CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES
SJIF Impact Factor: 7.187
https://doi.org/10.5281/zenodo.17228192

https://www.iajps.com/volumes/volume12-september-2025/24-issue-09-september-25/

Available online at: http://www.iajps.com *Review Article*

UNLOCKING POTENTIAL: EMULGEL TECHNOLOGY FOR EFFECTIVE TOPICAL TREATMENTS

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Abstract:

Emulgels have come to be recognized as a innovative a practical and efficient technique for drug administration through skin, offering enhanced skin penetration, controlled release, and improved therapeutic efficacy. Recent advances in emulgel technology have focused on optimizing formulation parameters, evaluating their physicochemical properties, and investigating their potential for delivering a comprehensive selection of therapeutic techniques agents. This review highlights the current state of emulgel research, including formulation strategies, characterization techniques, a long with uses in topical medication administration. The benefits and challenges of emulgel-based systems are discussed, and future directions for research and development are explored. By leveraging emulgel technology, topical treatments can be tailored to specific skin conditions, enhancing treatment outcomes and patient compliance. The versatility of emulgels allows for the delivery of diverse therapeutic agents, making them a compelling choice for managing a range of conditions, dermatological disorders. Furthermore, emulgels can provide a sustained release of active ingredients, reducing the need for frequent applications and improving patient convenience. As research within this domain continues to evolve, emulgel-based topical treatments are anticipated to be key contributors to addressing unmet needs in dermatological therapy.

Keywords: Emulsion-based gel, Topical application, Skin penetration enhancement, Controlled release.

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Please cite this article in press** Sobhitha B **et al., Unlocking Potential: Emulgel Technology For Effective Topical Treatments., Indo Am. J. P. Sci, 2025; 12(09).

INTRODUCTION:

Topical administration of medications involves direct application to specific body sites, including skin, ocular, rectal, or vaginal surfaces, to produce localized therapeutic benefits. This method is especially effective in managing dermatological conditions, such as acne, eczema, and psoriasis, by delivering active ingredients precisely to the affected area. Topical formulations confer a range of benefits, among them greater bioavailability, minimized systemic side effects, and enhanced patient adherence. Furthermore, this targeted delivery approach can be particularly advantageous for substances with a limited therapeutic window, enabling more precise and effective treatment outcomes[1].

Topical formulations come in various consistencies, including solid, semisolid, and liquid forms. However, delivering hydrophobic drugs through topical routes can be challenging. To overcome this, formulations often incorporate multiple excipients aiming to optimize drug administration. Occasionally, combining different formulation types can improve therapeutic efficacy[2]. Topical pharmaceutical preparations are designed to exert local effects on the skin, with minimal systemic absorption. These preparations are utilized to address multiple skin- related conditions, for example infections, fungal diseases, and dry skin, using antiseptics, antifungals, emollients, and protectants.

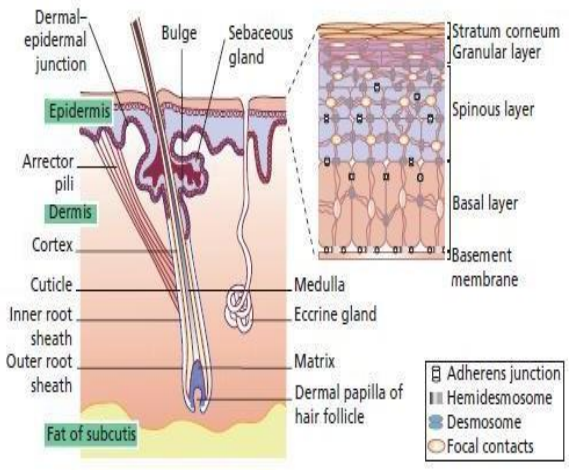

Fig 1: Structure of skin[3]

The primary benefits of topical delivery include avoiding first-pass metabolism, reducing the potential hazards linked to intravenous treatment, and minimizing the consequences of gastrointestinal variables, notably, pH fluctuations, enzymatic activity, and gastric emptying time, on drug absorption[4].

EMULGEL

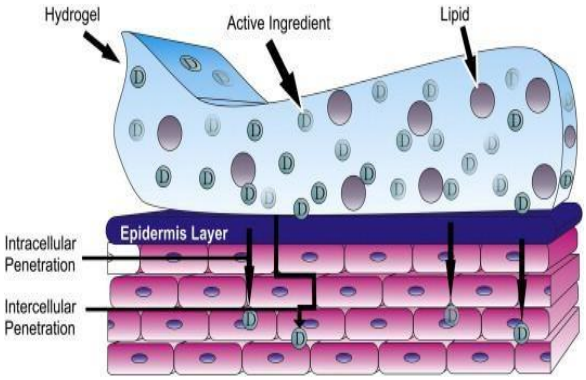

Fig 2: Schematic presentation of Emulgel penetration through skin[7]

Gels are semisolid systems where a large amount of liquid is entrapped within a network of colloidal particles. Although gels offer several benefits, They exhibit a substantial limitation, poor transporting hydrophobic drugs. To resolve this issue challenge, emulgels have been created as a possible solution[5]. Emulgels are stabilized systems that combine the benefits pertaining to emulsions and gels. They have the potential to be formulated as oil-in-water or water-in-oil emulsions, which are then gelled using a gelling agent. This unique combination makes emulgels a reliable delivery mechanism for hydrophobic or poorly water-soluble drugs[6].

KEY ADVANTAGES OF EMULGEL – SYSTEMS[8,9]

- **Effective incorporation of hydrophobic drugs:** Emulgels can successfully hold and distribute lipophilic compounds.
- **Enhanced drug incorporation and stability:** Emulgels provide a stable platform for medication transport, enabling enhanced loading capacity.
- **Controlled release:** Emulgels enable predictable and sustained release of active ingredients, improving therapeutic outcomes.
- **Feasible production process:** Emulgel production involves straightforward steps, eliminating requiring specialized instruments and reducing costs.
- **Cost-effective materials:** Adoption of readily available and affordable materials contributes to lower production costs.
- **Gentle production method:** Unlike other formulations, emulgel production avoids intensive sonication, minimizing the risk of drug degradation and leakage, making it suitable for sensitive ingredients.

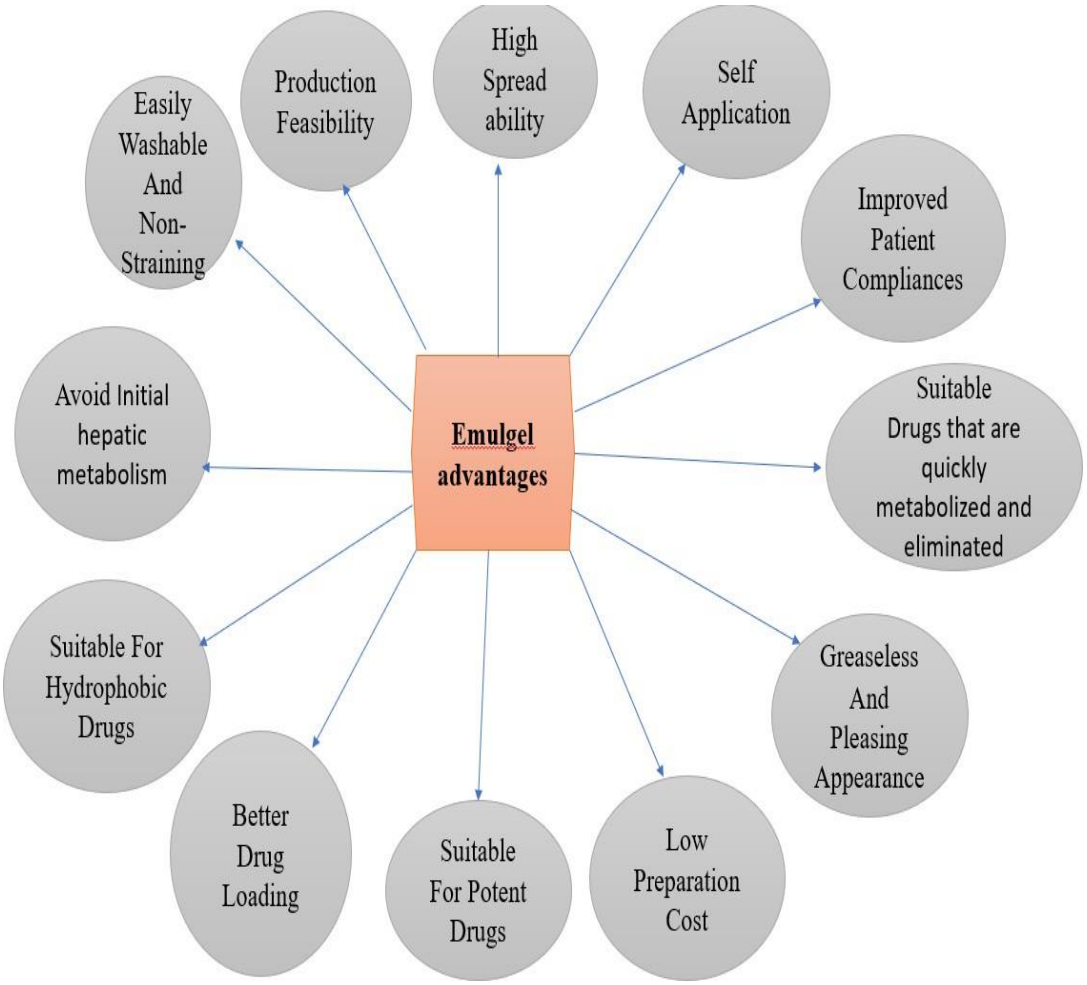

Fig 3: Emulgel Benefits[10]

POTENTIAL DRAWBACKS OF EMULGEL[11-13]

- **Skin irritation:** Certain ingredients may exacerbate pre-existing skin conditions, such as contact dermatitis.
- **Limited skin permeability:** Some medications may struggle to penetrate the skin, reducing their therapeutic effectiveness.
- **Poor absorption:** Large molecules or particles can hinder drug absorption, limiting the treatment's efficacy.
- **Air bubble entrapment:** Trapped tiny air inclusions within emulgels can impede therapeutic agent administration and compromise treatment outcomes.
- **Particle size limitations:** Pharmaceuticals with substantially sized particles may face difficulty penetrating the skin, making it challenging to achieve optimal absorption.

EMULGELS FORMULATIONS: A CATEGORIZATION[14]

1. **Microemulsion-based Emulgels:** They maintain equilibrium and display consistent properties in all directions systems featuring droplet sizes that vary between 10-100 nm, stabilized by surfactants exhibiting droplet dimensions ranging between gelling agents enhances their viscosity, modifying them to be appropriate for use on the skin applications.
2. **Nanoemulgels:** These are transparent or translucent oil-in-water dispersions with globule sizes between 1-100 nm. Their thermodynamic stability is attributed owing to the presence of both surfactant and co-surfactant agents molecules, which enables enhanced transdermal and dermal delivery.
3. **Macroemulsion-based Emulgels:** These emulsions are characterized by bigger droplet sizes particle sizes (>400 nm) and demonstrate unfavorable thermodynamic properties. However, they can be stabilized using surface-active entities, thereby allowing their application in various applications.

DRUG ATTRIBUTES FAVORING EMULGEL FORMULATION [15]

Desirable traits for emulgel development , including:

1. Minimal therapeutic dose (<10 mg)
2. Molecular mass ≤ 400 Da
3. Short plasma half-life (≤ 10 hours)
4. Optimal partition coefficient (Log P: 0.4-0.8)
5. High skin permeability coefficient (> 0.5 × 10^ (-3) cm/h)
6. Low oral bioavailability and narrow therapeutic index
7. Non-irritating and non-sensitizing with low polarity.

Justification for Emulgel as a skin-targeted drug delivery approach

Topical gel-emulsion hybrids offer a viable option for region-specific therapeutic delivery through the skin by combining the beneficial properties of both emulsions and gels. This hybrid system creates a flexible platform capable of delivering both hydrophilic and hydrophobic drugs. Traditional topical formulations such as ointments, creams, and lotions often face issues like stickiness, poor spreadability, and stability concerns. In contrast, emulgels are thixotropic, non-greasy, easy to apply, and does not require effort to wash off. They also provide emollient effects, are non-staining, and have a longer shelf life. Emulgels have been validated as efficient in delivering a diverse collection of pharmaceutical agents, including steroids, antibiotics, analgesics, and antifungals. The emulsion-based structure enhances the incorporation and delivery of hydrophobic drugs within the gel. By overcoming the limitations of conventional topical products, emulgels offer a more efficient and patient-friendly delivery system, making them a valuable option in topical drug delivery.[16,17]

FORMULATION OF EMULGEL

1 Oils

Oils serve as the oily phase in emulsions. For topical applications, mineral oils are commonly used, often in combination with soft or hard paraffins, due to their occlusive and sensory properties. In oral preparations, various oils are utilized, including mineral oil and castor oil for their laxative effects, and nutritional oils like fish liver oil or vegetable oils (such as arachis, cottonseed, and maize oils) as dietary supplements[18]

2 Vehicle

A suitable emulgel vehicle should possess the following properties:

- Uniform drug distribution over the skin
- Effective the liberation of the drug to the specific destination
- Focused drug administration
- Sustained therapeutic drug levels
- Anatomical site-specific suitability
- Cosmetic appeal

The stratum corneum's barrier function restricts topical drug penetration.The scope and velocity of absorption are determined by both the vehicle's properties and the active ingredient's characteristics[19]

3 Gelling agents

Gelling agents or thickeners are instrumental in emulgel preparation. They form a gel-like matrix by swelling in the aqueous phase, thereby enhancing the consistency of the formulation. By incorporating these agents, the resulting emulgel exhibits a thixotropic behavior, becoming less viscous when agitated and more viscous when at rest. This property contributes to the robustness and straightforwardness of a application of the emulgel[20]

4 Emulsifiers

Surfactants enable emulsification and enhance product stability by lowering interfacial tension. The HLB system guides surfactant selection: HLB > 8 for oil-in-water emulsions and HLB < 8 for water-in-oil emulsions. Specific surfactants suit particular phases, such as Tweens for aqueous phases and Spans for oily phases. Blending Tweens and Spans often yields better stability than single surfactant use. Common surfactants include Tween 80, Span 80, Polyethylene glycol, Stearic acid, Labrasol, and Sodium stearate, each with distinct properties.[21]

5 Penetration enhancers

Permeation enhancers work by interacting with skin components to temporarily increase permeability. They work through a range of biological mechanisms, including:

- Disrupting the stratum corneum's compact structure
- Enhancing drug or solvent partitioning into the stratum corneum
- Interacting with intercellular proteins, causing conformational changes or solvent swelling

Different enhancers can improve protein fluidity or disrupt multilaminate pathways, increasing drug diffusion through skin proteins. The choice of enhancer significantly impacts product design. Examples of permeation enhancers include:

- Eucalyptus oil
- Linoleic acid
- Lecithin
- Oleic acid
- Chenopodium oil
- Isopropyl myristate

- Urea

These enhancers can be used to advance the distribution of drugs through the skin.[22]

6 Preservatives

Preservatives are incorporated into emulgels to ensure their stability and safety by preventing microbial contamination and growth. These agents hold an essential position in extending the product's shelf life. Frequently used preservatives include parabens (like methyl and propyl paraben), benzalkonium chloride, benzoic acid, and benzyl alcohol, all of necessary to ensure the stability of the product's quality.[23]

7 PH adjustment

The pH of emulgel formulations should be compatible with the skin's natural pH to diminish the potential for irritation. The skin's pH typically ranges from 4.1 to 5.8, and topical formulations are often adjusted to around pH 5.4 or 5.5. Triethanolamine (TEA) is commonly used to adjust the pH in emulgel formulations, particularly when using Carbopol as a thickener, as it helps to uncoil the polymer chain and form a gel structure.[24]

PREPARATION OF EMULGEL[25,26]

1. Emulsion Preparation: Formulate either an oil-in-water (O/W) or water-in-oil (W/O) emulsion.
2. Gel Base Preparation: Prepare a gel base using a fitting gelation component agent.
3. Emulgel Formation: Incorporate the prepared integrating the emulsion within the gel network maintained by steady stirring for the purpose of acquiring a uniform emulgel formulation

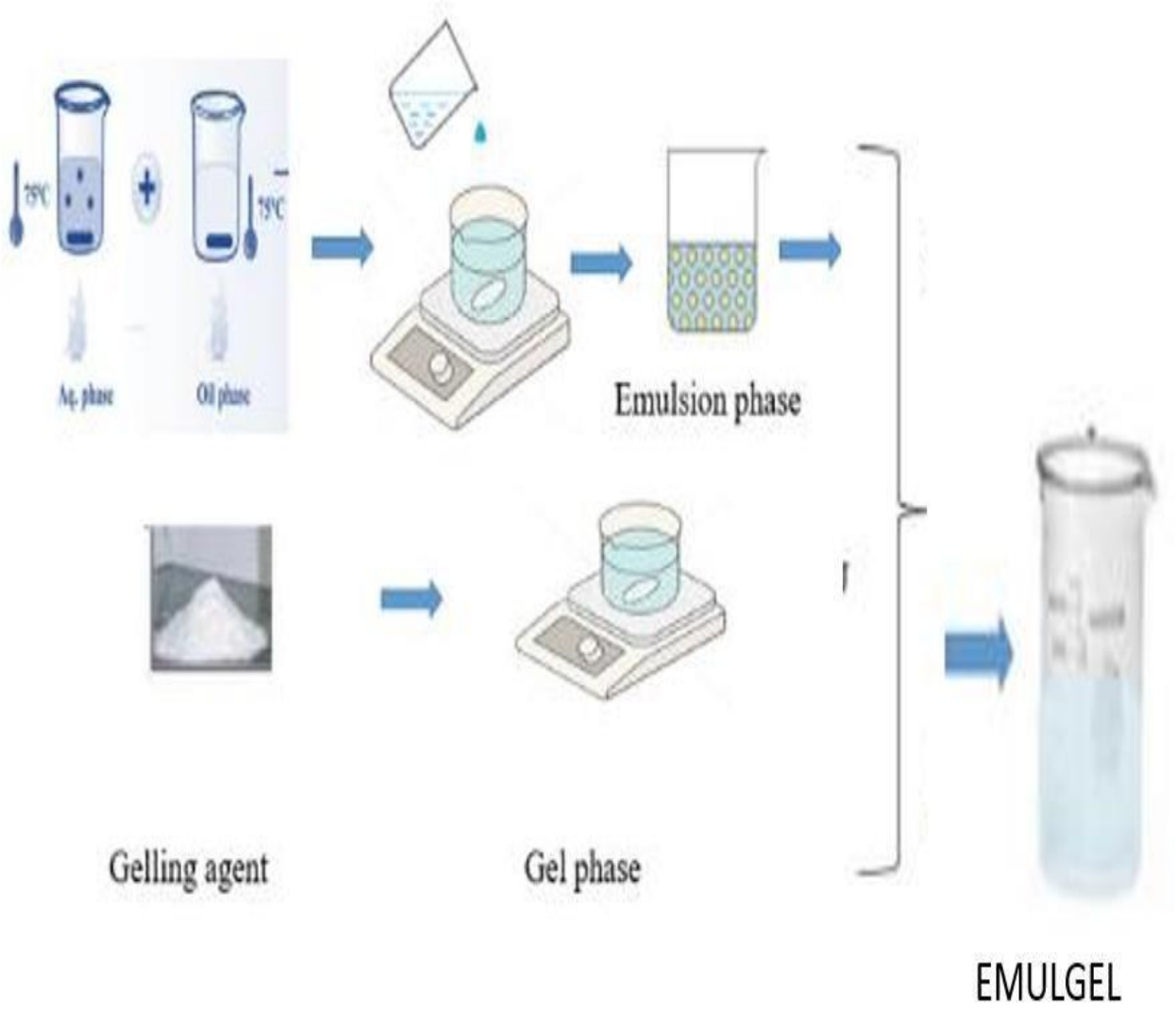

Fig 4: Schematic representation of preparation of Emulgel[27]

CHARACTERISATION OF EMULGEL

Infrared Spectral Assessment

Spectroscopic evaluation via FTIR was performed utilized to assess the compatibility between the drug and excipients, ensuring formulation. This analysis aimed to identify potential interactions and confirm the suitability of excipients for the formulation. By assessing the infrared spectra, FTIR helped determine the stability and compatibility of the drug-excipient mixture, facilitating the establishment of a robust formulation.[28]

Organoleptic Evaluation

The emulgel formulations underwent assessment of visual characteristics such as color, evenness, and consistency. Additionally, their texture and feel were assessed on the skin to evaluate smoothness and absence of grittiness, ensuring a pleasant user experience. This evaluation helped determine the formulations aesthetic and sensory properties, crucial for user acceptance and compliance.[29]

pH Determination

The emulgel's pH was measured by means of a calibrated electronic pH measuring instrument, with a thorough rinse of the electrode utilized distilled water during the process before immersion in the formulation. Triplicate readings were taken to confirm consistency and accuracy of the pH measurements.[30]

Rheological Evaluation

The flow resistance of the emulgel was formulated and examined using a viscometer maintained at 25°C. Measurements were taken in triplicate at defined time intervals, with the mean values subsequently obtained with the mean values subsequently obtained to ensure accuracy and consistency.[31]

Spreadability

Spreadability was quantified by placing a 0.5 g emulgel specimens held between two glass plates under a 500 g weight for 5 minutes, measuring the resulting diameter, and calculating spreadability using the formula.[32]

$S = m / (l \times t)$ Where,

S – Spreadability

M – An external load was affixed to the upper slide

L – Linear extent of the glass slide

T- Time elapsed before the slides separated

Extrudability Evaluation

The extrudability pertaining to the emulgel formulation was assessed using a tube test, where the proportion of weight required to extrude a 0.5 cm ribbon of emulgel in 10 seconds was measured. The extrudability was calculated as the comparative amount of applied weight to the region, where increased values suggest better extrudability. Data were collected in three distinct experiments were performed for each formulation, with the average results being determined reported.[33]

Swelling Index Determination

The swelling index of the emulgel was calculated by placing a 1 gm sample on a porous aluminium foil immersed in 0.1 N NaOH. The sample underwent weighed at different time intervals, and the swelling capacity was assessed through the use of the formula.[34]

Swelling Index = $[(Wt - Wo) / Wo] \times 100$, Where,

Wt is the weight after time t Wo is the initial weight.

Drug Content Evaluation

With the aim of assessing the drug content, 1 gram quantity of the emulgel was precisely weighed, dissolved in an appropriate solvent, and subjected to sonication to achieve full dissolution. The solution underwent then filtered, and its absorbance values were obtained through a UV spectrophotometer. Quantification of the drug concentration was performed using the procedure below formula[35]:

Drug Content = (Concentration × Dilution coefficient× Volume) × Using the conversion multiplier

Skin Irritation Evaluation (Patch Test)

The preclinical safety assessment of Etoricoxib emulgel involved Wistar rats (100-150 g) after obtaining ethical approval. The animals were housed in standard conditions with unlimited food and water. The study design included three distinct groups: untreated controls, placebo- treated (gel base only), and test subjects (receiving the Etoricoxib emulgel formulation)[36-38].

A 4 cm^2 area on the dorsal surface of each rat was shaved and demarcated for topical application. Approximately 100 mg of either the gel base or emulgel was applied morning and evening each day for 14 days. Skin reactions, including erythema and edema, were assessed and scored to evaluate potential irritation. Additional evaluations were performed on days 7 and 14 for the groups receiving the gel base and emulgel to detect any signs of skin sensitization or adverse reactions [39,40].

***In-Vitro* Drug Release Study**

An investigation was conducted on the drug release pattern using a customized version of the Franz diffusion cell was employed, where the formulation was implemented on a dialysis membrane separating the application side and the receiving side compartment. The receptor phase

was filled using methanol as the dissolution medium, Preserved at a physiological temperature of 37± 0.5 °C and continuously stirred. Aliquots were taken at specific intervals, replaced with fresh medium, and analyzed spectrophotometrically at 230 nm to calculate the cumulative drug release.[41]

Fig 5*: In-vitro* diffusion cell[42]

Kinetic Simulation Regarding Drug Release Profiles

The temporal pattern concerning therapeutic agent release was investigated by fitting the data to various models, including:

1. Zero-order kinetics (cumulative % release vs. time)

Zero-order kinetics involves the release concerning a drug at a consistent rate, uninfluenced by concentration gradients. The mathematical representation of this process can be described by the equation: $Q = K_0t$, where Q denotes the aggregate amount of drug released, K_0 signifies the discharge rate constant, and t represents time.

Defining Features:

- Uniform release velocity
- Concentration-independent release
- Direct proportionality between cumulative release and time[43]

Graphical Representation: A plot of depicting the progressive drug release over a time period produces a linear graph, signifying a steady release pattern[44].

2. First-order kinetics (log % retained vs. time)[45]
3. Higuchi model (% release vs. square root of time)[46]

to determine the best-fit model describing the drug release mechanism**.**

Globule Size Analysis

The globule size was measured by dispersing 1.0 gm of the product in water, followed by analysis using a Malvern Zetasizer[47]

Antimicrobial Evaluation[48]

The ditch plate technique was implemented to measure the antimicrobial efficacy of the emulgel. A 3 gm sample was placed in a ditch on Sabouraud's agar plates, and fungal cultures were streaked perpendicular to the ditch. After 18-24 hours of incubation at 25°C, inhibition of fungal proliferation was measured by calculating the percentage inhibition utilizing the formula:

% inhibition = (L2 / L1) × 100, Where,

L1 is the total length of the culture streak L2 is the length of inhibition.

Haemocompatability study

The haemocompatibility an investigation was performed to examine the capabilities of the emulgel formulation to induce hemolysis when in contact with blood. This study aimed to ensure that the formulation remains localized at the site of application without causing significant hemolytic effects. In this investigation, a drug solution was assembled by placing the emulgel blend in a membrane pouch that was later dipped into 50ml of normal saline for 30 minutes. Three sample sets were prepared: a positive control (0.5ml of 0.1N HCl and 0.5ml of diluted blood), a negative control (0.5ml of diluted blood and 0.5ml of normal saline), and a test sample (0.5ml of extract and 0.5ml of diluted blood in 10ml of normal saline). The samples were incubated at 37°C for 1 hour and then centrifuged at 3000rpm for 10 minutes. The supernatant underwent hemoglobin assessment concentration using a UV-Visible spectrophotometer. This study helped determine the hemocompatibility of the emulgel formulation and its potential for safe use.[49]

The percentage of hemolysis was assessed through the equation:

Hemolysis (%) = [(ODtest - ODnegative control) / (ODpositive control - ODnegative control)] x 100

where OD represents the optical density of the respective samples.

Emulgel Stability Assessment Using Centrifugation

The Steadiness of the formulations was assessed through centrifugation, where specimens were subjected to spun at 4000 rpm for 10 minutes. Following this, visual evaluation of the samples was performed to identify signs of instability, such as phase separation or the formation of cream layers.[50]

Accelerated Stability Assessment

The optimized emulgel formulation was subjected to stability testing at various conditions: 5°C, 25°C/60% RH, 30°C/65% RH, and 40°C/75% RH for 3 months. The samples, stored in 10 gm collapsible tubes, were evaluated at specific intervals for pH, appearance, rheological

properties, and drug content to assess stability.[51,52]

PACKING OF EMULGEL

Emulgels are often filled in tubes made of lacquered aluminum with a phenoxy-epoxy inner coating or aluminum laminates. The tubes are hermetically sealed with propylene screw caps and provide a barrier against external factors. The laminate materials used offer distinct benefits, including protection from light, air, and moisture or chemical resistance, depending on the formulation's requirements. This packaging approach ensures the integrity and quality of emulgel products.[53]

APPLICATION OF EMULGEL[54-58]

Emulgels serve various functions in numerous routes of administration:

❖ **Topical Applications**

1. Skin care: Moisturizers, emollients, and care options for skin ailments such as dryness and irritation, often containing ingredients like glycerin and aloe vera.
2. Hair care: Conditioners, styling agents, and treatments for conditions like dandruff, often containing proteins, oils, and keratin.
3. Cosmetics: Foundations, lip balms, sunscreens, and more, utilizing pigments, waxes, silicones, and emulsifiers.

❖ **Parenteral Applications**

Emulgels provide sustained release of drugs via injection, reducing dosing frequency and maintaining therapeutic levels.

❖ **Oral Applications**

1. Emulgels: Controlled-release drug delivery systems combining emulsions and gels.
2. Liquid-filled gelatin capsules (LFGCs): Site-specific release of drugs.
3. Self-emulsifying drug delivery systems (SEDDS): Enhance solubility, absorption, and bioavailability.
4. Microemulsions: Thermodynamically stable, isotropic systems featuring droplets smaller than 100nm, suitable for lipophilic, amphiphilic, and hydrophilic drugs.

MARKETED FORMULATION OF EMULGEL[59-62]

Commercial name	Key ingredient	Fabricator
Miconaz -H-emulgel	Miconazole nitrate,hydrocortisone	Medical union pharmaceutics
Voltaren	Diclofenac -diethyl-ammonium	Novartis pharma
Excex	Clindamycin,adapalene	Zee laboratories
Topinate gel	Clobetsol propionate	Systopic pharma
Catafalm emulgel	Diclofenac potassium	Novartis
Avindo gel	Azithromycin	Cosme pharma lab

CONCLUSION:

The advent of emulgel technology has revolutionized topical treatment delivery, offering a stable and efficient platform for therapeutic agents. By synergistically combining the properties of emulsions and gels, emulgels facilitate precise targeting of various skin ailments. The enhanced solubility and permeation of active ingredients in emulgels make them an appealing choice for topical applications. Customization is a key benefit of emulgels, allowing formulators to tailor the delivery system to specific therapeutic needs. Emulgels have demonstrated potential in managing diverse dermatological conditions, including acne, psoriasis, and fungal infections. Controlled release of active ingredients from emulgels can boost effectiveness and simultaneously minimize negative impacts. The ease of application and non-greasy texture of emulgels can improve patient adherence to treatment regimens. As research in this area remains in a state of progression, emulgels are poised to play a crucial role in the development of innovative topical therapies. The prospect of emulgels to enhance patient results and life satisfaction makes them a promising area of investigation in topical treatment research. By leveraging the advantages of emulgel technology, formulators can develop effective, patient-centric topical treatments that meet specific therapeutic needs.

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