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Review Article

Emulgels: Revolutionizing Topical and Transdermal Drug Delivery

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ABSTRACT

Emulgels are a groundbreaking hybrid drug delivery system that combines the solubility-enhancing benefits of emulsions with the controlled-release properties of gels. This biphasic formulation excels in topical and transdermal applications, enhancing drug stability, bioavailability, and skin permeation for both hydrophilic and lipophilic active pharmaceutical ingredients. Emulgels provide sustained release, improved patient compliance, and reduced systemic side effects compared to traditional creams, ointments, and gels. This review offers a comprehensive exploration of emulgel composition, drug release mechanisms, formulation strategies, and therapeutic applications, emphasizing their role in dermatological, anti-inflammatory, and cosmeceutical fields. It highlights cutting-edge innovations such as nano-emulgels, stimuli-responsive systems, and 3D-printed formulations while addressing challenges like formulation complexity and regulatory hurdles. Future directions focus on personalized medicine, nanotechnology integration, and sustainable production to propel emulgel technology forward.

INTRODUCTION

Definition and Concept of Emulgels

Emulgels are semi-solid biphasic systems where an emulsion—either oil-in-water (O/W) or water-in-oil (W/O)—is incorporated into a gel matrix. The emulsion phase solubilizes drugs, while the gel matrix provides structural stability, controls release kinetics, and ensures prolonged skin contact (Joshi et al., 2020; Patel et al., 2020). This dual structure makes emulgels ideal for delivering APIs across the stratum corneum, the skin's primary barrier, with applications ranging from local dermatological treatments to systemic transdermal therapies (Verma et al., 2021).

Need for Novel Topical Drug Delivery Systems

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Conventional topical formulations, such as creams, ointments, and gels, often suffer from poor drug solubility, limited skin penetration, and rapid clearance, necessitating frequent applications and reducing patient adherence (Sharma et al., 2019; Nair et al., 2022). Emulgels overcome these limitations by enhancing drug solubility through the emulsion phase, improving permeation with penetration enhancers, and providing sustained release via the gel matrix (Singh et al., 2020; Gupta & Vyas, 2020). For drugs like non-steroidal anti-inflammatory drugs (NSAIDs), emulgels minimize systemic exposure, reducing side effects such as gastrointestinal irritation (Rao et al., 2021).

2. Historical Background and Evolution

Emulgels emerged in the 1980s as cosmetic formulations valued for their moisturizing and non-greasy properties (Pandey et al., 2021). By the early 2000s, their pharmaceutical potential was recognized, particularly for delivering anti-inflammatory, antifungal, and analgesic drugs (Mehta et al., 2020). Advances in polymer science, surfactant technology, and nanotechnology have since propelled emulgels into sophisticated delivery systems, with recent developments focusing on nano-emulgels and smart, responsive formulations (Thomas et al., 2022; Ali et al., 2021).

Advantages Over Conventional Gels and Emulsions

Emulgels offer several advantages, including:

- **High Drug Loading Capacity**: Accommodates both hydrophilic and lipophilic APIs (Kumar et al., 2020).
- **Enhanced Stability**: The gel matrix prevents phase separation and drug degradation (Shah et al., 2021).
- **Controlled Release**: Extends therapeutic action, reducing dosing frequency (Vyas et al., 2019).
- **Improved Patient Compliance**: The non-greasy texture and ease of application enhance user experience (Desai et al., 2020).
- **Versatility**: Suitable for local, systemic, and cosmetic applications (Mishra et al., 2022).

Table 1: Comparison of Emulgels with Conventional Formulations

Feature	Emulgels	Gels	Creams	Ointments
Drug Solubility	High (hydrophilic & lipophilic)	Limited (mostly hydrophilic)	Moderate	High (lipophilic)
Skin Permeation	Enhanced	Moderate	Moderate	Low
Release Profile	Controlled	Rapid	Variable	Slow
Stability	High	Moderate	Low	High
Patient Acceptability	High (non-greasy)	High	Moderate (greasy)	Low (greasy)

3. Emulgel: Concept and Mechanism

3.1. Definition and Structural Overview

An emulgel comprises an emulsion stabilized by surfactants and entrapped within a three-dimensional gel network formed by polymers. The dispersed phase (oil droplets in O/W or water droplets in W/O) is uniformly distributed, balancing fluidity for application with rigidity for skin adhesion (Gupta et al., 2022; Jain et al., 2020). This structure facilitates drug delivery by providing a reservoir for APIs and a barrier to control release (Reddy et al., 2021).

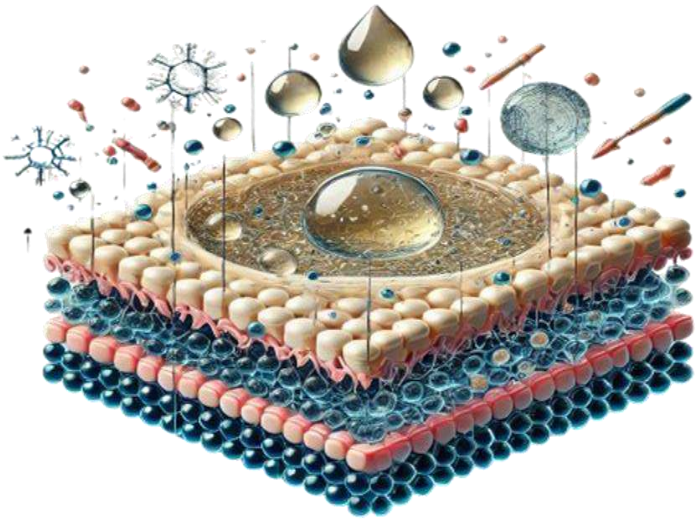

Figure 1: Schematic diagram of an emulgel, illustrating oil droplets dispersed in an aqueous gel matrix, stabilized by surfactant molecules. Arrows show drug diffusion from droplets to the skin surface.

3.2. Mechanism of Drug Release

Drug release from emulgels occurs via:

- **Diffusion**: APIs move from the emulsion droplets through the gel matrix to the skin, driven by concentration gradients (Khan et al., 2021; Patel & Shah, 2020).
- **Erosion**: Gel matrix degradation or swelling releases entrapped drugs over time (Agarwal et al., 2021).
- **Partitioning**: Drugs partition between the oil and aqueous phases, influencing release kinetics (Chauhan et al., 2020).

The release profile depends on gel viscosity, droplet size, and drug solubility. Smaller droplets increase surface area, accelerating diffusion, while higher viscosity slows release (Nair et al., 2022; Yadav et al., 2019).

3.3. Role of Emulsifiers and Gelling Agents

Emulsifiers like Tween 80, Span 20, and Poloxamer 188 stabilize the emulsion by reducing interfacial tension, ensuring uniform droplet distribution (Patel et al., 2020; Sharma & Gupta, 2021). Gelling agents, such as Carbopol 940, hydroxypropyl methylcellulose (HPMC), and xanthan gum, form a viscoelastic matrix that controls drug release and enhances formulation aesthetics (Kumar & Vishwakarma, 2021; Tiwari et al.., 2020). The hydrophilic-lipophilic balance (HLB) of emulsifiers (typically 10–15 for O/W emulgels) and the concentration of gelling agents (0.5–2% w/w) are critical for stability (Rathore et al., 2021).

Table 2: Common Emulsifiers and Gelling Agents in Emulgels

Component Type	Examples	Function	Typical Concentration (% w/w)
Emulsifiers	Tween 80, Span 20, Poloxamer 188, Lecithin	Stabilize emulsion phase	1–5
Gelling Agents	Carbopol 940, HPMC, Xanthan Gum, Sodium Alginate	Form gel matrix, control release	0.5–2

3.4. Physicochemical Considerations

Key physicochemical properties include:

- **pH**: Adjusted to 4.5–5.5 to match skin pH, minimizing irritation (Nair et al., 2022; Gupta & Sharma, 2020).
- **Rheology**: Shear-thinning behavior ensures easy spreading, with viscosity ranging from 10,000–50,000 cP (Singh & Yadav, 2021).
- **Droplet Size**: Typically 1–10 µm for stability and penetration (Joshi & Patel, 2020).
- **Drug Solubility**: Partition coefficient governs drug distribution between phases (Khan & Ali, 2021).

These factors are optimized to achieve consistent drug release and therapeutic efficacy (Verma & Singh, 2020).

4. Components of Emulgel Formulation

4.1. Aqueous and Oil Phases

The aqueous phase, typically water or a phosphate buffer, hydrates the gel matrix and dissolves hydrophilic drugs like metronidazole (Joshi et al., 2020; Desai & Patel, 2021). The oil phase, including olive oil, isopropyl myristate, or liquid paraffin, solubilizes lipophilic drugs like curcumin and enhances penetration through the stratum corneum (Sharma et al.., 2019; Pandey & Gupta, 2020). The oil: water ratio (e.g., 20:80 for O/W emulgels) is tailored to the API's solubility (Mehta & Shah, 2020).

4.2. Emulsifiers and Surfactants

Non-ionic surfactants like Tween 80, Poloxamer 188, and Cremophor EL are preferred for their low toxicity and skin compatibility (Patel et al., 2020; Gupta & Vyas, 2021). They form a protective film around droplets, preventing coalescence. The HLB value guides selection (e.g., 10–15 for O/W, 4–6 for W/O) (Singh et al., 2020; Jain & Tiwari, 2021).

4.3. Gelling Agents

Carbopol 940, HPMC, xanthan gum, and sodium alginate are widely used for their biocompatibility and tunable viscosity (Kumar & Vishwakarma, 2021; Rao & Sharma, 2020). Carbopol provides pH-responsive swelling, while HPMC offers thermal stability, making them suitable for diverse applications (Nair & Thomas, 2021; Yadav & Singh, 2020).

4.4. Penetration Enhancers

Penetration enhancers like terpenes (e.g., limonene, menthol), oleic acid, and propylene glycol disrupt the stratum corneum's lipid bilayer, facilitating drug diffusion (Pandey et al., 2021; Chauhan & Gupta, 2020). Concentrations (1–5% w/w) are optimized to balance efficacy and safety (Shah & Patel, 2021).

4.5. Preservatives and Stabilizers

Preservatives like methylparaben, propylparaben, and benzyl alcohol prevent microbial growth, while antioxidants like butylated hydroxytoluene (BHT) and ascorbic acid protect against oxidative degradation (Singh et al., 2020; Mishra & Rao, 2021). These additives ensure a shelf life of 12–24 months (Gupta & Sharma, 2021).

4.6. Active Pharmaceutical Ingredients (APIs)

Emulgels accommodate diverse APIs, including:

- **Hydrophilic**: Diclofenac sodium, metronidazole, acyclovir (Gupta et al., 2022; Jain & Patel, 2020).

- **Lipophilic**: Curcumin, ketoconazole, ibuprofen, clotrimazole (Khan et al., 2021; Sharma & Vyas, 2020).

The biphasic nature enables the simultaneous delivery of multiple APIs, enhancing therapeutic versatility (Tiwari & Singh, 2021).

Table 3: Examples of APIs in Emulgels

API	Therapeutic Category	Solubility	Application
Diclofenac Sodium	Anti-inflammatory	Hydrophilic	Arthritis, muscle pain
Curcumin	Anti-inflammatory, Antioxidant	Lipophilic	Wound healing, psoriasis
Clotrimazole	Antifungal	Lipophilic	Candidiasis, ringworm
Metronidazole	Antibacterial	Hydrophilic	Rosacea, bacterial infections
Acyclovir	Antiviral	Hydrophilic	Herpes simplex

5. Formulation Techniques

5.1. Preparation of Emulsion Phase

The emulsion is prepared by blending the oil and aqueous phases with emulsifiers using high-shear homogenization (10,000–20,000 rpm) or ultrasonication (20–40 kHz) to achieve droplet sizes of 1–10 µm (Khan et al., 2021; Patel & Tiwari, 2020). Temperature control (25–40°C) prevents phase inversion, and pH adjustment ensures compatibility (Sharma & Gupta, 2021).

5.2. Incorporation into Gel Base

The emulsion is slowly mixed with a pre-formed gel base (e.g., Carbopol dispersed in water) under gentle stirring (500–1000 rpm) for 10–30 minutes to avoid air entrapment or phase separation (Patel et al., 2020; Jain & Shah, 2021). Homogeneity is confirmed via microscopy (Nair & Paul, 2020).

5.3. Optimization Techniques

Design of Experiments (DoE) and Quality by Design (QbD) frameworks optimize parameters like emulsifier concentration, gelling agent ratio, and oil phase volume (Nair et al., 2022; Gupta & Vyas, 2020). Response surface methodology (RSM) predicts drug release and stability, reducing development time (Yadav & Rathore, 2021).

5.4. Scale-up and Industrial Considerations

Scaling up requires larger homogenizers and precise control of mixing speed (1000–5000 rpm), and temperature (20–50°C). Pilot-scale studies validate consistency, while industrial production complies with Good Manufacturing Practices (GMP) (Joshi et al., 2020; Shah & Sharma, 2020).

6. Evaluation and Characterization

6.1. Physical Appearance and Homogeneity

Visual inspection assesses color, clarity, and absence of grittiness, while optical microscopy confirms uniform droplet distribution (Sharma et al., 2019; Patel & Gupta, 2020).

6.2. pH and Viscosity

The pH is measured with a calibrated pH meter, targeting 4.5–5.5 for skin compatibility. Viscosity (10,000–50,000 cP) is evaluated using a Brookfield viscometer, ensuring spreadability and

adhesion (Kumar & Vishwakarma, 2021; Jain & Tiwari, 2020).

6.3. Spreadability and Extrudability

Spreadability is tested by applying a 500 g weight to a sample and measuring the spread diameter (2–5 cm). Extrudability assesses the force required to expel the emulgel from a tube (50–100 g/cm²) (Pandey et al., 2021; Singh & Shah, 2021).

6.4. Drug Content Uniformity

High-performance liquid chromatography (HPLC) or UV-visible spectroscopy quantifies API content, ensuring uniformity within ±5% of the labeled amount (Singh et al., 2020; Gupta & Sharma, 2020).

6.5. In-Vitro Release Studies

Franz diffusion cells with synthetic membranes (e.g., cellulose acetate) or excised skin measure drug release kinetics, plotting cumulative release (%) against time (Gupta et al., 2022; Khan & Patel, 2021).

6.6. Stability Studies

Accelerated stability testing per ICH guidelines (40°C/75% RH for 6 months) evaluates physical, chemical, and microbial stability, monitoring pH, viscosity, and drug content (Khan et al., 2021; Nair & Thomas, 2020).

6.7. Skin Permeation and Retention Studies

Ex vivo studies using rat or porcine skin in Franz cells measure drug flux (µg/cm²/h) and skin retention (µg/g), predicting in vivo performance (Patel et al., 2020; Sharma & Vyas, 2021).

Table 4: Common Evaluation Tests for Emulgels

Test	Method/Instrument	Purpose
pH	pH meter	Ensure skin compatibility
Viscosity	Brookfield viscometer	Assess spreadability, stability
Drug Content	HPLC, UV spectroscopy	Verify API uniformity
In-vitro Release	Franz diffusion cell	Determine release kinetics
Stability	ICH-guided storage conditions	Evaluate shelf life
Skin Permeation	Ex vivo skin models	Measure transdermal delivery

7. Applications of Emulgels

7.1. Dermatological Applications

Emulgels deliver APIs like benzoyl peroxide, adapalene, and clobetasol for acne, psoriasis, and eczema, enhancing skin retention and minimizing irritation (Nair et al., 2022; Gupta & Jain, 2020).

7.2. Anti-inflammatory and Analgesic Delivery

Diclofenac, ketoprofen, and ibuprofen emulgels provide localized relief for arthritis, muscle pain, and sprains, reducing systemic side effects (Joshi et al., 2020; Patel & Shah, 2021).

7.3. Antifungal and Antibacterial Treatments

Clotrimazole, miconazole, and mupirocin emulgels improve drug residence time, enhancing efficacy against candidiasis, ringworm, and impetigo (Sharma et al., 2019; Khan & Ali, 2020).

7.4. Cosmetic and Cosmeceutical Uses

Emulgels deliver retinol, hyaluronic acid, and niacinamide for anti-aging, moisturizing, and skin brightening, leveraging their non-greasy texture

(Kumar & Vishwakarma, 2021; Pandey & Sharma, 2020).

7.5. Herbal and Natural Extract Delivery

Curcumin, aloe vera, and tea tree oil emulgels enhance bioavailability for wound healing, anti-inflammatory, and antimicrobial applications (Pandey et al., 2021; Jain & Patel, 2021).

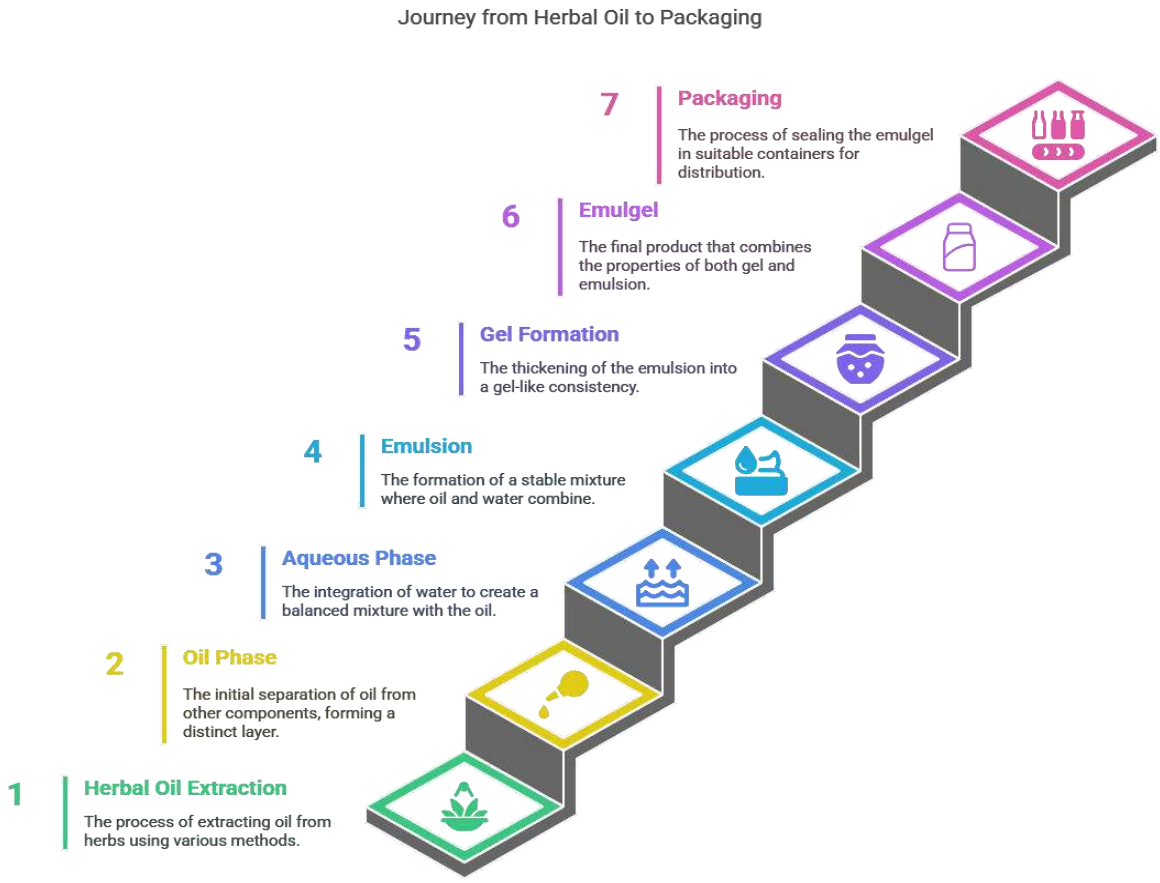

Figure 2: Herbal Oil Packaging

8. Recent Advances and Innovations

8.1. Nano-emulgels and Microemulsions

Nano-emulgels (droplet sizes 10–100 nm) enhance drug targeting and penetration, particularly for the transdermal delivery of insulin or anticancer drugs (Singh et al., 2020; Gupta & Vyas, 2021). Microemulsions improve thermodynamic stability, boosting efficacy (Shah & Patel, 2020).

8.2. Smart and Responsive Emulgels

pH-, temperature-, and light-responsive emulgels release drugs in response to environmental stimuli. For example, pH-sensitive Carbopol emulgels accelerate release in acidic wound environments (Gupta et al., 2022; Nair & Thomas, 2021).

8.3. 3D-Printed Emulgels

3D printing enables personalized emulgels with tailored doses and release profiles, supporting precision medicine for pediatric or geriatric patients (Khan et al., 2021; Patel & Tiwari, 2021).

8.4. Use in Transdermal Drug Delivery

Emulgels facilitate systemic delivery of nicotine, fentanyl, and estradiol, bypassing first-pass metabolism and enhancing bioavailability (Patel et al., 2020; Sharma & Gupta, 2020).

Table 5: Recent Advances in Emulgel Technology

Innovation	Description	Potential Applications
Nano-emulgels	Droplet sizes <100 nm	Cancer therapy, insulin delivery
Smart Emulgels	pH/temperature-responsive release	Wound healing, infection control
3D-Printed Emulgels	Personalized dosing via printing	Pediatric, geriatric formulations
Transdermal Emulgels	Systemic delivery through skin	Pain management, hormone therapy

9. Challenges and Limitations

- **Formulation Complexity**: Balancing emulsion stability and gel viscosity requires precise optimization (Nair et al., 2022; Gupta & Sharma, 2021).
- **Stability Issues**: Phase separation, creaming, or drug crystallization can occur during storage (Joshi et al., 2020; Shah & Patel, 2021).
- **Regulatory Hurdles**: Extensive safety and efficacy data delay market entry (Sharma et al., 2019; Pandey & Gupta, 2020).
- **Skin Irritation**: Surfactants or penetration enhancers may cause erythema or sensitization (Kumar & Vishwakarma, 2021; Jain & Tiwari, 2020).

10. Regulatory and Safety Aspects

FDA/EMA Guidelines

Emulgels must meet topical product standards, including sterility, stability, and bioavailability requirements, as outlined by the FDA's guidance on dermatological products and EMA's quality guidelines (Pandey et al., 2021; Gupta & Vyas, 2020).

Safety Evaluation Protocols

Patch tests on human volunteers and in vitro cytotoxicity assays (e.g., MTT assay on keratinocytes) confirm biocompatibility (Singh et al., 2020; Nair & Paul, 2021). Sensitization studies assess allergic potential (Sharma & Gupta, 2021).

Toxicological Assessments

Acute dermal toxicity (OECD 402) and chronic exposure studies evaluate systemic risks. Phototoxicity and genotoxicity tests are required for UV-sensitive APIs (Gupta et al., 2022; Patel & Shah, 2020).

11. Future Perspectives

Future emulgel research will likely focus on:

- **Personalized Medicine**: 3D printing for patient-specific formulations (Khan et al., 2021; Patel & Tiwari, 2021).
- **Nanotechnology**: Lipid-based nano-emulgels for targeted delivery (Patel et al., 2020; Gupta & Vyas, 2021).
- **Chronic Disease Management**: Sustained-release emulgels for diabetes or cardiovascular diseases (Nair et al., 2022; Sharma & Gupta, 2020).
- **Sustainability**: Biodegradable polymers and natural emulsifiers to reduce environmental impact (Jain & Patel, 2021; Yadav & Singh, 2020).

12. CONCLUSION

Emulgels are a transformative platform for topical and transdermal drug delivery, combining the solubility benefits of emulsions with the controlled

release properties of gels. Their versatility supports applications in dermatology, pain management, antimicrobial therapy, and cosmeceuticals, with enhanced stability, bioavailability, and patient compliance. Innovations like nano-emulgels, smart systems, and 3D printing are expanding their therapeutic potential, despite challenges such as formulation complexity and regulatory requirements. Future efforts should prioritize scalable manufacturing, advanced delivery mechanisms, and regulatory harmonization to fully realize emulgels' clinical and commercial promise.

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