

Nanoemulsions as Advanced Drug Delivery Systems: Recent Advances, Challenges, and Future Perspectives

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ABSTRACT

Nanoemulsions are versatile drug delivery systems characterized by droplet sizes in the nanometer range (typically 20–200 nm), stabilized by surfactants and co-surfactants. Their unique physicochemical properties, including high surface area, transparency, and kinetic stability, enable them to enhance the solubility, stability, and bioavailability of poorly water-soluble drugs. Over the past two decades, significant advances have been made in the design, preparation, and application of nano-emulsions across pharmaceutical, biomedical, cosmetic, and nutraceutical domains. This review provides a comprehensive and critical analysis of recent developments in nano-emulsion research, covering preparation methods, characterization techniques, therapeutic applications, marketed formulations, and regulatory considerations. Special emphasis is placed on their role in targeted and site-specific therapeutic delivery, including cancer therapy, central nervous system (CNS) delivery, and antimicrobial treatment. Furthermore, emerging strategies such as stimuli-responsive nano-emulsions, theranostic platforms, and computational optimization approaches are discussed. Challenges related to stability, scalability, toxicity, and regulatory approval are critically examined. The review concludes with insights into future perspectives, highlighting the potential of nano-emulsions in personalized medicine, nanotheranostics, and translational drug development.

Keywords: Nanoemulsion, therapeutic delivery, solubility enhancement, targeted delivery, nano-medicine.

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INTRODUCTION

The development of novel delivery systems remains a critical focus in pharmaceutical sciences due to the limitations of conventional dosage forms, such as poor solubility, low bioavailability, systemic toxicity, and lack of site-specificity. Among nanocarrier systems, including liposomes, solid lipid nanoparticles, polymeric nanoparticles, and dendrimers, nano-emulsions have attracted growing interest as versatile and efficient therapeutic delivery platforms [1-2].

Nanoemulsions are thermodynamically unstable but kinetically stable dispersions of two immiscible liquids, typically oil and water, stabilized by a surfactant or surfactant-co-surfactant mixture. Their droplet size ranges between 20–200 nm, which imparts them with a high degree of transparency,

improved solubilization capacity, and enhanced stability compared to conventional emulsions.

The pharmaceutical relevance of nano-emulsions lies in their ability to [3-4]:

- Improve the solubility and dissolution rate of poorly water-soluble drugs.
- Enhance oral bioavailability by promoting lymphatic uptake.
- Provide controlled and sustained drug release.
- Facilitate topical and transdermal penetration.
- Enable parenteral delivery of lipophilic drugs.

- Permit targeted delivery for cancer and CNS disorders.

In addition, nano-emulsions have been extensively explored for herbal and phytoconstituent delivery, cosmetic formulations, and nutraceuticals, highlighting their multidisciplinary potential.

The global market for nano-emulsion-based products is rapidly expanding, with several commercial formulations already approved, including parenteral nutrition emulsions and topical products. However, despite promising laboratory-scale results, scale-up, long-term stability, and regulatory acceptance remain critical hurdles [5].

This review provides a comprehensive and critical evaluation of current nano-emulsion research, focusing on their formulation principles, preparation methods, characterization tools, therapeutic applications, and future directions.

2. Physicochemical Basis of Nanoemulsions [6-8]

The unique properties and functional applications of nano-emulsions arise primarily from their nanoscale droplet size, large surface area-to-volume ratio, and stabilizing surfactant-co-surfactant systems. A deeper understanding of their physicochemical principles is crucial for designing stable and effective formulations.

Nanoemulsions

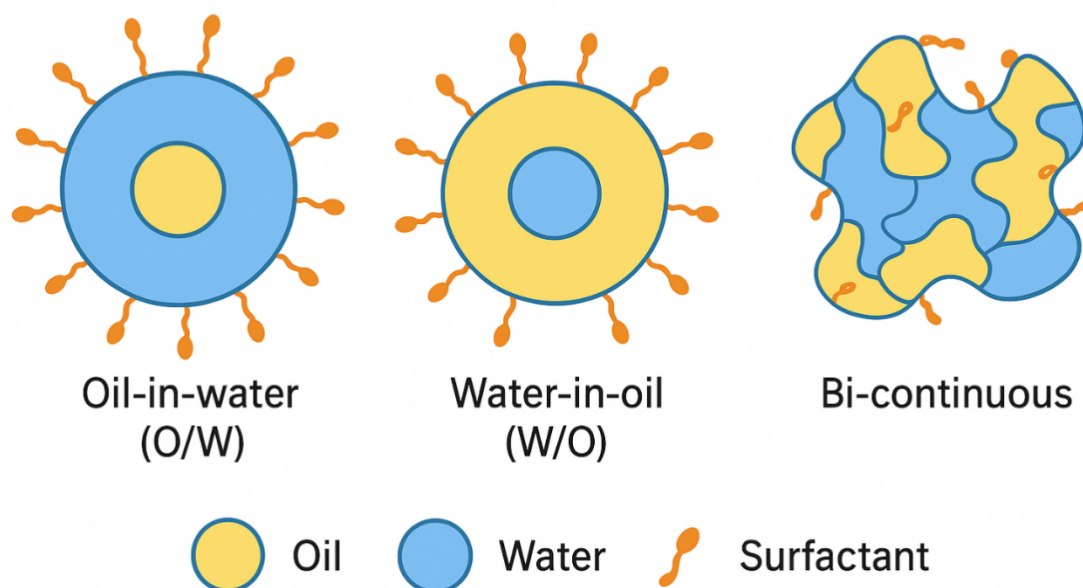


Figure 1: Schematic representation of O/W, W/O, and bi-continuous nanoemulsions

2.1 Structure and Components [9]

Nanoemulsions are biphasic systems composed of three major components:

- Oil phase – serves as the solubilizing medium for lipophilic drugs. Examples include triglycerides (e.g., medium-chain triglycerides), essential oils, and synthetic oils.
 - Aqueous phase: water or buffered solution that constitutes the continuous or dispersed medium.
 - Surfactants and co-surfactants: amphiphilic molecules that reduce interfacial tension, enhance miscibility, and stabilize nano-emulsion droplets.
- Depending on the ratio of oil and water phases, nano-emulsions can be classified as:
 - Oil-in-water (O/W): oil droplets dispersed in water (common in oral and parenteral delivery).
 - Water-in-oil (W/O): water droplets dispersed in oil (useful for transdermal delivery).
 - Bi-continuous systems: intermediate structures with interpenetrating oil and water domains.

2.2 Droplet Size and Distribution

Droplet size typically ranges between 20–200 nm, though ultrafine systems with <50 nm droplets are sometimes referred to as mini-emulsions or microemulsions [10].

Smaller droplet sizes enhance drug dissolution rate, absorption, and bioavailability, in accordance with the Noyes–Whitney equation. Polydispersity index (PDI) provides insight into droplet size uniformity; values <0.3 indicate a homogenous distribution, while higher values suggest instability.

2.3 Interfacial Phenomena

The stability of nano-emulsions is governed by interfacial free energy. Surfactants lower interfacial tension, facilitating spontaneous dispersion. The packing parameter of surfactants (ratio of hydrophobic to hydrophilic segments) determines the curvature of droplets, influencing whether O/W or W/O systems form. Zeta potential is an essential parameter that reflects droplet surface charge. Higher absolute zeta potential values ($>\pm 30$ mV) generally prevent coalescence due to electrostatic repulsion [11].

2.4 Thermodynamic and Kinetic Stability

Nanoemulsions are not thermodynamically stable like microemulsions; instead, they exhibit kinetic stability due to their small droplet size and surfactant coverage. Stability challenges include [12]:

- Flocculation aggregation of droplets without fusion.
- Coalescence merging of droplets into larger ones.
- Ostwald ripening diffusion of oil molecules from smaller to larger droplets, driven by differences in Laplace pressure.
- Creaming/sedimentation migration of droplets due to density differences.

Formulation scientists mitigate instability by:

- Selecting oils with low water solubility (e.g., long-chain triglycerides reduce Ostwald ripening).

- Optimizing surfactant/co-surfactant ratios.
- Using additives such as polymers to enhance steric stabilization.

2.5 Drug Solubilization and Release Mechanisms

Lipophilic drugs dissolve in the oil core, while amphiphilic drugs localize at the oil–water interface. Drug release can occur by diffusion across the surfactant layer or through droplet degradation in biological environments. Enhanced intestinal lymphatic uptake is a key advantage, allowing bypass of hepatic first-pass metabolism [13].

2.6 Critical Formulation Parameters

Several factors influence the performance of nanoemulsions [14–18]:

- Hydrophilic lipophilic balance (HLB) of surfactants O/W systems generally require surfactants with HLB values of 8–18, while W/O systems require values of 3–6.
- Oil-to-surfactant ratio excessive surfactant may cause toxicity, while insufficient surfactant leads to instability.
- Type of co-surfactant short-chain alcohols and glycols enhance flexibility of the interfacial film.
- pH and ionic strength impact surfactant ionization and droplet stability.

3. Methods of Preparation of Nanoemulsions [15–19]

The preparation of nano-emulsions is a critical step in ensuring droplet size control, stability, and scalability. Broadly, nano-emulsion preparation techniques are divided into high-energy methods, which rely on external mechanical devices, and low-energy methods, which utilize the physicochemical properties of the system. In recent years, novel approaches focusing on green chemistry, microfluidics, and scalable continuous manufacturing have gained prominence.

3.1 High-Energy Methods

These methods employ external mechanical forces to break down large droplets into nanoscale droplets.

NANOEMULSION PREPARATION METHODS

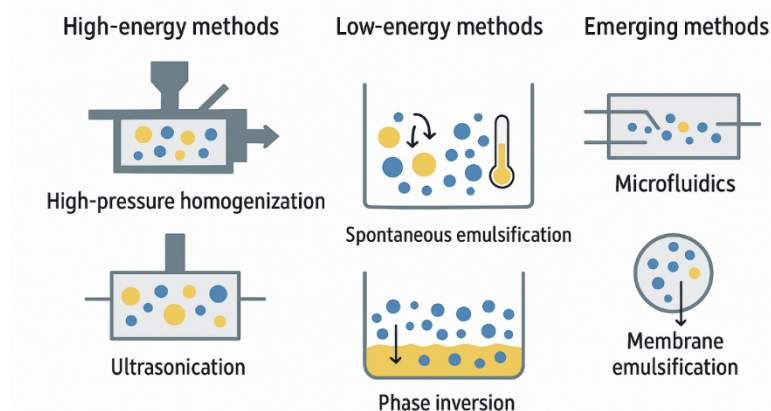


Figure 2: Preparation of nanoemulsion methods

3.1.1 High-Pressure Homogenization (HPH) [20]

One of the most widely used techniques. Oil and water

phases are forced through a narrow orifice under high pressure (500–5000 psi), generating intense shear, turbulence, and cavitation. Produces uniform droplets with size <200 nm. Suitable for large-scale manufacturing but requires high surfactant concentration and energy input.

Limitations: include heat generation, which may degrade thermolabile drugs.

3.1.2 Ultrasonication

Uses ultrasonic waves (20–100 kHz) to generate cavitation bubbles that collapse and disrupt droplets into smaller ones. Produces nanoemulsions with narrow droplet size distribution. Energy efficient for laboratory-scale production but difficult to scale up uniformly.

Limitations: possible metal contamination from sonicator probes, risk of oxidation.

3.1.3 Microfluidization [21]

Employs a microfluidizer where oil and aqueous phases are forced at high velocities through microchannels, leading to intense shear and impact. Results in highly uniform nanoemulsions with droplet sizes often <100 nm. Well-suited for heat-sensitive drugs, as the process can be performed under controlled temperature.

Limitation: expensive equipment and maintenance.

3.2 Low-Energy Methods

These techniques utilize spontaneous physicochemical phenomena at the oil–water interface without the need for high mechanical force.

3.2.1 Spontaneous Emulsification

Based on the diffusion of solvents between oil and aqueous phases. Oil, surfactant, and co-surfactant mixture is injected into water under mild stirring, forming nanosized droplets. Simple, low-cost, and

suitable for thermolabile compounds.

Limitation: often requires organic solvents, which must be removed to avoid toxicity.

3.2.2 Phase Inversion Temperature (PIT) Method [22–24]

Relies on the temperature-dependent solubility of nonionic surfactants (e.g., polyoxyethylene derivatives). At low temperatures, surfactants are hydrophilic, stabilizing O/W emulsions at high temperatures, they become lipophilic, stabilizing W/O emulsions. Rapid cooling after reaching PIT yields stable O/W nanoemulsions. Suitable for thermosensitive drugs only if temperature conditions are carefully optimized.

3.2.3 Phase Inversion Composition (PIC) Method [25]

Achieved by gradually altering the oil-to-water ratio at constant temperature. Induces inversion of the emulsion system, resulting in nanoemulsion formation.

Advantage: requires lower energy input and simple equipment.

Limitation: droplet size may vary depending on mixing rate and composition.

3.3 Novel and Emerging Methods

3.3.1 Microfluidic Approaches

Utilize lab-on-a-chip devices with microchannels for controlled mixing. Allow precise control over droplet size, polydispersity, and reproducibility. Highly suitable for personalized medicine and high-throughput screening.

Limitation: not yet practical for large-scale industrial manufacturing.

3.3.2 Membrane Emulsification

Oil phase is pressed through a porous membrane into the aqueous phase, forming uniform droplets.

Advantages: low energy consumption, uniform droplet size.

Limitation: prone to membrane fouling and clogging.

3.3.3 Supercritical Fluid Techniques

Use of supercritical CO₂ as a green solvent for emulsification. Environmentally friendly, solvent-free, and avoids thermal degradation. Still in developmental stage with limited commercial adoption.

3.4 Comparative Evaluation

Both high- and low-energy methods have distinct

advantages and limitations. High-energy methods offer better droplet size control and scalability but require specialized equipment and may degrade sensitive drugs. Low-energy methods are simpler and cost-effective but less suitable for large-scale, uniform production. Emerging techniques like microfluidics and supercritical methods aim to bridge these gaps by combining precision with sustainability [26-30].

Table 1. Comparative Summary of Nanoemulsion Preparation Methods [31-33]

Method	Principle	Advantages	Limitations	Applications
High-Pressure Homogenization	Mechanical disruption at high pressure	Uniform droplets, scalable	Heat generation, costly equipment	Oral, IV formulations
Ultrasonication	Acoustic cavitation	Simple, effective at lab scale	Probe erosion, oxidation risk	Topical, small-batch production
Microfluidization	High-velocity shear in microchannels	Highly uniform, good for heat-sensitive drugs	Expensive, high maintenance	Industrial production
Spontaneous Emulsification	Solvent diffusion	Simple, low-cost, mild conditions	Solvent residue, less scalable	Thermolabile drugs, phytoconstituents
PIT Method	Temp.-dependent surfactant solubility	Fine control over O/W or W/O transition	Not suitable for all drugs	Parenteral, oral
PIC Method	Gradual change in composition	Low energy, simple equipment	Variable droplet size	Oral, topical
Microfluidics	Controlled mixing in microchannels	Precise, reproducible, personalized therapy	Not scalable for bulk production	High-throughput research
Membrane Emulsification	Droplet extrusion through membranes	Uniform droplets, low energy	Membrane clogging	Food, nutraceuticals
Supercritical Fluids	CO ₂ -based emulsification	Eco-friendly, solvent-free	Developmental, costly	Sensitive drugs, green pharma

4. Characterization Techniques of Nanoemulsions [34-38]

The stability, efficacy, and performance of nanoemulsions depend on accurate characterization. A variety of analytical methods are used to assess droplet size, distribution, surface charge, morphology, rheology, compatibility, and release behavior.

4.1 Droplet Size and Distribution [39-41]

- Measured using Dynamic Light Scattering (DLS), which provides average diameter and polydispersity index (PDI).
- Transmission Electron Microscopy (TEM) and Scanning Electron Microscopy (SEM) provide direct visualization of droplet morphology.
- Small droplet size (<200 nm) ensures transparency, enhanced solubilization, and improved drug absorption.

4.2 Zeta Potential

- Assesses surface charge and stability.
- Values $>\pm 30$ mV indicate strong repulsive forces, reducing coalescence risk.
- Influenced by pH, ionic strength, and surfactant type.

4.3 Rheology and Viscosity

Evaluated using rotational viscometers or rheometers. Important for topical formulations, as viscosity influences spreadability and release profile.

4.4 Differential Scanning Calorimetry (DSC) [42-44]

Assesses thermal behavior, crystallinity, and stability of drug within the oil phase. Useful for detecting drug–excipient interactions.

4.5 Fourier Transform Infrared Spectroscopy (FTIR)

Confirms compatibility between drug and excipients by analyzing characteristic functional group peaks.

Can detect molecular interactions at the oil–water interface [45].

4.6 Nuclear Magnetic Resonance (NMR) Spectroscopy

Used to probe droplet structure, surfactant arrangement, and dynamics. Provides insights into

drug localization within the system.

4.7 In Vitro Drug Release Studies

Conducted using dialysis bag or Franz diffusion cell methods. Simulated gastrointestinal, skin, or ocular fluids help predict in vivo release [46].

Table 2. Common Characterization Techniques for Nanoemulsions

Parameter	Technique	Purpose
Droplet size, PDI	DLS, TEM, SEM	Stability, absorption prediction
Zeta potential	Electrophoretic mobility	Surface charge, stability
Viscosity	Rheometry	Topical/transdermal suitability
Thermal properties	DSC	Crystallinity, stability
Compatibility	FTIR	Drug–excipient interactions
Drug release	Franz diffusion, dialysis	Release kinetics

5. Applications in Drug Delivery

Nanoemulsions are highly versatile and have been applied across oral, topical, parenteral, ocular, nasal, and pulmonary routes [47–48].

5.1 Oral Drug Delivery

- Enhance solubility of BCS class II/IV drugs.
- Improve intestinal lymphatic transport, bypassing hepatic first-pass metabolism.
- Examples: Cyclosporine, ritonavir.

5.2 Topical and Transdermal Delivery

- Improve penetration through the stratum corneum.
- Provide sustained drug release and minimize systemic side effects.
- Common in dermatological, cosmetic, and anti-inflammatory formulations.

5.3 Parenteral Delivery

- IV nanoemulsions used for anesthesia (e.g., propofol in lipid nanoemulsion).
- Provide controlled release and reduced toxicity of anticancer agents.

5.4 Ocular and Intranasal Delivery

- Nanoemulsions improve corneal permeability and nasal mucosal absorption.
- Potential for brain targeting via the nose-to-brain route.

5.5 Pulmonary Delivery

- Inhalable nanoemulsions enhance deposition in alveoli.

- Useful for antifungal, anticancer, and anti-inflammatory drugs.

6. Nanoemulsion in Specialized Therapeutic Areas [49]

6.1 Cancer Therapy

- Improve solubility of poorly soluble anticancer drugs like paclitaxel and docetaxel.
- Can be functionalized with ligands for tumor-targeted delivery.
- Reduce systemic toxicity.

6.2 Central Nervous System (CNS) Delivery

- Overcome blood–brain barrier limitations.
- Intranasal and IV nanoemulsions have shown promise for antiepileptic and antidepressant drugs.

6.3 Antimicrobial and Antifungal Therapy

- Essential oil–based nanoemulsions exhibit strong antimicrobial activity.
- Effective for topical fungal infections due to enhanced penetration.

6.4 Anti-Inflammatory and Analgesic Formulations

- Nanoemulsions of NSAIDs reduce gastric irritation compared to oral tablets.

6.5 Herbal and Phytoconstituent Delivery

Improve bioavailability of plant-based compounds like curcumin, quercetin, and resveratrol.

Table 3. Marketed Nanoemulsion-Based Formulations

Brand/Product	Drug	Route	Indication
Diprivan®	Propofol	IV	General anesthesia
Restasis®	Cyclosporine	Ophthalmic	Dry eye syndrome
Norvir®	Ritonavir	Oral	HIV therapy
Cleviprex®	Clevidipine	IV	Hypertension
Flexogan®	Diclofenac	Topical	Anti-inflammatory

7. Recent Advancements in Nanoemulsion Research [50]

- Stimuli-responsive nanoemulsions release drugs in response to pH, temperature, or redox triggers.
- Theranostic nanoemulsions integrate imaging and therapy (MRI contrast + drug).
- Hybrid nanoemulsions combine polymeric or lipid nanoparticles with emulsions for multifunctionality.
- Vaccine delivery nanoemulsions enhance antigen stability and immune response.
- QbD (Quality by Design) systematic optimization of formulations.
- AI and computational modeling predicting stability and release behavior.

8. Challenges and Limitations [51]

- Despite their promise, nanoemulsions face several challenges:
- Thermodynamic instability – prone to Ostwald ripening, coalescence, and creaming.
- Surfactant toxicity – high concentrations of surfactants may irritate skin or cause hemolysis.
- Scalability – laboratory methods may not translate efficiently to industrial scale.
- Cost-effectiveness – advanced techniques like microfluidics are expensive.
- Regulatory hurdles – few standardized guidelines exist for nanoemulsions.
- Long-term stability – need for improved storage conditions and shelf-life data.

9. Future Perspectives

- Personalized medicine tailoring nanoemulsions for patient-specific therapies.
- Nanotheranostics combining diagnosis, targeted delivery, and therapy.
- Green and sustainable methods solvent-free, eco-friendly production.
- Integration with nutraceuticals nanoemulsions for functional foods.
- Regulatory harmonization development of global standards for quality and safety.

10. Conclusion

Nanoemulsions represent one of the most promising nanocarrier systems for modern drug delivery due to their ability to enhance solubility, stability, and targeted delivery of therapeutic agents. They have demonstrated success in oral, parenteral, topical, and ocular routes, with several marketed formulations already available. Recent advancements, such as stimuli-responsive systems, hybrid carriers, and theranostics, further extend their utility. However,

challenges related to stability, toxicity, scalability, and regulation must be addressed before widespread clinical translation is achieved. With growing integration of AI-driven formulation design, green chemistry approaches, and personalized medicine, nanoemulsions are poised to play a central role in the future of nanomedicine and drug delivery.

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