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A COMPREHENSIVE REVIEW ON CHARACTERISTICS, APPLICATIONS, AND COMPONENTS OF ELMULGEL DRUG DELIVERY SYSTEM

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ABSTRACT

Applying medication to the skin for therapeutic purposes or to treat skin conditions is known as a topical drug delivery system. Emulgels are a big improvement over regular gels, which frequently have trouble delivering hydrophobic medications. Emulgels are a dual-release control method that improves the effectiveness of medications by combining emulsions with gels. This breakthrough greatly increases patient compliance and bioavailability, making it crucial for topical delivery systems. Emulgels are commonly used in many cosmetic products as well as in medicinal applications as anti-inflammatory, antifungal, analgesic, and anti-acne treatments. A major benefit of these topical administration systems is their ability to avoid first-pass metabolism, which increases the active compounds' bioavailability. For dermatological uses, emulgels possess several advantageous qualities: they are non-greasy, thixotropic, and easily spreadable. They also have a longer shelf life due to being water-soluble, emollient, and simple to remove. Furthermore, their translucent and visually pleasant appearance improves user experience, making emulgels a noteworthy advancement in topical drug administration. This area of research is highly productive, and its application in humans has yielded triumphant outcomes in modifying the clinical and therapeutic effectiveness of drugs with low bioavailability.

Keywords: Characteristics, Applications, Components, Emulgel, Drug delivery system

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INTRODUCTION

Topical drug delivery systems, including creams, lotions, gels, foams, and other similar formulations, are used to apply drugs directly to the skin or to the mucosal lining of certain organs and body cavities. This approach allows for localized treatment, improving the efficacy of the formulation while minimizing systemic side effects, increasing patient compliance, and maximizing therapeutic value. A primary goal of these systems is to facilitate the systemic absorption of hydrophobic drugs through the skin, a challenge often faced by conventional delivery methods. Novel drug delivery systems are therefore employed to enhance the effective delivery of these hydrophobic compounds [1-3]. Formulations are carefully prepared by combining active pharmaceutical ingredients with various excipients to optimize drug delivery. Skin conditions are widespread throughout the world, impacting people of all ages and places. These diseases, which range in severity from mild to severe, can affect how the skin looks, behaves, and

operates. Acne, dermatitis, psoriasis, eczema, and fungal infections are common skin conditions [4-7].

Many skin disorders are commonly treated with topical drugs, including corticosteroids, antibiotics, antifungals, and antipruritics. These methods of administration are essential for improving medication absorption via the skin, which can result in either systemic therapeutic advantages throughout the body or localized effects at the application site [8, 9].

Research in this field focuses on optimizing drug delivery efficiency and efficacy by exploring innovative formulations, advanced techniques, and novel drug carriers. This contributes significantly to improving the bioavailability of existing drugs, enhancing therapeutic outcomes, and overcoming clinical challenges.

Advantages of Topical Drug Delivery Systems

Avoids pre-systemic metabolism that occurs with oral medication.



User-friendly, efficient, and designed for patient comfort and ease of use.

Allows for easy termination of medication when needed.

Enables selective drug delivery to a specific site.

Avoids drug fluctuations in plasma [10, 11].

Topical medication delivery systems' drawbacks

Drugs with high molecular weight and non-lipid solubility have trouble permeating the skin and mucous membranes, which decreases their topical effectiveness and hinders therapeutic absorption.

The application site may experience localized skin discomfort.

Contact dermatitis may result from certain drugs or excipients.

This method is only applicable to drugs that need low plasma concentrations.

With a pH of 5.5, topical formulations must provide the best possible drug penetration into the skin. This may cause the pH of the formulation to vary when it is applied. This technique allows for targeted treatment and improved therapeutic results by producing pharmacological effects on the skin's surface or deeper layers [12-16].

CLASSIFICATION OF TOPICAL DRUG DELIVERY SYSTEM

The formulation type, mode of action, and application site all influence its classification. Creams, gels, ointments, patches, and sprays are common varieties.

To choose the best system to maximize medication administration and therapeutic results, it is essential to comprehend these classes. The physiological processes of the skin must be taken into account when formulating topical medications because they are applied directly to the skin. To develop safe, efficient topical dose forms that optimize therapeutic advantages, it is essential to comprehend these processes.

These therapies are intended to provide focused and localized therapeutic effects, enhance the quality of the skin, restore vital functions, and successfully treat particular disorders. However, stickiness, a low spreading coefficient, and stability problems are common problems with conventional topical products like creams, lotions, or ointments. Gels, especially those that use emulsion-based methods, are becoming more and more popular for incorporating hydrophobic medications into pharmaceutical and cosmetic preparations in order to get around the constraints of semisolid formulations [17-19].

EMULGEL AS DRUG DELIVERY SYSTEM

An emulgel is a specialized topical formulation created by blending an emulsion with a gel base. Its dual-release mechanism, incorporating both gel and emulsion systems, makes it particularly important for topical drug delivery. The main goal of this delivery system is to facilitate the penetration of

hydrophobic medications through the skin barrier and into the bloodstream.

These emulgels possess several desirable properties for dermatological applications, including a non-greasy texture, ease of removal, effortless spreadability, emollient properties, non-staining characteristics, extended shelf-life, transparency, appealing appearance, and a reduced risk of severe side effects. An emulsion-based strategy effectively addresses the challenges associated with delivering hydrophobic medications. This approach enables these compounds to leverage the unique benefits of gels, enhancing their stability, absorption, and overall therapeutic effectiveness in various formulations. Emulgel, formulated as either oil-in-water (o/w) or water-in-oil (w/o), can be stabilized with a gelling agent. It offers a stable and effective platform for incorporating poorly water-soluble drugs.

Emulgel can handle both lipophilic and hydrophilic medications because of its dual aqueous and non-aqueous phases. It also works as a controlled-release formulation by enhancing drug loading capacity and stability through the use of a biphasic technique. It functions as a dual-controlled release method, combining the advantages of emulsions and gels for improved distribution and effectiveness. Numerous pharmaceutical companies have started producing emulgel commercially as a result of these benefits. Voltaren® Emulgel® (diclofenac sodium), Pernox (benzoyl peroxide), Miconaz-H (miconazole nitrate), and CLINAGEL (clindamycin phosphate) are a few examples of such products [20-24].

By encasing medication particles in their internal phase, emulsions serve as controlled-release drug delivery methods that guarantee a slow and steady release.

This process enables the medication to gradually permeate the skin and diffuse through the exterior phase of the emulsion, resulting in extended release, increased medication efficacy, and gradual, steady absorption. A cross-linked gel network that efficiently captures tiny particles supports the regulated release and guarantees a consistent supply of the active ingredient over time. Furthermore, these formulations' mucoadhesive qualities prolong the drug's skin contact time, enhancing therapeutic results. Because of their emollient properties, water-in-oil emulsions are highly prized for their ability to treat dry skin disorders. On the other hand, oil-in-water emulsions are frequently utilized in cosmetics since they are simple to remove with water, making them practical for daily use.

Microemulsion Gel: Microemulsion gels combine biphasic oil-in-water formulations, stabilized by a surfactant to ensure thermodynamic stability and optical clarity. These systems contain droplets

ranging from 10 to 100 μm , comprising precise amounts of water, surfactant, co-surfactant, and oil. Microemulsions exhibit distinct properties, including high surface area, low interfacial tension, and the ability to dissolve both water- and oil-soluble compounds. These features improve drug penetration into the skin by reducing the stratum corneum's resistance to absorption, which is beneficial for drug delivery. Gelling agents like Carbopol 940, HPMC K100M, and guar gum are added to microemulsions to create microemulsion-based gels in order to solve the problem of inadequate absorption. Better control over medication release and increased skin penetration are made possible by these gels' increased stability and consistency when applied directly to the skin. These gels improve the therapeutic efficacy of pharmaceutical drugs and address inadequate absorption by changing the composition.

Clear oil-in-water dispersions known as nanoemulsion gels have globule sizes ranging from 1 to 100 nm, are thermodynamically stable, and are stabilized by surfactant and co-surfactant molecules. They create nanoemulgel formations when mixed with a gel. Nanoemulsions improve both in-vitro and in-vivo transdermal and dermal distribution capabilities; they are frequently added to emulgels. Nanoemulsions greatly increase transdermal medication permeability when compared to conventional products like emulsions and gels. Their high loading capacity and tiny globule size promote better drug absorption into the skin, hastening the therapeutic effect.

Emulgels classified as macroemulsion gels have emulsion droplet particles larger than 400 nm. Although physically undetectable to the naked eye, each droplet can be plainly seen under a microscope. Given their thermodynamic instability, macroemulsion gels can be stabilized through the use of surface-active agents.

COMPOSITION OF EMULGEL

Vehicle

Emulgels utilize both aqueous and oily vehicles to accommodate a wide range of drugs. Aqueous phase vehicles (e.g., alcohol, water, and other water-based substances) dissolve and incorporate hydrophilic drugs, while oily vehicles assist with hydrophobic drugs, ensuring a well-balanced formulation.

Oils

Various oils are combined in the oily phase of emulsion preparation:

Mineral Oils: These can be used alone or with hard or soft paraffin as a drug delivery system for external applications.

Oral Preparation Oils: Oils like castor and mineral oils used in oral preparations are not recyclable and often have localized laxative effects.

Nutritional Oils: Fish liver oils and various

vegetable oils (e.g., arachis, cottonseed, maize) are frequently used in dietary supplements due to their nutritional benefits and health properties.

Emulsifiers

Emulsifying agents are vital for smooth emulsification and maintaining emulsion stability over time. Formulated emulsions can remain stable for days, while commercial preparations can last for months or even years. Examples include polyethylene glycol (PEG) 4031 stearate, stearic acid, sodium stearate, sorbitan monooleate (Span 80), and polyoxyethylene sorbitan monooleate (Tween 80).

Gelling Agent

Gelling agents are thickening substances that increase the viscosity, consistency, and stability of various dosage forms. In emulgel preparation, they provide viscosity, stability, and rheological properties, transforming the emulsion into a semi-solid gel matrix. This enhances spreadability, adhesion, and retention on the skin, thereby optimizing drug delivery and therapeutic efficacy.

Gelling agents used in emulgels include both synthetic and natural polymers. Natural Polymers originate from organic materials such as proteins (gelatin, collagen, egg whites, casein) and polysaccharides (guar gum, acacia gum, tragacanth gum, pectin, starch, xanthan gum, dextran, succinoglycan, etc.). Semi-Synthetic Polymers are polymers containing both synthetic and natural components, such as carboxymethylcellulose, hydroxypropylcellulose, ethylcellulose, hydroxyethylcellulose, silicate (Veegum®), methylcellulose, sodium alginate, and Carbopol-940. Synthetic Polymers are purely synthetic and manufactured in laboratories on a large scale. Examples include carbopols® (now known as carbomers), poloxamers (Pluronic®), and polyvinyl alcohol [25-27].

Penetration Enhancers

By making it easier for drugs to pass through biological barriers like the skin or mucous membranes, penetration enhancers improve medication delivery. They improve the therapeutic results of topical and transdermal applications by increasing medication absorption and effectiveness.

METHODS FOR PREPARATION OF EMULGEL

An emulgel combines an emulsion and a gel, commonly used in topical formulations for delivering active ingredients in skincare or pharmaceutical products.

Cold Process Method

This method involves preparing the gel and emulsion phases independently at room temperature. The emulsion phase is created using oil, water, and an emulsifier, while gelling agents (e.g., carbomers or cellulose derivatives) form the gel phase. The emulsion is then gradually

introduced into the gel phase with continuous stirring to create a homogenized emulgel [28, 29].

Hot Process Method

This process involves preparing the gel and emulsion phases independently and heating them both until they become liquid. Until an emulgel forms, the hot emulsion is gradually added to the hot gel phase while being continuously mixed. Heat-sensitive materials may benefit from this technique, but careful temperature control is necessary to avoid deterioration [30-33].

Method of In-situ Gelation

Using this technique, gelling chemicals are added straight to the emulsion phase, allowing the gel matrix to form naturally without the need for external molds or prefabricated structures. For example, thermoresponsive polymers gel as they cool, but pH-sensitive polymers gel when they come into touch with physiological fluids [34, 35].

Polymerization Method

This technique disperses monomers within the emulsion phase. The polymerization process is then initiated to create a 3D network, converting the emulsion into a gel. This method often produces a cross-linked polymer network with desirable characteristics such as mechanical strength and controlled drug release kinetics [36-39].

Hydrophobic Modification Method

By adding hydrophobic or lipophilic materials, such as liposomes or lipid-based gelling agents, into the gel phase, emulgels with improved stability and extended-release characteristics can be created. This method works especially well for giving hydrophobic medications [40, 41].

Method of Solvent Evaporation

This process creates the emulgel by dispersing drug-loaded liposomes or nanoparticles into a hydrogel matrix and then evaporating the solvent. The bioavailability and durability of hydrophobic medications are improved by the addition of nanoparticles [42-44].

EVALUATION OF EMULGEL

Visual Examination

Visually inspect the emulgel for appearance, color, odor, phase separation, and uniformity.

Homogeneity

This can be evaluated by looking at the gel's appearance and noting any aggregates in the mixture.

pH

To find the pH, dissolve the emulgel in water to create a 1% solution. Next, use a digital pH meter to accurately measure the pH of this solution.

Spreadability

Spreadability is determined by applying an excess sample between two glass slides. The slides are compressed to a uniform thickness by placing a 1kg weight on them for 5 minutes. A precisely weighed amount (50g) is added to the lower plate. The time required for the upper glass slide to move over the lower plate is taken as a measure of spreadability (S).

$$\text{Spreadability (S)} = M \times L / T$$

Where:

- M = weight tied to the upper slide
- L = length moved on the glass slide
- T = time taken

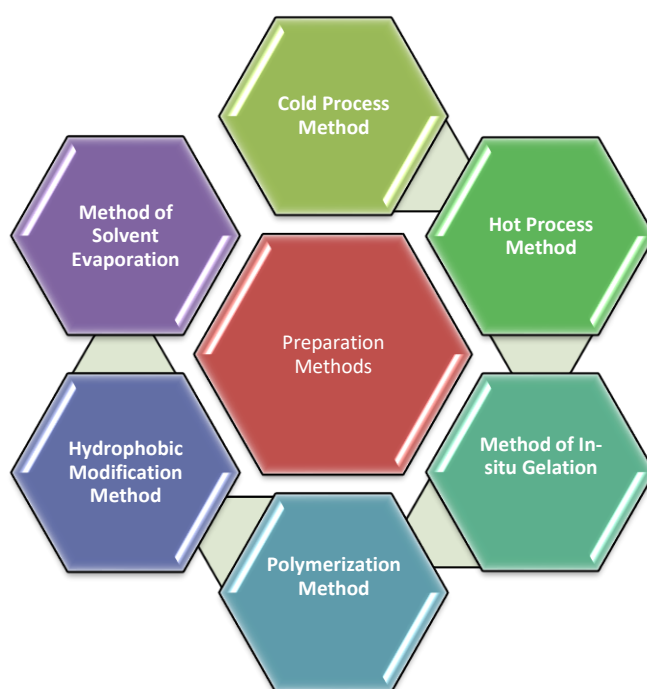


Figure 1: Various methods of emulgel preparation.

Drug Content Determination

To determine the drug content in the emulgel, dissolve 1 gram of the emulgel in 100 ml of solvent. Filter the solution to improve clarity, then dilute it appropriately for spectrophotometric measurement [45-47].

Centrifugation Analysis

Centrifugation is used to assess the stability of emulgel formulations by simulating high-speed conditions. Typically performed one week after preparation, this technique evaluates the formulation's stability and detects any phase separation or changes over time. The emulgel is centrifuged for 30 minutes at 3000 rpm. Centrifugation can reveal phase separation, sedimentation, or other instabilities within the emulgel.

Determination of Viscosity

A Brookfield digital viscometer with a cone and plate arrangement was used to measure the viscosity of several emulgel compositions at room temperature. This device provides crucial information on the consistency of the emulgel by precisely measuring its resistance to flow. While spindle 6 revolves freely at 100 rpm, viscosity values are obtained [48-51].

Skin Irritation Test

For topical dose formulations, a skin irritation test is necessary. The optimum formulation is administered to a 3 cm² skin area in order to assess irritation following a single topical emulgel application. After 24 hours, responses like erythema and edema are assessed. Following the removal of the emulgel, the treatment sites are cleansed.

Extrudability Study

The force needed to drive the emulgel out of a tube determines extrudability. This method measures the applied shear in the area where plug flow is assumed to occur when the shear rate surpasses the yield value. In this study, an aluminum collapsible tube is used for extrusion. The weight in grams needed to extrude an emulgel ribbon in ten seconds is used to calculate extrudability. Better extrudability is indicated by a higher weight. The average value is computed for accuracy after this procedure is carried out three times [52, 53]. The following formula is used to determine extrudability:

Extrudability = Area (cm²) / Weight

(g) applied to extrude emulgel from the tube.

Size and Dispersion of Globules in Emulgel

The size and dispersion of the globules inside the sample are ascertained using a Zetasizer instrument. A one-gram sample is dissolved in filtered water and thoroughly mixed by spinning to achieve uniform dispersion. This guarantees precise measurement of globule properties. This sample is then placed within the photocell of the Zetasizer,

and measurements are made of the mean globule diameter and distribution.

Percentage *In-vitro* Cumulative Drug Release Studies

The outer shell membrane of an egg is prepared by immersing the egg in a 50% aqueous HCl solution to dissolve the calcified layer. After carefully cutting the membrane to release the contents of the egg, it is cleaned with regular saline solution. The inner membrane is kept in distilled water after being repeatedly cleaned with water.

The diffusion cell is put in a beaker with 100 milliliters of pH 5.5 phosphate buffer after a suitable length of egg membrane has been cut and tied with thread to the bottom (grounded) layer. For the purpose of stirring the contents during the investigations, a magnetic bead is inserted to the outer compartment. The temperature is kept at 37 ±1 °C by placing the complete unit on a magnetic stirrer. Samples are withdrawn at different time intervals (up to 12 hours), and absorbance is measured spectrophotometrically [54, 55].

Swelling Index

The formulation with the highest swelling index demonstrates the greatest ability to absorb wound exudates. To calculate the swelling index, 1 gram of emulgel is placed in a Petri dish containing 10 mL of 0.1 N NaOH and covered with permeable aluminum foil. Samples are then collected at various time intervals, briefly dried, and weighed. The swelling index is subsequently calculated using the following formula:

Swelling index (SW) % = [(Wt-Wo)/Wo] × 100

Where:

- (SW) % = Equilibrium percent swelling
- Wo = Original weight of emulgel at zero time
- Wt = Weight of swollen emulgel after a fixed time

Stability Analysis

The ability of a drug formulation to maintain its unique chemical, physical, toxicological, and therapeutic qualities inside a particular container is referred to as stability. Every stability investigation is carried out in compliance with ICH standards (Q1R2). The following describes the various time intervals and storage conditions [56-58].

ADVANTAGES OF EMULGEL OVER CONVENTIONAL TOPICAL DOSAGE FORMS

Increased Stability

Emulgels offer greater stability compared to other topical preparations. Unlike powders that readily degrade, creams that may exhibit phase inversion, or ointments that can become rancid due to their oily phase, emulgels maintain their integrity more effectively.

Greater Loading Capacity

Emulgels offer a higher loading capacity due to their extensive structure, in contrast to alternative

novel approaches like nanosized liposomes and niosomes, which are prone to lower trapping efficiencies and leakage.

Simple Incorporation of Hydrophobic Medication: Hydrophobic drugs often present solubility challenges, hindering their release when directly incorporated into gels. Emulgels overcome this by blending oily droplets into a water base, facilitating better integration of oil-soluble medications. This creates an oil-in-water emulsion that can be effectively combined with a gel base, enhancing drug efficacy [59-62].

Production Feasibility

The emulgel preparation method involves short, straightforward phases, making production more feasible.

Low Preparation Costs: Emulgel preparation does not require specialized equipment. Furthermore, the materials used are less expensive and more widely available.

Lack of Vigorous Sonication

Producing vesicular preparations, such as liposomes and niosomes, typically requires powerful sonication, which can lead to medication leakage and degradation. However, emulgels do not necessitate strong sonication, thus avoiding potential drug degradation issues. For drugs with a shorter half-life, emulgels can extend their effects through controlled medication release [63-65].

Patient Compliance

Emulgels are easier to apply and less greasy, improving patient compliance.

CONCLUSION

Emulgels are innovative medicinal compositions applied to the skin that integrate the characteristics of both emulsions and gels. They offer significant potential for the pharmaceutical and cosmetic industries due to their versatile nature, making them appropriate for a variety of uses, including cosmetic goods and medical therapies.

This adaptability provides better therapeutic and

cosmetic results and creates new opportunities for product development.

Both hydrophilic and lipophilic medications can be released under controlled conditions thanks to these formulations, which guarantee stability and convenience of use. Emulgels' special emulsion and gel mix improves drug penetration through the skin, enabling more efficient administration of active substances. Because of this, they are especially useful for treating dermatological conditions where accurate and long-lasting drug delivery is essential.

Future studies might concentrate on creating unique formulations suited to particular therapeutic requirements. Emulgels, for example, can be made for targeted drug administration, providing accurate treatment for a range of skin disorders with little side effects.

Furthermore, improvements in emulgel technology may result in the development of sophisticated transdermal systems that allow for the systemic distribution of medicines through transdermal application, potentially transforming the way that some drugs are administered.

Emulgels can also be used by the cosmetics industry to create products with better skin absorption and long-lasting benefits. Researchers and developers can open up new avenues for innovation and exploration in this field, which will ultimately improve the ease and effectiveness of topical treatments and cosmetic applications.

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