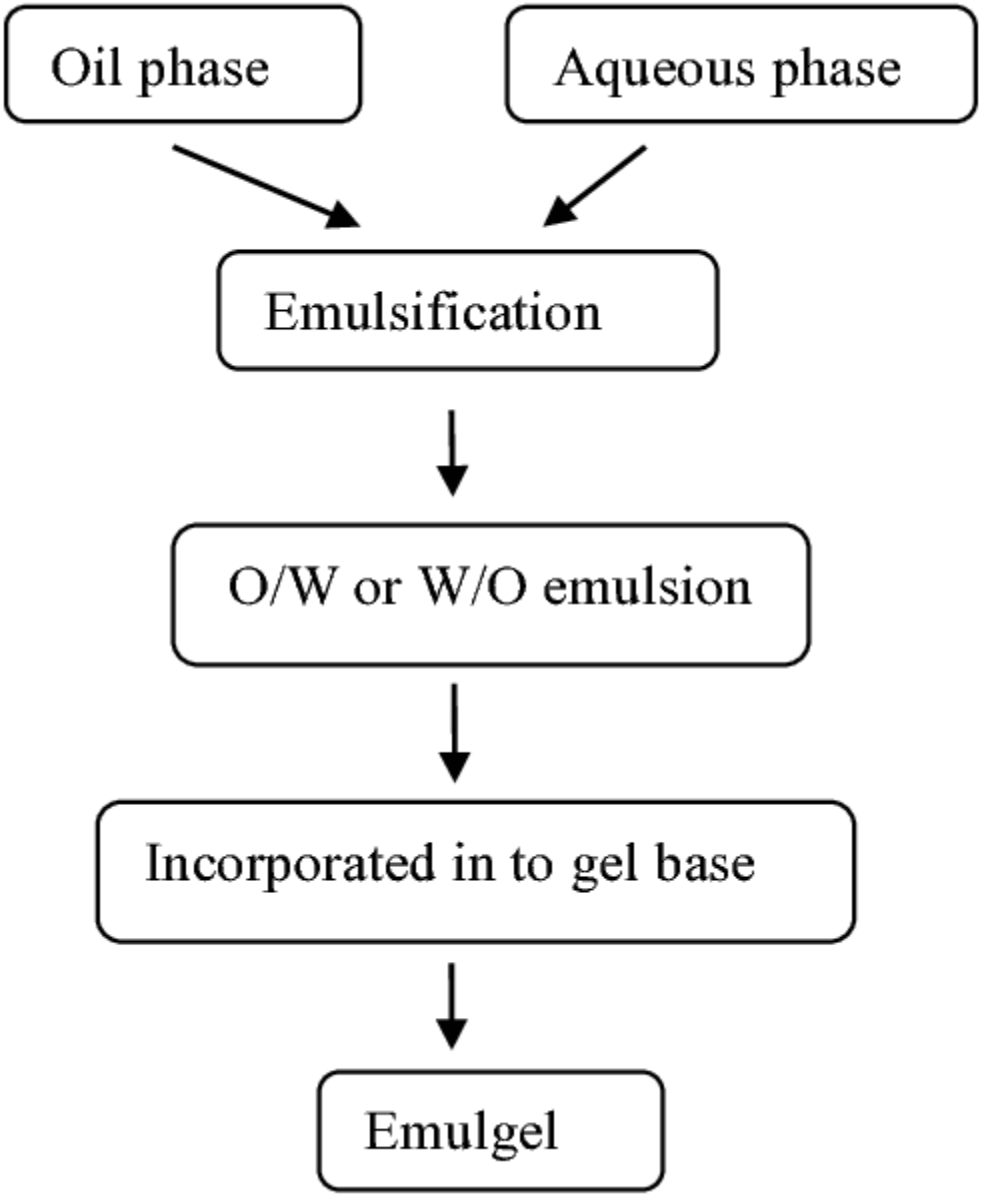
pH Adjustment [36]

These ingredients are used to maintain the pH stability of the formulations. E.g., triethanolamine, NaOH, etc.

Humectants [37]

Humectants are included in formulations to stop moisture loss. They reduce the drying of emulgels, which enhances their consistency and ease of application. Examples of humectants include propylene glycol, glycerine, etc.

EMULGEL PREPARATION [38]



Gel Preparation

- In a 100-ml beaker, add about 40 ml of water and mix at a speed of around 800 rpm.
- A precisely measured amount of Carbopol 934 was added pinch by pinch to the stirring solution mentioned above and stirred for 10 minutes.

Emulsion Preparation

- 10 ml of distilled water was used to dissolve 0.5% w/w tween 20 in order to create an aqueous phase.
- Then propylene glycol was combined with methyl paraben and propyl paraben, and they were eventually mixed in with the aqueous phase.
- 1% w/w spam 20 was mixed with the liquid paraffin in order to create an oil phase, and in this oil phase, 0.25% of the medication was dissolved in ethanol.
- The oily phase and aqueous phase were heated independently in a water bath to 80 °C.
- The oil phase and aqueous phase were mixed to create the emulsion by using a mechanical stirrer for 20 minutes.
- The mixture was cooled to room temperature after being stirred.

Emulgel Preparation

- Add gel solution to the emulsion drop by drop, stirring continuously at a moderate speed.
- Triethanolamine (TEA) has been used to bring the pH down to 6 or 6.5.
- Continued stirring for 5 minutes, led to the creation of emulgels that were more consistent.

ASSESSMENT OF EMULGELS

Physical Assessment [39]

A visual inspection was conducted to assess the color, homogeneity, and consistency of the emulgel formulations.

Measurement of pH [2]

A digital pH meter was used to measure the formulation's pH. To test pH, distilled water was used to clean the pH meter electrode before it was dipped into the mixture, and this process was carried out three times.

Rheological Properties [40, 41]

20g of the created emulgel is placed in a 25-ml beaker, and the viscosity of the various emulgel formulations is measured using a Brookfield viscometer (cone and plate) with spindle numbers 55, 63, or 64.

Spreadability [40]

It can be determined by using the slip and drag technique as recommended by Mutimer. Take 2 grams of emulgel and apply it to the bottom side. Side that is attached to a wooden block and make a sandwich by using another glass slide of the same size that is bound with a hook and has 500 milligrams of weight put on it. The pan linked to the second slide was given additional weight after five minutes. The time taken to cover a distance of 5cm for the top slides was noted.

The spreadability was determined using the formula

$$\textbf{Spreadability (S) = M * L / T}$$

Where, M = Weight tied to upper slide

L = Length of glass slides

T = Time taken to cover distance by upper slide

Swelling Index [21]

One gram of the produced topical emulgels is put on porous aluminum foil and then placed separately in a 50-ml beaker with 10 ml of 0.1 NaOH. In order to calculate the swelling index of the gel, the samples were taken out of beakers at various times and placed on a dry surface until they were weighed again.

The formula for the swelling index is as follows:

$$\textbf{Swelling Index (SW) \% = [(Wt –Wo) /Wo] × 100}$$

Where, (SW) % = Equilibrium percent swelling

Wt = Weight of swollen emulgel after time

Wo = Original weight of emulgel at zero time

Fourier Transforms Infrared Spectroscopy (FTIR) [42]

The purpose of this investigation was to identify stable storage surroundings for the drug in a solid state and determine compatible excipients for formulations.

Drug Content Assessment [43, 44]

The medication concentration in the emulgel was determined using a spectrophotometer. The amount of drug present in the gellified emulsion was determined by dissolving 2 grams of emulgel in a solvent (methanol) by sonication. After an appropriate dilution, absorbance was measured using UV-Visible Spectroscopy (1700 CE) from Shimadzu Corporation in Japan.

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

Stability Studies [45]

The emulgels were kept in harsh environments and packaged in aluminum collapsible tubes, and their stability was examined.

Skin Irritation Test [46]

Human volunteer's skin is often tested for skin irritation with their informed consent agreement in writing. The produced medication is applied to the hand's skin, and any negative effects are monitored.

Emulgel Globule Size and Distribution [47]

The Malven Zeta Sizer is used to measure the globule size of the produced emulgel formulation. The emulgel formulation, whose globule size was ascertained, was dissolved in distilled water and shaken to produce a homogeneous solution. Place a precisely measured amount of sample in the zeta sizer's photocell. The prepared emulgel's mean globule size and distribution are measured.

In Vitro Drug Release Study [48]

In vitro drug release study is done with a Franz diffusion cell in emulgel. It aids in figuring out the medication release.

Microbiological Assay [49]

The ditch plate technology is embedded in this method. By using this technique, the activity of bacteria and fungi is assessed.

PACKAGING OF EMULGEL [50]

Emulgels are typically packed in either an aluminum tube closed by a molded seal or a membrane-sealed lacquered tube with an inner coating of a phenoxy-epoxy-based lacquer and a propylene screw cap.

MARKETED FORMULATION OF EMULGEL

S.no	Product Name	Drug	Manufacture	Use
1.	Nucoxia Emulgel	Etoricoxib	Zydus Cadila	Anti-Inflammatory
2.	Voveran Emulgel	Diclofenac	Dr. Reddy's Laboratories	Anti-Inflammatory
3.	Kojitin Emulgel	Kojic Acid Dipalmitate	KVM Laboratories Pvt Ltd	Hyper-pigmentation
4.	Curcu Actin	Curcumin	Fourrts India	Anti-Inflammatory

	Emulgel		Laboratories Pvt Ltd	
5.	Sorobet Emulgel	Clobetasol	Geluk Pharma	Anti-Inflammatory

CONCLUSION

In recent years, because of improved patient compliance, topical medication administration has been extensively employed, and emulgel has become a widely used drug delivery technique. Since it has an advantage in terms of spreadability, adhesion viscosity, and extrusion. Additionally, they will provide a means of encapsulating hydrophobic medication in gel bases that are soluble in water.

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