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EMULGEL FORMULATION: A PROMISING STRATEGY FOR ENHANCED DRUG PENETRATION AND EFFICACY

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ABSTRACT

Topical drug delivery offers advantages such as site-specific action, avoidance of first-pass metabolism, and improved patient compliance. Conventional formulations like creams and ointments often suffer from poor drug solubility, limited skin penetration, and instability. Emulgels, which combine the properties of emulsions and gels, provide an effective alternative by enhancing solubility, skin retention, and controlled drug release. This review outlines the formulation components, methods, and mechanisms that contribute to the superior performance of emulgels in transdermal and topical applications. Evaluation parameters such as viscosity, pH, drug content, and skin irritation—are discussed to ensure quality and safety. Emulgels are especially effective in delivering anti-inflammatory, antifungal, antimicrobial, and cosmeceutical agents. Recent advancements, regulatory considerations, and formulation challenges are also addressed. With their multifunctionality and improved therapeutic profiles, emulgels show strong potential in advancing dermatological drug delivery.

KEYWORDS: Emulgel, drug delivery, Transdermal delivery, Novel drug delivery systems.

1. INTRODUCTION

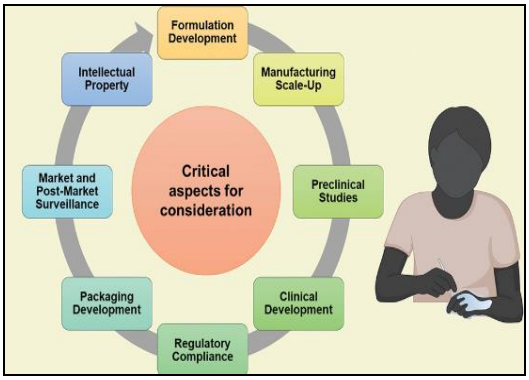
Topical drug delivery has witnessed remarkable advancements in recent years as researchers continue to seek alternatives to traditional systemic drug administration routes. This mode of drug delivery involves the application of pharmaceutical formulations directly onto the skin to achieve local or systemic therapeutic effects. Its popularity is largely driven by several advantages, including non-invasiveness, avoidance of gastrointestinal degradation, bypassing hepatic first-pass metabolism, enhanced patient compliance, and the possibility of achieving targeted therapy at the site of action. The effectiveness of topical drug delivery is largely hindered by the natural protective barrier of the skin, particularly the stratum corneum—the outermost layer that restricts the permeation of most therapeutic molecules. The stratum corneum consists of densely packed corneocytes embedded in a lipid matrix, forming a "brick-and-mortar" structure that effectively prevents the entry of foreign substances. As a result, achieving sufficient drug permeation through this barrier to reach the intended layers of the skin or systemic circulation is a significant formulation challenge. (Saini et al., 2023).

To overcome these limitations, a variety of advanced topical and transdermal drug delivery systems have been developed over the past two decades. Technologies such as liposomes, solid lipid nanoparticles, niosomes, ethosomes, nanoemulsions, and microemulsions have been investigated for their ability to enhance drug solubility and penetration across the skin barrier. Despite these innovations, there remain challenges related to formulation complexity, physical stability, scale-up, and cost-effectiveness. In this context, emulgel formulations have emerged as a promising hybrid system that combines the beneficial properties of both emulsions and gels, offering a novel and effective approach for topical delivery of various therapeutic agents.(Sriaandhal Sabalingam & Malitha Aravinda Siriwardhene, 2022).

An emulgel is essentially an emulsion (either oil-in-water or water-in-oil) that is incorporated into a gel base. This unique combination enhances the formulation's ability to deliver both hydrophilic and lipophilic drugs effectively. The gel component imparts desirable properties such as a non-greasy texture, good spreadability, ease of application, and excellent patient acceptability. At the same time, the emulsion facilitates the solubilization and

sustained release of poorly water-soluble drugs. The dual nature of emulgels provides better penetration through the skin as compared to conventional creams, ointments, or gels alone. The presence of suitable surfactants and co-surfactants in the emulsion phase can further disrupt the lipid layers of the stratum corneum, thereby facilitating enhanced drug permeation. Another advantage of emulgels is their rheological behavior. They exhibit thixotropic properties, meaning their viscosity decreases with shear stress during application and recovers afterward. This feature is particularly beneficial for patient compliance, allowing the product to spread easily on the skin surface and remain in place for prolonged periods. Additionally, emulgels offer better stability than standalone emulsions, which are prone to phase separation, creaming, and sedimentation over time. The gel matrix in emulgels helps to stabilize the emulsion droplets, thereby extending the shelf life of the formulation. emulgels are relatively simple and cost-effective to manufacture compared to other advanced systems like liposomes or solid lipid nanoparticles. They can be easily scaled up for industrial production using conventional mixing and homogenization equipment. Their compatibility with a wide range of excipients, such as natural and synthetic gelling agents (e.g., Carbopol, HPMC, xanthan gum), oils (e.g., isopropyl myristate, liquid paraffin), and surfactants (e.g., Tween 80, Span 20), makes them highly adaptable for various therapeutic applications.(Mayangsari et al., 2022).

The versatility of emulgel technology is further highlighted by its application across multiple therapeutic categories. It has been extensively explored for the delivery of anti-inflammatory, antifungal, antimicrobial, anti-acne, and pain-relieving drugs. Additionally, in the field of dermatology and cosmetology, emulgels are being used to deliver active ingredients such as retinoids, vitamin E, herbal extracts, and antioxidants, demonstrating their potential in both pharmaceutical and cosmetic markets. The successful formulation of an emulgel still requires a thorough understanding of the physicochemical properties of the drug, the choice of appropriate excipients, and optimization of formulation parameters. Considerations include the selection of a compatible gelling agent, the stability of the emulsion phase, the pH and viscosity of the final product, and the efficacy of the drug release and permeation. (Khullar et al., 2012).



2. CONCEPT AND RATIONALE OF EMULGEL

The emergence of emulgel technology in topical drug delivery represents a significant innovation that synergizes two well-established systems—emulsions and gels—to overcome the inherent limitations posed by the skin barrier and to enhance drug bioavailability. Traditional topical formulations, such as creams, ointments, and gels, although widely used, often fall short in achieving optimal therapeutic outcomes due to issues like poor drug penetration, instability, greasiness, or limited compatibility with certain types of drugs. Emulgel technology offers a versatile and elegant solution by combining the solubilizing power of emulsions with the patient-friendly and rheological benefits of gels.(Surini et al., 2020).

An **emulgel** is a biphasic delivery system composed of an emulsion—either oil-in-water (O/W) or water-in-oil (W/O)—integrated into a gel base using suitable gelling agents. This hybrid formulation is designed to encapsulate both hydrophobic and hydrophilic drugs. The emulsion component allows for the dissolution and incorporation of lipophilic drugs, while the gel base ensures even dispersion, improved viscosity, and excellent aesthetic qualities, such as a smooth, non-greasy feel on the skin. Together, these characteristics enhance the permeation of active pharmaceutical ingredients (APIs) through the skin's stratum corneum and into deeper layers, thereby increasing their therapeutic efficacy.(Satapathy et al., 2020).

The **rationale behind the development of emulgels** lies primarily in the need to overcome the drawbacks associated with standalone emulsions or gels. Emulsions, though effective for delivering hydrophobic drugs, often suffer from physical instability problems such as coalescence, creaming, and phase separation. They may also feel oily or greasy, reducing patient compliance. On the other hand, gels are known for their superior aesthetic and rheological properties, including good spreadability, non-greasy texture, and thixotropic behavior, but they are generally more suitable for hydrophilic drugs. By incorporating the emulsion into a gel matrix, emulgels stabilize the formulation while simultaneously improving the release and penetration of the drug. (Malavi et al., 2022).

2.1 Emulsion Component

An emulsion is a biphasic system consisting of oil and water phases stabilized by emulsifying agents. It is particularly effective for the incorporation of lipophilic (oil-soluble) drugs, which may have limited solubility in aqueous vehicles. Emulsions improve the solubilization, distribution, and skin penetration of such compounds. Traditional emulsions can be unstable and often lack viscosity, which can result in rapid runoff from the skin surface and reduced contact time.

2.2 Gel Component

Gels are semisolid systems comprising a network of gelling agents dispersed in an aqueous or hydroalcoholic base. They are non-greasy, easily spreadable, and offer cooling and soothing effects upon application. Gels also exhibit thixotropic behaviour a property that allows them to become less viscous upon application and regain viscosity afterward, increasing skin retention and enhancing drug absorption.

2.3 Synergistic Integration in Emulgels

By combining emulsions into a gel base, **emulgels** provide.

- **Improved Stability:** The gel network stabilizes the emulsion, preventing phase separation and sedimentation.
- **Enhanced Permeation:** The emulgel matrix maintains prolonged contact with the skin, while emulsified droplets facilitate better diffusion of drugs across the stratum corneum.
- **Dual Solubility Accommodation:** Emulgels can effectively deliver **both hydrophilic and lipophilic drugs**, making them versatile.
- **Superior Patient Acceptability:** Non-greasy texture, easy application, and lack of irritation contribute to better adherence to therapy.
- **Sustained and Controlled Release:** The gelling matrix slows down the release rate, leading to longer therapeutic action and reduced dosing frequency.

2.4 Rationale for Use in Drug Delivery

The rationale behind emulgel development stems from the need to **overcome the limitations** of traditional topical systems—such as ointments (greasy and sticky), creams (moderate drug loading and stability issues), and pure gels (less efficient for lipophilic drugs). Emulgels address these issues by.

- **Extending drug residence time** on the skin surface,
- **Enhancing percutaneous absorption**, and
- **Providing controlled and targeted delivery** with fewer side effects.

Thus, emulgels represent a **cost-effective, stable, and efficacious platform** for dermal and transdermal delivery, with growing interest in both pharmaceutical and cosmeceutical industries.

3. COMPONENTS OF EMULGEL

The formulation of an emulgel involves a careful selection of excipients that not only stabilize the system but also improve drug solubility, skin permeability, and overall therapeutic efficacy. Emulgel is a complex yet elegant delivery system comprising two immiscible phases (oil and water), emulsifiers to stabilize the interface, gelling agents for viscosity and structure, and often, penetration enhancers to improve drug diffusion through the stratum corneum. Each of these components plays a distinct role in achieving a stable, patient-friendly, and bioavailable product. (Donthi et al., 2023) (Azam et al., 2023) (Shadab & Shamsi, 2020).

3.1. Oil Phase

The oil phase of an emulgel plays a dual role: it serves as a carrier for lipophilic (hydrophobic) drugs and also contributes to skin moisturization and permeation enhancement. Lipophilic drugs often face formulation challenges due to their poor aqueous solubility, and incorporating them into the oil phase of an emulsion helps enhance their solubilization and release characteristics. Oils also soften the stratum corneum by disrupting its lipid structure, which can facilitate better drug penetration.

Commonly used oils include **isopropyl myristate**, **liquid paraffin**, and **olive oil**. Isopropyl myristate, in particular, is widely recognized for its excellent skin penetration-enhancing properties, making it suitable for use in emulgels targeting deeper skin layers. Liquid paraffin offers good occlusive properties and is suitable for sustained moisturization, while olive oil provides antioxidant benefits in addition to its emollient properties. The selection of the oil phase is crucial, as it influences the emulsion type, drug release rate, and patient acceptability.

3.2. Aqueous Phase

The aqueous phase forms the continuous medium in oil-in-water (O/W) emulgels and serves primarily as the solvent for hydrophilic drugs and excipients. It supports the dispersion of water-soluble agents and often includes buffers, preservatives, or humectants to maintain the pH and stability of the formulation. The hydration of the stratum corneum via the aqueous phase can also aid in loosening the tightly packed lipid layers, thereby facilitating better drug permeation.

Water, being the major component in the aqueous phase, is usually purified or distilled. In some formulations, additional agents such as **glycerin** or **propylene glycol** may be included to enhance hydration and prevent the drying of skin. These agents also improve the overall feel and texture of the emulgel upon application.

3.3. Emulsifiers/Surfactants

Emulsifiers are critical to the formation and stabilization of emulsions by reducing interfacial tension between the oil and water phases. In emulgels, surfactants ensure that

the dispersed phase remains uniformly distributed throughout the formulation, preventing coalescence and phase separation during storage. The choice of surfactants is influenced by the Hydrophilic-Lipophilic Balance (HLB) value, which determines their suitability for forming either O/W or W/O emulsions. Commonly used surfactants include Span 20 (sorbitan monolaurate) and Tween 80 (polyoxyethylene sorbitan monooleate). These are often used in combination to achieve optimal emulsification. Poloxamers, also known as Pluronics, are non-ionic surfactants that can enhance stability and provide thermoreversible gelation properties. An ideal surfactant system not only stabilizes the emulsion but may also contribute to skin penetration by interacting with the lipid bilayers of the stratum corneum.

3.4. Gelling Agents

The gel base is a defining component of the emulgel system, providing it with the necessary viscosity, thixotropy, and physical stability. Gelling agents convert the liquid emulsion into a semi-solid form that is easier to apply and retains its position on the skin, thereby extending drug contact time. They also impart desirable sensory properties like non-greasiness and smooth texture.

Widely used gelling agents include Carbopol 940 (carbomer), hydroxypropyl methylcellulose (HPMC), and xanthan gum. Among these, Carbopol 940 is particularly favored for its high clarity, good skin feel, and effective viscosity even at low concentrations. It requires neutralization (commonly with triethanolamine) to form a gel, which provides the ideal consistency for topical applications. HPMC, a cellulose derivative, offers good film-forming properties and compatibility with various active pharmaceutical ingredients (APIs).

3.5. Penetration Enhancers

Penetration enhancers are optional but highly beneficial components in emulgel formulations, especially when targeting deeper dermal layers or systemic absorption. These agents work by temporarily disrupting the barrier function of the stratum corneum, increasing skin hydration, or interacting with lipid and protein domains to enhance drug diffusion.

Examples of effective penetration enhancers include dimethyl sulfoxide (DMSO), urea, and oleic acid. DMSO is a powerful solvent that can carry small molecules through the skin but must be used with caution due to potential irritation and systemic toxicity. Urea acts by disrupting hydrogen bonds in keratin and enhancing water retention, while oleic acid integrates into lipid bilayers and fluidizes them, improving drug flux.

4. FORMULATION STRATEGIES

Formulating an emulgel is a multi-step process that requires precision and optimization to achieve a stable, homogenous, and effective topical delivery system. The strategy integrates two fundamental systems—emulsion and gel—which are individually prepared and then combined. (Kandale et al., 2023) (Aji et al., 2023).

4.1 Step-by-Step Formulation Process

- **Preparation of the Emulsion**
  - The oil phase (containing the lipophilic drug, oils, and oil-soluble emulsifiers) and the aqueous phase (containing hydrophilic components and water-soluble surfactants) are heated separately to around 70–75°C.
  - Under continuous stirring, the aqueous phase is slowly added to the oil phase (or vice versa depending on desired emulsion type: oil-in-water [o/w] or water-in-oil [w/o]).
  - The mixture is homogenized to form a stable emulsion with uniform droplet distribution.

- **Preparation of the Gel Base**
  - A suitable gelling agent (e.g., Carbopol 940, HPMC) is dispersed in purified water or a hydroalcoholic vehicle.
  - The dispersion is allowed to hydrate and swell, often overnight, and is then neutralized (e.g., using triethanolamine) to develop a clear gel.

- **Incorporation of Emulsion into Gel Base**
  - The prepared emulsion is slowly incorporated into the gel base under gentle yet continuous stirring to prevent air entrapment.
  - The stirring continues until a uniform, homogenous emulgel is obtained.

- **Adjustment of pH and Viscosity**
  - The final pH is adjusted (typically between 5.5 and 6.5) to match the skin's natural pH and to optimize drug stability.
  - Viscosity modifiers may be added to achieve the desired consistency for spreadability and drug release.

4.2 Critical Factors Influencing the Formulation

- **Oil to Water Ratio:** Determines the type of emulsion (o/w or w/o) and affects drug solubilization and release.
- **Surfactant Concentration:** Influences the droplet size and stability of the emulsion. Overuse can cause irritation.
- **Type and Concentration of Gelling Agent:** Controls viscosity, spreadability, and the rate of drug diffusion.
- **Drug-Excipient Compatibility:** Physical and chemical stability must be assessed to prevent degradation or phase separation.
- **pH and Ionic Strength:** Must be compatible with the skin and stable for both drug and excipients.

4.3 Optimization and Evaluation

Formulations are typically subjected to **pre-formulation studies** and **optimization** using design tools such as

Design of Experiments (DoE) or **factorial designs**. Parameters like.

- Spreadability,
- Extrudability,
- Drug release profile,
- Stability (under accelerated conditions),

Are evaluated to ensure a robust and reproducible product.

5. Mechanism of Drug Penetration

Topical and transdermal drug delivery systems must overcome the primary barrier of the skin: the stratum corneum, the outermost layer composed of keratinized cells embedded in a lipid matrix. While it protects against environmental damage, this barrier also limits the permeation of therapeutic agents, especially hydrophilic and high molecular weight drugs.(Wu et al., 2022) (Gul et al., 2018).

Emulgel formulations offer a promising strategy to enhance drug permeation across this barrier by combining the advantages of emulsions and gels into a synergistic delivery platform. The following mechanisms contribute to their superior drug penetration ability.

5.1 Disruption of the Lipid Matrix of the Stratum Corneum

One of the most important pathways for drug penetration through the skin is via the intercellular lipid matrix. The stratum corneum contains tightly packed lipids (primarily ceramides, cholesterol, and free fatty acids), which function as a semi-permeable membrane.

Emulgel formulations incorporate surfactants (e.g., Tween 80, Span 20, poloxamers) and penetration enhancers (e.g., DMSO, oleic acid) that interact with these lipids. Surfactants lower the surface and interfacial tension between formulation and skin, enabling the emulgel to spread more uniformly. More importantly, these agents fluidize or extract the lipids in the stratum corneum, disrupting the ordered bilayer structure and opening pathways for drug molecules.

This lipid disruption facilitates the penetration of both hydrophilic and lipophilic drugs by reducing the resistance of the skin's outer layer, thereby allowing deeper diffusion into the epidermis and even into systemic circulation for transdermal applications.

5.2 Increased Hydration of the Skin

Another vital factor contributing to drug penetration is the hydration state of the stratum corneum. Dehydrated skin tends to be more resistant to drug permeation due to reduced fluidity in lipid bilayers. Emulgels, especially those based on oil-in-water emulsions and humectants like glycerin or propylene glycol, contribute significantly to skin hydration.

The aqueous phase in the emulgel retains moisture on the skin surface, and the occlusive nature of the gel layer prevents transepidermal water loss (TEWL). This prolonged hydration leads to swelling of the corneocytes and loosening of the lipid bilayers, making the skin more permeable. increased water content acts as a solvent reservoir, allowing better dissolution and subsequent diffusion of hydrophilic drug molecules Thus; hydration not only softens the stratum corneum but also creates a thermodynamic gradient that promotes the movement of drug molecules from the higher-concentration gel base to the lower-concentration skin layers.

5.3 Prolonged Contact Time and Occlusive Properties

One of the main limitations of conventional topical formulations like creams or lotions is their low retention time on the skin surface. Gravity, sweating, and inadvertent wiping reduce the contact period, leading to insufficient drug absorption. (Ibrahim et al., 2007).

Emulgels, due to their thixotropic and adhesive properties, offer longer residence time at the site of application. The gel matrix—often composed of carbomers or cellulose derivatives—provides a semi-solid, non-dripping consistency that allows the drug to remain in contact with the skin for extended periods. This ensures.

- Sustained drug release over time,
- Greater opportunity for drug absorption, and
- Higher local bioavailability.

Additionally, emulgels exhibit occlusive properties depending on their oil content and gelling agents. This occlusion creates a microenvironment that traps moisture and maintains hydration, a known enhancer of dermal penetration.

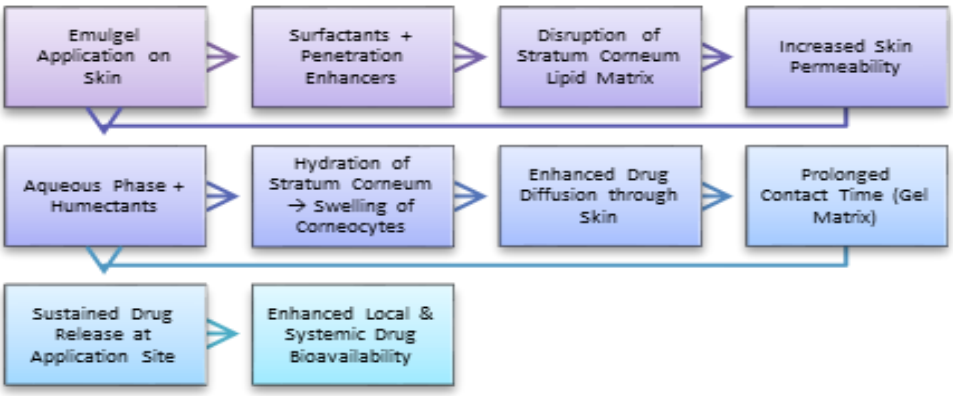
5.4 Enhanced Solubilization of Poorly Water-Soluble Drugs

One of the key challenges in transdermal delivery is the administration of poorly water-soluble drugs. Emulgel formulations effectively address this issue by utilizing oil phases and emulsifiers to create a microenvironment where lipophilic drugs are solubilized in the oil droplets. The emulsified structure provides a high surface area for drug release, and once on the skin, the drug partitions between the oil phase, aqueous phase, and the skin layers based on its solubility profile and diffusion coefficient. The gel component ensures that the drug remains localized and available for absorption without rapid evaporation or degradation. This mechanism is especially useful for delivering NSAIDs, antifungals, corticosteroids, and other lipophilic agents, where conventional aqueous gels would fail to provide adequate solubilization or absorption.

5.5Additional Contributing Mechanisms

- **Thermodynamic Activity:** Emulgels are designed to maintain a high **thermodynamic activity** of the drug, which increases the driving force for drug diffusion through the skin.

- **Particle Size Reduction:** The homogenization process during emulsion preparation leads to **fine droplet sizes**, which enhances drug surface area and facilitates faster absorption.
- **Viscosity Optimization:** Controlled viscosity ensures that the formulation is not only stable but also allows for easy application and uniform spreading, both of which contribute to enhanced skin contact and better drug diffusion.



Flowchart: 1 Mechanism of Drug Penetration from Emulgel.

6. Evaluation Parameters

The comprehensive evaluation of emulgel formulations is fundamental in pharmaceutical development to ensure that the product meets desired standards of safety, efficacy, quality, and stability. Given the complex structure of emulgels, which integrate the properties of both emulsions and gels, multiple parameters must be carefully assessed to confirm the integrity and performance of the final product. These evaluation criteria not only influence patient acceptability but also determine the formulation's therapeutic success. (Kausar & Akhtar, 2017) (Shah, 2021).

The initial and most straightforward parameter to assess is the **physical appearance** of the emulgel. A visually uniform and aesthetically pleasing product is crucial for patient compliance. The emulgel should appear homogenous, without any phase separation, clumping, or gritty particles. Parameters like color, consistency, and texture are examined visually and manually. The absence of phase separation over time indicates physical stability, which is essential for long-term storage. Homogeneity also reflects proper emulsification and dispersion of the drug within the formulation. (Kalayi et al., 2022).

Another key parameter is **pH measurement**, which ensures that the emulgel is compatible with the skin's natural pH. The average pH of human skin ranges between 4.5 and 6.5. Therefore, the pH of emulgel formulations should fall within this range to prevent skin irritation or allergic reactions. pH is typically measured using a calibrated digital pH meter. Any significant deviation from this range may compromise the skin barrier or cause discomfort during application, especially when the formulation is intended for chronic use.

Viscosity and **spreadability** are also crucial attributes, as they influence both the application and the bioavailability of the drug. Viscosity determines the consistency of the emulgel and its ability to remain on the application site without running off. A well-balanced viscosity ensures that the formulation is neither too thick (which may hinder drug release and application) nor too thin (which may reduce residence time on the skin). Viscosity is usually evaluated using a Brookfield viscometer under controlled temperature conditions. Spreadability, on the other hand, relates to how easily the emulgel spreads on the skin surface. It is tested using glass slide techniques, where the time and area of spread under a fixed weight are recorded. High spreadability improves patient convenience and ensures even distribution of the drug, enhancing therapeutic outcomes.

Drug content and content uniformity are essential for ensuring consistent dosing. These tests evaluate the amount of active pharmaceutical ingredient (API) present in the formulation and how uniformly it is dispersed. Inconsistent drug content can lead to subtherapeutic or toxic doses, defeating the purpose of controlled drug delivery. Samples from different parts of the emulgel batch are tested using analytical techniques such as UV-visible spectrophotometry or high-performance liquid chromatography (HPLC). Results must fall within acceptable pharmacopoeial limits (typically ±5%) to qualify for further development.

The **in vitro drug release** profile provides crucial information about the rate and mechanism by which the drug diffuses from the emulgel into the skin. It is commonly assessed using Franz diffusion cells with synthetic or semi-permeable membranes. A receptor

compartment beneath the membrane is filled with a suitable dissolution medium, and samples are withdrawn at regular intervals to determine drug release over time. The data is analyzed to fit various kinetic models (zero-order, first-order, Higuchi, Korsmeyer-Peppas) to understand the release mechanism, whether it is diffusion-controlled, erosion-controlled, or a combination of both.

Following in vitro studies, **ex vivo permeation studies** are performed using excised animal or human cadaver skin. This method is more biologically relevant and evaluates the ability of the drug to permeate through the skin layers and reach target tissues. These studies are again performed using Franz diffusion cells, and the drug permeated through the skin is quantified at predetermined time intervals. Such studies help in estimating the flux, permeability coefficient, and lag time, offering insights into how the formulation will behave in real-world clinical settings.

Skin irritation studies are another essential part of the evaluation process, especially for products intended for repeated or long-term application. These studies are usually conducted on albino rabbits or Wistar rats to determine any dermal toxicity or irritation potential of the emulgel. The formulation is applied on shaved skin, and observations for erythema (redness), edema (swelling), and other signs of inflammation are recorded over a defined period, generally 24 to 72 hours. A scoring system is used to quantify irritation levels. A non-irritating formulation is necessary to gain regulatory approval and ensure patient safety.

stability studies are conducted to assess the physical, chemical, and microbiological stability of the emulgel over time. These tests are done under different environmental conditions, as per ICH guidelines, such as 25°C/60% RH (real-time), 30°C/65% RH (intermediate), and 40°C/75% RH (accelerated conditions). Formulations are evaluated at regular intervals for changes in pH, viscosity, appearance, drug content, and microbial contamination. Stability studies help in determining the shelf life of the product and are mandatory for regulatory submissions and commercialization.

Table 1: Evaluation Parameters for Emulgel Formulations.

S.No.	Parameter	Purpose	Method/Instrument	Expected Outcome
1	Physical Appearance	Check for color, phase separation, homogeneity	Visual inspection	Uniform, no separation or grittiness
2	pH Measurement	Ensure skin compatibility	Digital pH meter	pH between 5.5 – 6.5
3	Viscosity	Determine consistency and application behavior	Brookfield viscometer	Optimal viscosity for spreadability and retention
4	Spreadability	Assess ease of application and coverage	Glass slide method / Spreadability apparatus	High spreadability
5	Drug Content Uniformity	Confirm uniform distribution of API	UV-Vis spectrophotometer / HPLC	95%–105% of labeled drug content
6	In Vitro Drug Release	Study release profile of the drug	Franz diffusion cell with synthetic membrane	Controlled, sustained release pattern
7	Ex Vivo Permeation Study	Evaluate drug penetration through biological membranes	Franz cell with animal/human skin	Significant permeation compared to control
8	Skin Irritation Study	Assess safety and irritation potential	In vivo (animal skin) observation post-application	No erythema or edema (non-irritant)
9	Stability Study	Evaluate formulation stability over time	ICH guidelines (real-time & accelerated storage)	Stable appearance, pH, drug content maintained

7. Applications of Emulgel in Therapeutics

7.1. Anti-inflammatory Agents

Emulgels have emerged as a versatile and effective platform for topical and transdermal drug delivery across a wide spectrum of therapeutic categories. Their unique ability to incorporate both hydrophilic and lipophilic drugs, combined with superior spreadability, prolonged skin retention, and enhanced permeation through the stratum corneum, has made them an attractive alternative to conventional creams, ointments, and gels. The incorporation of drugs in an emulgel system can improve therapeutic efficacy, reduce systemic side effects, and enhance patient compliance. Below are key therapeutic applications of emulgels:(Singh et al., 2016) (Deol et al., 2023).

7.1. Anti-inflammatory Agents

One of the most extensively studied applications of emulgel technology is in the delivery of anti-inflammatory drugs, particularly nonsteroidal anti-inflammatory drugs (NSAIDs). Topical administration of NSAIDs through emulgels allows for localized action at inflamed sites, such as muscles and joints, while minimizing gastrointestinal side effects associated with oral administration. Drugs like diclofenac sodium and ibuprofen have been effectively formulated as emulgels

to treat conditions such as arthritis, sports injuries, and muscular pain. Emulgels offer improved percutaneous absorption of these lipophilic drugs, ensuring better penetration to the inflamed tissues and faster relief with minimal systemic exposure.(Amgaonkar et al., 2021).

7.2. Antifungal Agents

Topical fungal infections, including dermatophytosis, candidiasis, and tinea, require sustained drug delivery to the affected area for complete eradication of pathogens. Emulgels provide an excellent delivery platform for antifungal agents such as clotrimazole and ketoconazole, which are poorly water-soluble and benefit from the oil-in-water emulsion base of emulgels for enhanced solubilization. The gel matrix aids in better retention and spreadability, while the emulsion phase helps in penetrating the deeper layers of the epidermis, targeting fungal colonies more effectively. the non-greasy nature and patient-friendly feel of emulgels increase adherence to therapy, especially for long-term treatment of fungal infections.

7.3. Antimicrobial Agents

The use of emulgels in delivering antimicrobial agents is particularly advantageous in treating skin wounds, burns, ulcers, and bacterial infections. Agents such as metronidazole and silver sulfadiazine have been incorporated into emulgel formulations to offer broad-spectrum antimicrobial activity with sustained release and deep skin penetration. Silver sulfadiazine emulgel is especially valuable in burn care, where its enhanced skin absorption leads to better microbial control and faster wound healing. The emulgel matrix also acts as a semi-occlusive layer, maintaining moisture and protecting the wound area from environmental pathogens while allowing for easy application and removal.

7.4. Anti-acne Drugs

Acne is a common dermatological condition often requiring topical therapy to minimize systemic side effects. Emulgels have proven to be ideal carriers for anti-acne drugs such as tretinoin and benzoyl peroxide. These agents are known to cause skin irritation when delivered in traditional forms; their incorporation into emulgels significantly reduces irritation potential by ensuring controlled release and better skin tolerance. Furthermore, the gel base prevents pore clogging and offers a cooling effect, which is beneficial in soothing inflamed acne lesions. The emulsion component enhances the penetration of active ingredients into the pilosebaceous unit, the primary site of acne pathology.(Parihar et al., 2020).

7.5. Cosmeceuticals

The cosmeceutical industry has increasingly adopted emulgel formulations due to their non-greasy texture, superior aesthetic appeal, and ability to deliver both synthetic and natural actives effectively. Ingredients such as retinoids, vitamin E, aloe vera, green tea extracts, and other herbal constituents have been incorporated into emulgels for anti-aging, moisturizing, skin brightening, and antioxidant effects. Emulgels facilitate the controlled release of these actives, prolonging their activity on the skin and enhancing penetration into deeper skin layers. They also maintain skin hydration and offer a pleasant, non-sticky finish, which is highly desirable in cosmetic formulations. Herbal emulgels are particularly popular in Ayurveda-inspired and organic skincare lines, combining traditional knowledge with modern formulation technology.

8. Advantages of Emulgel Formulation

Emulgel formulations represent a significant advancement in topical and transdermal drug delivery systems by combining the benefits of both emulsions and gels. This hybrid system overcomes several limitations associated with conventional dosage forms, making it highly suitable for dermatological, cosmeceutical, and pharmaceutical applications.

Below are the key advantages of emulgel formulations.

• Suitable for Hydrophobic Drugs

One of the most significant advantages of emulgels is their ability to incorporate lipophilic or poorly water-soluble drugs. The oil phase of the emulsion solubilizes hydrophobic drugs, while the gel matrix ensures effective delivery to the skin or systemic circulation.

• Enhanced Drug Penetration and Retention

Emulgels improve drug diffusion through the stratum corneum due to the presence of surfactants and penetration enhancers, which disrupt lipid barriers and increase skin permeability. Furthermore, the gel matrix provides prolonged contact time, enhancing the residence time and bioavailability of the drug at the target site.

• Non-Greasy and Easily Washable

Unlike ointments or creams, emulgels are non-oily and non-staining, giving them a cosmetically elegant appeal. They are easily spreadable, leave no residue, and can be washed off with water, enhancing user acceptability and compliance.

• Good Patient Compliance

Due to their smooth texture, pleasant skin feel, and ease of application, emulgels are more acceptable to patients compared to greasy topical formulations. This is particularly advantageous in chronic conditions requiring long-term topical therapy.

• Controlled Drug Release

Emulgel matrices allow for sustained or controlled release of drugs by modulating the composition of the gel and emulsion components. This feature is valuable for maintaining therapeutic drug levels, reducing dosing frequency, and minimizing side effects.

• Better Stability Than Pure Emulsions

Gels stabilize the emulsion system by inhibiting coalescence and phase separation, resulting in improved physical and chemical stability. Emulgels are less prone to creaming, cracking, and sedimentation compared to conventional emulsions.

CONCLUSION

In recent years, emulgel formulations have emerged as a powerful tool for transdermal and topical medication administration, surpassing several of the drawbacks of more traditional approaches. Emulgels are a hybrid material that combines the best features of emulsions and gels to increase the solubilization and stability of hydrophilic and hydrophobic drug delivery. Because of their distinctive semi-solid structure, they are simple to apply, distribute evenly, and, because to their pleasant, non-greasy texture, increase patient compliance. Emulgels improve treatment adherence by reducing dosage frequency and systemic adverse effects via controlled and prolonged medication release. Optimized emulsifier systems and penetration enhancers further boost therapeutic effectiveness and medication bioavailability. In addition to its anti-inflammatory and antifungal properties, emulgels offer antibacterial, anti-acne, and cosmeceutical uses that have shown promising results. Their extended shelf life and economic viability are guaranteed by their improved physical stability compared to typical emulsions. The potential of emulgels is being expanded by advancements in bioenhancers, nanotechnology, and natural excipients, which allow for targeted and tailored therapies. Because of their versatility, ease of production, and compatibility with many active components, emulgels hold great promise as a material for novel drug delivery systems. To enhance treatment results and quality of life, emulgels combine stability, patient acceptability, and effectiveness to bridge the gap between drug solubilization and efficient topical distribution.

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