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Emulgel Drug Delivery Systems: Formulation Strategies, Characterization, and Therapeutic Applications

Bhale Sonali Dadaso[1], Dr. Onkar Bharat Doke[2]
Research Scholar[1], Research Guide[2]
Master of Pharmacy, Department of Pharmaceutics[1,2]
Vidya Niketan College of Pharmacy, A/P Lakhewadi, Tal - Indapur, Dist-Pune, 413103[1,2]

Abstract

Emulgels have emerged as a promising topical drug delivery system that combines the advantages of emulsions and gels to enhance the delivery of both hydrophilic and lipophilic therapeutic agents. Conventional topical formulations such as creams, ointments, and gels often suffer from limitations including poor drug solubility, low stability, greasiness, and reduced patient compliance. Emulgels overcome these challenges by incorporating an emulsion system into a gel matrix, resulting in improved drug loading capacity, enhanced skin permeation, controlled drug release, and better formulation stability. The present review highlights the fundamental aspects of emulgel drug delivery systems, including their composition, formulation strategies, and evaluation parameters. The roles of key formulation components such as oil phase, aqueous phase, surfactants, gelling agents, and penetration enhancers are discussed in detail. Various characterization techniques, including pH determination, viscosity measurement, spreadability assessment, drug content analysis, in-vitro drug release, ex-vivo permeation studies, and stability evaluation, are also reviewed. Furthermore, the therapeutic applications of emulgels in anti-inflammatory, antifungal, antibacterial, anti-acne, wound healing, and herbal drug delivery are summarized. Recent advances such as nanoemulgels, microemulgels, liposomal and niosomal emulgels, and natural polymer-based emulgels have significantly expanded the scope of this delivery platform. The application of Quality-by-Design (QbD) approaches, including Design of Experiments (DoE) and optimization strategies, has improved formulation development and product quality. Additionally, emerging technologies such as artificial intelligence-assisted formulation design and smart stimuli-responsive emulgels are expected to shape the future of topical drug delivery. Overall, emulgels represent a versatile, patient-friendly, and efficient drug delivery system with significant potential for pharmaceutical and dermatological applications.

Keywords: Emulgel; Topical Drug Delivery; Emulsion; Gel; Nanoemulgel; Microemulgel; Skin Permeation; Controlled Drug Release; Quality-by-Design (QbD); Design of Experiments (DoE); Liposomal Emulgel; Niosomal Emulgel; Herbal Emulgel; Drug Permeation Enhancers; Topical Formulations.

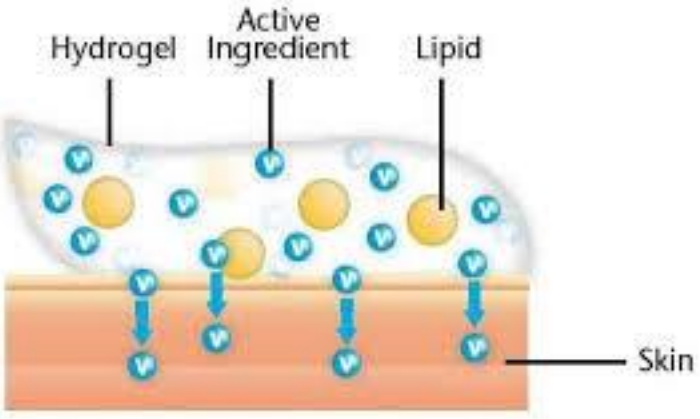
1. Introduction

1.1 Overview of Emulgels

The skin is the largest organ of the human body and serves as an effective barrier against external agents. Topical drug delivery systems have gained considerable attention due to their ability to deliver drugs directly to the site of action, thereby reducing systemic side effects and improving patient compliance. Conventional topical dosage forms such as creams, ointments, lotions, and gels have been extensively used; however, each possesses certain limitations regarding drug loading, stability, and patient acceptability.

Emulgels are novel topical drug delivery systems formed by incorporating an emulsion into a gel matrix. They combine the advantages of both emulsions and gels, resulting in improved stability, enhanced drug loading, and better therapeutic efficacy. Emulgels are particularly suitable for the delivery of hydrophobic drugs that exhibit poor water solubility. In these systems, the drug is dissolved in the oil phase of the emulsion and subsequently incorporated into the gel base, facilitating enhanced drug permeation through the skin.

An emulgel may be prepared as either an oil-in-water (O/W) or water-in-oil (W/O) emulsion depending on the physicochemical properties of the drug and therapeutic requirements. The incorporation of a gelling agent improves viscosity, spreadability, stability, and patient acceptability. Due to their non-greasy nature and ease of application, emulgels have emerged as promising carriers for various pharmaceutical and cosmetic applications.



1.2 Advantages of Emulgels Over Creams, Ointments, and Gels

Emulgels offer numerous advantages compared with conventional topical dosage forms:

Enhanced Drug Loading Capacity

Lipophilic drugs that are difficult to incorporate into gels can be effectively loaded into the oil phase of emulgels, improving formulation flexibility.

Improved Stability

The gel matrix minimizes phase separation, coalescence, and creaming, thereby enhancing the physical stability of the formulation.

Better Patient Compliance

Emulgels possess a non-greasy texture, smooth consistency, and pleasant appearance, making them more acceptable to patients.

Controlled Drug Release

The gel network regulates drug diffusion and provides sustained release characteristics, improving therapeutic efficacy.

Enhanced Skin Penetration

The presence of surfactants and penetration enhancers promotes drug permeation through the stratum corneum.

Easy Application and Removal

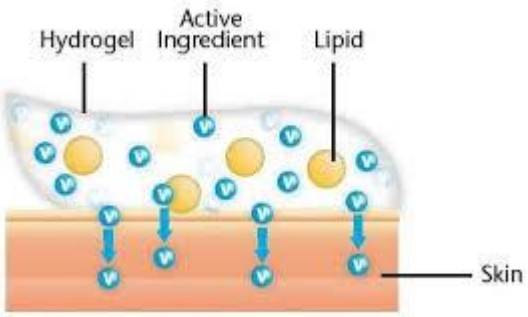
Unlike ointments, emulgels spread easily on the skin and can be washed off without difficulty.

Reduced Systemic Side Effects

Localized drug delivery reduces systemic exposure and associated adverse effects.

Comparison of Emulgels with Conventional Topical Formulations

Parameter	Emulgel	Cream	Ointment	Gel
Greasiness	Low	Moderate	High	Very Low
Spreadability	Excellent	Good	Poor	Excellent
Drug Loading	High	Moderate	High	Limited
Washability	Easy	Moderate	Difficult	Easy
Patient Compliance	Excellent	Good	Moderate	Excellent
Stability	High	Moderate	High	High
Drug Release	Controlled	Moderate	Slow	Rapid



2. Components of Emulgel

The performance of an emulgel formulation depends largely on the selection and concentration of its components.

2.1 Oil Phase

The oil phase serves as a reservoir for lipophilic drugs and contributes to drug solubilization and skin permeation. The choice of oil affects drug release, viscosity, stability, and therapeutic performance.

Commonly used oils include:

- Liquid paraffin
- Isopropyl myristate
- Isopropyl palmitate
- Mineral oil
- Oleic acid
- Castor oil
- Sesame oil
- Coconut oil
- Olive oil

Functions:

- Solubilization of hydrophobic drugs
- Improvement of skin hydration
- Enhancement of drug penetration
- Formation of emulsion droplets

2.2 Aqueous Phase

The aqueous phase forms the continuous phase in oil-in-water emulsions and provides hydration to the skin.

Common aqueous components include:

- Purified water
- Distilled water
- Ethanol
- Propylene glycol
- Glycerin

Functions:

- Solubilization of hydrophilic ingredients
- Maintenance of skin moisture
- Facilitation of drug diffusion
- Improvement of formulation consistency

2.3 Surfactants

Surfactants are essential for stabilizing the emulsion by reducing interfacial tension between oil and water phases.

Common surfactants:

Non-Ionic Surfactants

- Tween 20
- Tween 80
- Span 20
- Span 80

Anionic Surfactants

- Sodium lauryl sulfate

Cationic Surfactants

- Cetyltrimethylammonium bromide

Functions:

- Emulsion stabilization
- Improved drug solubilization
- Enhanced skin penetration
- Prevention of phase separation

2.4 Gelling Agents

Gelling agents provide viscosity and convert the emulsion into a semisolid emulgel system.

Common gelling agents:

- Carbopol 934
- Carbopol 940
- Hydroxypropyl methylcellulose (HPMC)
- Sodium carboxymethyl cellulose (NaCMC)
- Xanthan gum
- Guar gum
- Poloxamer 407

Functions:

- Increase viscosity
- Improve spreadability
- Enhance stability
- Control drug release

2.5 Penetration Enhancers

The stratum corneum acts as a major barrier to drug absorption. Penetration enhancers improve drug transport across the skin.

Common penetration enhancers:

- Oleic acid
- Clove oil
- Eucalyptus oil
- Menthol
- Dimethyl sulfoxide (DMSO)
- Propylene glycol
- Isopropyl myristate
- Transcutol®

Functions:

- Disruption of lipid bilayers
- Increased skin permeability
- Enhanced drug absorption
- Improved therapeutic response

3. Formulation Strategies

The successful development of emulgels requires careful selection of formulation components and optimization of processing conditions.

3.1 Selection of Drug and Excipients

Selection of Drug

An ideal drug candidate for emulgel formulation should possess:

- Poor aqueous solubility
- Suitable molecular weight
- Adequate lipophilicity
- Potent therapeutic activity
- Stability under formulation conditions

Examples include:

- Diclofenac sodium
- Ketoprofen
- Aceclofenac
- Clotrimazole
- Ketoconazole
- Adapalene

Selection of Excipients

Excipients are selected based on:

- Drug compatibility
- Solubilization capacity
- Stability requirements
- Safety profile
- Regulatory acceptance

Key excipients include:

- Oils
- Emulsifiers
- Gelling agents
- Preservatives
- Antioxidants
- Humectants
- Penetration enhancers

3.2 Preparation Methods

The preparation of emulgels generally involves three major steps.

Step 1: Preparation of Emulsion

The oil-soluble components are dissolved in the oil phase, while water-soluble components are dissolved in the aqueous phase. Both phases are heated separately to approximately 70–80°C and mixed with continuous stirring to form an emulsion.

Step 2: Preparation of Gel Base

The selected gelling agent is dispersed in purified water and allowed to hydrate completely. pH adjustment is performed using triethanolamine or sodium hydroxide to obtain the desired gel consistency.

Step 3: Incorporation of Emulsion into Gel

The prepared emulsion is gradually added to the gel base under continuous stirring to obtain a homogeneous emulgel.

3.3 Factors Affecting Formulation

Several factors influence the quality and performance of emulgels.

Drug Solubility

Poor solubility may lead to precipitation and reduced therapeutic efficacy.

Type of Oil Phase

The nature and concentration of oil significantly affect drug release and skin permeation.

Surfactant Concentration

Excessive surfactant may cause irritation, while insufficient concentration may result in emulsion instability.

Viscosity of Gel Base

Viscosity influences spreadability, drug release, and patient acceptability.

pH of Formulation

The pH should be compatible with skin physiology to avoid irritation.

Particle Size Distribution

Smaller droplet sizes generally provide enhanced stability and drug release.

Temperature and Storage Conditions

Storage conditions influence physical stability, viscosity, and shelf life.

Drug-Excipient Compatibility

Incompatibility can result in degradation and reduced formulation performance.

4. Characterization and Evaluation of Emulgels

The evaluation of emulgels is essential to ensure their quality, stability, safety, and therapeutic efficacy. Various physicochemical and performance parameters are assessed to determine the suitability of the formulation for topical application.

4.1 pH Determination

The pH of an emulgel is an important parameter because it influences drug stability, skin compatibility, and patient acceptance. The pH should ideally be within the physiological skin pH range (4.5–6.5) to avoid irritation and discomfort.

Method

A calibrated digital pH meter is used for pH measurement. Approximately 1 g of emulgel is dispersed in distilled water and allowed to equilibrate before measurement.

Significance

- Ensures skin compatibility.
- Prevents irritation and allergic reactions.
- Maintains drug stability.
- Influences drug release and permeation.

4.2 Viscosity

Viscosity determines the consistency and flow characteristics of the emulgel. It significantly affects spreadability, drug release, and patient compliance.

Method

Viscosity is measured using a Brookfield viscometer at different spindle speeds and temperatures.

Significance

- Controls retention of formulation on the skin.
- Influences drug diffusion.
- Determines ease of application.

- Reflects formulation stability.

4.3 Spreadability

Spreadability indicates the ease with which an emulgel can be applied uniformly on the skin surface.

Method

A known quantity of emulgel is placed between two glass slides. A standard weight is applied, and the time required for the upper slide to move a specified distance is recorded.

Significance

- Ensures uniform drug distribution.
- Improves patient compliance.
- Facilitates easy application.
- Enhances therapeutic effectiveness.

4.4 Drug Content Determination

Drug content analysis ensures uniform distribution of the active pharmaceutical ingredient throughout the formulation.

Method

A weighed quantity of emulgel is dissolved in a suitable solvent, filtered, and analyzed using UV-visible spectrophotometry or HPLC.

Significance

- Ensures dosage uniformity.
- Confirms formulation accuracy.
- Detects drug degradation.
- Assesses manufacturing consistency.

4.5 In-vitro Drug Release Studies

In-vitro release studies evaluate the rate and extent of drug release from the emulgel.

Method

Drug release is commonly studied using a Franz diffusion cell equipped with a synthetic membrane. Samples are withdrawn at predetermined intervals and analyzed spectrophotometrically.

Significance

- Predicts therapeutic performance.
- Assesses release kinetics.
- Compares formulations.
- Supports formulation optimization.

4.6 Ex-vivo Skin Permeation Studies

Ex-vivo permeation studies determine the ability of a drug to penetrate biological membranes.

Method

Excised animal or human skin is mounted between donor and receptor compartments of a Franz diffusion cell. Drug permeation is monitored over time.

Significance

- Evaluates skin penetration.
- Determines permeation rate.
- Predicts in-vivo performance.
- Assesses effectiveness of penetration enhancers.

4.7 Stability Studies

Stability studies are conducted to assess the physical, chemical, and microbiological stability of emulgels during storage.

Method

Formulations are stored under accelerated and real-time conditions according to ICH guidelines.

Typical conditions include:

- 25 ± 2°C / 60 ± 5% RH
- 30 ± 2°C / 65 ± 5% RH
- 40 ± 2°C / 75 ± 5% RH

Parameters Evaluated

- Appearance
- pH
- Viscosity
- Drug content
- Phase separation
- Drug release profile

Significance

- Determines shelf life.
- Ensures product quality.
- Evaluates storage requirements.
- Supports regulatory approval.

5. Therapeutic Applications of Emulgels

Emulgels have been extensively explored for the treatment of various dermatological and systemic conditions due to their ability to enhance topical drug delivery.

5.1 Anti-inflammatory Applications

Inflammation is one of the most common therapeutic targets for emulgel formulations.

Common Drugs

- Diclofenac sodium
- Aceclofenac
- Ibuprofen
- Ketoprofen
- Piroxicam

Benefits

- Localized drug delivery.
- Reduced gastrointestinal side effects.
- Enhanced penetration into inflamed tissues.
- Sustained therapeutic action.

5.2 Antifungal Applications

Fungal skin infections require prolonged treatment and adequate drug penetration.

Common Drugs

- Clotrimazole
- Ketoconazole
- Miconazole
- Fluconazole

Benefits

- Increased residence time.
- Improved skin permeation.

- Enhanced antifungal efficacy.
- Reduced dosing frequency.

5.3 Antibacterial Applications

Emulgels have been investigated for the treatment of bacterial skin infections.

Common Drugs

- Mupirocin
- Gentamicin
- Fusidic acid
- Ciprofloxacin

Benefits

- Improved local drug concentration.
- Reduced systemic toxicity.
- Enhanced patient compliance.
- Better infection control.

5.4 Acne Treatment

Acne vulgaris is a chronic inflammatory skin disorder involving sebaceous glands.

Common Drugs

- Adapalene
- Benzoyl peroxide
- Clindamycin
- Tretinoin

Benefits

- Reduced skin irritation.
- Controlled drug release.
- Improved cosmetic acceptability.
- Enhanced treatment effectiveness.

5.5 Wound Healing Applications

Emulgels provide a moist environment that promotes tissue regeneration and wound repair.

Therapeutic Effects

- Enhanced collagen synthesis.

- Improved epithelialization.
- Reduced microbial contamination.
- Accelerated wound closure.

Common Agents

- Silver sulfadiazine
- Aloe vera
- Curcumin
- Honey extracts

5.6 Herbal Emulgel Formulations

Plant-derived bioactive compounds are increasingly incorporated into emulgel systems.

Common Herbal Agents

- Aloe vera
- Curcuma longa
- Azadirachta indica
- Bryophyllum pinnatum
- Clitoria ternatea

Advantages

- Natural origin.
- Reduced toxicity.
- Enhanced patient acceptance.
- Multifunctional therapeutic activity.

6. Recent Advances in Emulgel Technology

Recent innovations have significantly improved the performance and therapeutic potential of emulgel systems.

6.1 Nanoemulgels

Nanoemulgels combine nanoemulsions with gel systems.

Characteristics

- Droplet size below 200 nm.
- Enhanced drug solubilization.
- Improved skin permeation.
- Higher bioavailability.

Applications

- Anti-inflammatory therapy.
- Antifungal treatment.
- Transdermal drug delivery.

Advantages

- Increased stability.
- Faster onset of action.
- Better therapeutic efficacy.

6.2 Microemulgels

Microemulgels consist of thermodynamically stable microemulsions incorporated into a gel matrix.

Characteristics

- Transparent appearance.
- Small droplet size.

- High drug loading capacity.
- Excellent permeation properties.

Advantages

- Improved stability.
- Enhanced drug release.
- Better patient compliance.

6.3 Liposomal and Niosomal Emulgels

Liposomal Emulgels

Liposomes are phospholipid vesicles capable of encapsulating drugs.

Advantages

- Targeted drug delivery.
- Improved bioavailability.
- Reduced toxicity.
- Sustained release.

Niosomal Emulgels

Niosomes are vesicular systems composed of non-ionic surfactants.

Advantages

- Greater stability.
- Cost-effectiveness.
- Improved drug penetration.
- Controlled release characteristics.

6.4 Natural Polymer-Based Emulgels

Natural polymers have attracted considerable interest because of their biocompatibility and biodegradability.

Common Natural Polymers

- Xanthan gum
- Guar gum
- Chitosan
- Sodium alginate
- Pectin

Advantages

- Eco-friendly nature.
- Non-toxic profile.
- Sustainable sourcing.
- Enhanced patient safety.

7. Quality-by-Design (QbD) in Emulgel Development

Quality-by-Design is a systematic scientific approach that emphasizes product quality through formulation and process understanding.

7.1 Design of Experiments (DoE)

DoE is a statistical tool used to investigate the effects of formulation variables on product performance.

Common Experimental Designs

- Factorial design
- Central composite design
- Box-Behnken design
- Mixture design

Benefits

- Reduced experimental workload.
- Identification of critical variables.
- Improved process understanding.
- Efficient optimization.

7.2 Optimization Approaches

Optimization aims to achieve the desired formulation characteristics while maintaining quality.

Critical Quality Attributes (CQAs)

- pH
- Viscosity
- Spreadability
- Drug content
- Drug release
- Stability

Critical Material Attributes (CMAs)

- Oil concentration
- Surfactant concentration
- Gelling agent concentration

Advantages

- Robust formulations.
- Reduced batch-to-batch variation.
- Improved product quality.
- Faster development timelines.

. Challenges and Future Perspectives

Despite significant progress, several challenges remain in the development and commercialization of emulgels.

8.1 Scale-Up Issues

Laboratory-scale formulations often face difficulties during industrial production.

Challenges

- Maintaining droplet size.
- Reproducibility of viscosity.
- Homogeneous mixing.

- Equipment-related variations.

Future Strategies

- Process analytical technologies.
- Continuous manufacturing.
- Advanced homogenization techniques.

8.2 Regulatory Aspects

Regulatory approval requires comprehensive quality, safety, and efficacy data.

Major Considerations

- Stability requirements.
- Microbial quality.
- Bioavailability studies.
- GMP compliance.

Future Trends

- Harmonized global guidelines.
- Risk-based quality assessment.
- Enhanced regulatory flexibility.

8.3 AI-Assisted Formulation Design

Artificial intelligence is transforming pharmaceutical formulation development.

Applications

- Excipient selection.
- Formulation optimization.
- Prediction of stability.
- Drug release modeling.

Benefits

- Reduced development time.
- Lower research costs.
- Improved formulation accuracy.
- Data-driven decision making.

8.4 Smart and Stimuli-Responsive Emulgels

Smart emulgels respond to environmental stimuli such as pH, temperature, light, or enzymes.

Types

- Thermoresponsive emulgels
- pH-responsive emulgels
- Photoresponsive emulgels
- Enzyme-sensitive emulgels

Advantages

- Site-specific drug release.
- Personalized therapy.
- Reduced side effects.
- Improved therapeutic outcomes.

Conclusion

Emulgel drug delivery systems represent a versatile and promising platform for topical and transdermal drug administration. Their unique combination of emulsion and gel characteristics provides enhanced drug loading, improved skin permeation, controlled release, and superior patient compliance. Advances in nanoemulgels, microemulgels, vesicular emulgels, and natural polymer-based systems have expanded their therapeutic potential. Furthermore, the integration of Quality-by-Design principles and artificial intelligence-driven formulation strategies is expected to revolutionize emulgel development. Future research focusing on smart responsive systems, large-scale manufacturing, and regulatory standardization will further strengthen the role of emulgels in modern pharmaceutical sciences.

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