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Review Article

Nanoemulsion-Based Drug Delivery System for Poorly Soluble Drugs

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ABSTRACT

The increasing prevalence of poorly water-soluble drugs presents significant challenges in modern pharmaceutical development. More than 40% of newly discovered drug candidates and nearly 60% of marketed drugs suffer from low solubility and poor bioavailability, limiting their therapeutic potential [1,2]. Nanoemulsion-based drug delivery systems (NEDDS) have emerged as an effective strategy to address these limitations. Nanoemulsions are kinetically stable, isotropic colloidal dispersions of oil and water stabilized with surfactants and co-surfactants, with droplet sizes typically in the range of 20–200 nm [3,4]. Due to their small droplet size, they enhance solubilization, stability, absorption, and targeted delivery of poorly soluble drugs across various administration routes. Moreover, they demonstrate versatility in pharmaceutical, food, cosmetic, and agricultural applications. This review provides a comprehensive overview of nanoemulsion systems, focusing on their formulation strategies, characterization techniques, mechanisms of enhanced bioavailability, therapeutic applications, regulatory considerations, and future prospects. Emphasis is placed on recent advancements such as stimuli-responsive systems, surface-modified carriers, and artificial intelligence-based optimization.

INTRODUCTION

The success of drug therapy largely depends on the ability of a formulation to deliver the active pharmaceutical ingredient (API) in a bioavailable form at therapeutic concentrations. However, a considerable number of new chemical entities (NCEs) are poorly water-soluble, which restricts their dissolution in gastrointestinal fluids and thereby reduces systemic absorption [1,5]. This solubility challenge is considered one of the primary barriers in drug development, leading to failure of otherwise potent molecules in clinical translation. To overcome these challenges, innovative drug delivery systems have been explored, including solid dispersions, liposomes,

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polymeric nanoparticles, and self-emulsifying drug delivery systems [6,7].

Among these, nanoemulsion-based drug delivery systems (NEDDS) have gained remarkable attention due to their ability to enhance solubility, protect labile molecules, improve permeability, and enable lymphatic transport [8,9]. Nanoemulsions consist of oil, water, surfactants, and sometimes co-surfactants, which form droplets in the nanoscale range (20–200 nm) [10]. Their high surface area, transparency, thermodynamic activity, and kinetic stability distinguish them from conventional emulsions and microemulsions [11,12].

Applications of nanoemulsions span multiple fields, including oral drug delivery, parenteral formulations, topical and transdermal therapies, ophthalmic systems, nasal/brain targeting, and vaccine adjuvants [13–16]. Beyond pharmaceuticals, they have been employed in food, cosmetics, and agriculture for efficient delivery of bioactives, improved stability, and eco-friendly formulations [17–19].

Despite significant progress, challenges remain in large-scale manufacturing, regulatory approval, long-term stability, and toxicity evaluation. Addressing these issues is crucial for the successful translation of nanoemulsion formulations into clinical practice [20]. This review systematically discusses the fundamentals of nanoemulsion systems, their formulation and characterization, mechanisms of enhanced drug delivery, therapeutic and non-therapeutic applications, current challenges, and emerging trends, with reference to recent advancements reported in literature.

2. Nanoemulsion Basics

2.1 Definition and Properties

Nanoemulsions are **nanoscale dispersions** of two immiscible liquids (typically oil and water) stabilized by surfactants, co-surfactants, and sometimes cosolvents. The droplet size typically ranges from 20 to 200 nm, resulting in a transparent or translucent appearance [3,21]. Unlike microemulsions, nanoemulsions are kinetically stable but not thermodynamically stable, meaning they require energy input for their formation but can remain stable for long durations [22].

2.2 Types of Nanoemulsions

Nanoemulsions can be broadly classified into three types:

- **Oil-in-water (O/W) nanoemulsions:** Oil droplets dispersed in a continuous aqueous phase. Commonly used for oral and parenteral delivery of hydrophobic drugs [8,23].

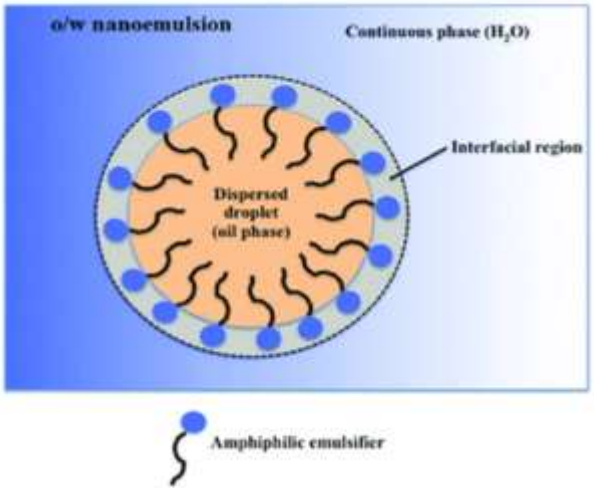

Figure 1.1. O/W nanoemulsion.

- **Water-in-oil (W/O) nanoemulsions**: Water droplets dispersed in a continuous oil phase. Used for transdermal, cosmetic, and certain parenteral applications [9].

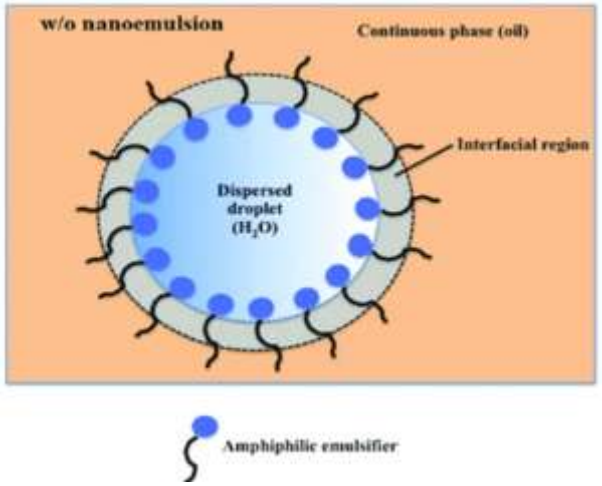

Figure 1.2. W/O nanoemulsion.

- **Bicontinuous nanoemulsions**: Complex structures with interpenetrating oil and water domains, useful for co-delivery of hydrophilic and lipophilic drugs [10].

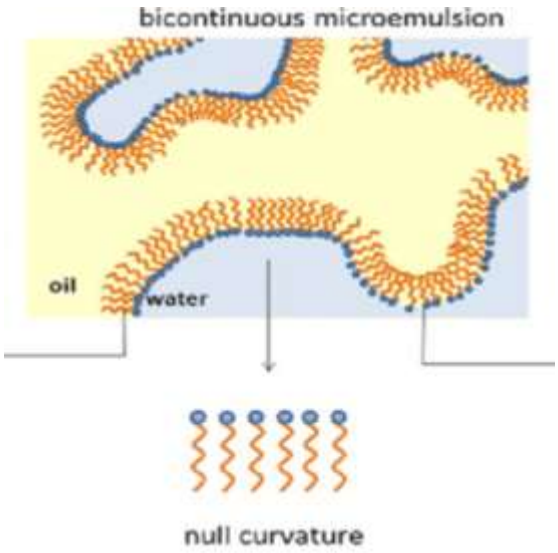

Figure 1.3. Bicontinuous nanoemulsion.

2.3 Components of Nanoemulsions

The selection of components is crucial for stability and efficacy [24,25]:

1. **Oil phase**: Solubilizes poorly soluble drugs. Examples include medium-chain triglycerides (MCTs), long-chain triglycerides (LCTs), essential oils, and isopropyl myristate [40–42].
2. **Aqueous phase**: Generally water or buffer solutions with pH 5–7.4 for biocompatibility [43].
3. **Surfactants**: Reduce interfacial tension and stabilize oil–water interfaces. Examples: Tween 20, Tween 80, Span 20, Cremophor EL, poloxamers [44,46].
4. **Co-surfactants**: Enhance interfacial flexibility and prevent droplet coalescence. Examples: ethanol, propylene glycol, PEG 400 [47–49].
5. **Additives**: Antioxidants (α-tocopherol, BHT) and preservatives (benzalkonium chloride, parabens) improve oxidative stability and shelf life [50,51].

Table 1. Common Components of Nanoemulsions and Their Functions

Component	Function	Examples
Oil phase	Solubilize hydrophobic drug	MCTs, essential oils, isopropyl myristate
Aqueous phase	Dispersion medium	Water, buffers
Surfactant	Stabilization of interface	Tween 80, Span 20, Poloxamers
Co-surfactant	Improve stability, reduce tension	Ethanol, PEG 400, Propylene glycol
Additives	Antioxidant, preservative	Vitamin E, BHT, parabens

2.4 Distinction Between Nanoemulsions and Microemulsions

Although the terms are sometimes used interchangeably, nanoemulsions differ from microemulsions in stability, droplet size, and formation mechanism. Microemulsions are thermodynamically stable and form spontaneously, whereas nanoemulsions are kinetically stable and require external energy for their preparation [22]. This distinction is crucial

when selecting the delivery system for pharmaceutical applications.

3. Formulation Strategies

3.1 High-Energy Methods

High-energy methods involve the application of mechanical forces to reduce droplet size. These include high-pressure homogenization, microfluidization, and ultrasonication [18].

- **High-pressure homogenization**: Forces oil and water through a narrow gap under high pressure, reducing droplet size.
- **Ultrasonication**: Uses acoustic energy to create cavitation and break droplets into nanoscale sizes.
- **Microfluidization**: Employs a microchannel-based system to produce uniform nano-sized droplets.

These methods offer reproducibility and scalability but require high energy input, which may degrade sensitive drugs [44].

3.2 Low-Energy Methods

Low-energy approaches exploit spontaneous emulsification or phase inversion due to changes in temperature or composition [12].

- **Phase inversion temperature (PIT) method**: Involves heating surfactant–oil–water mixtures to induce phase changes.
- **Spontaneous emulsification**: Occurs when an oil/surfactant mixture is introduced into water, leading to self-assembly into nano-sized droplets.

These methods are energy-efficient and suitable for thermolabile compounds but require careful excipient selection [44].

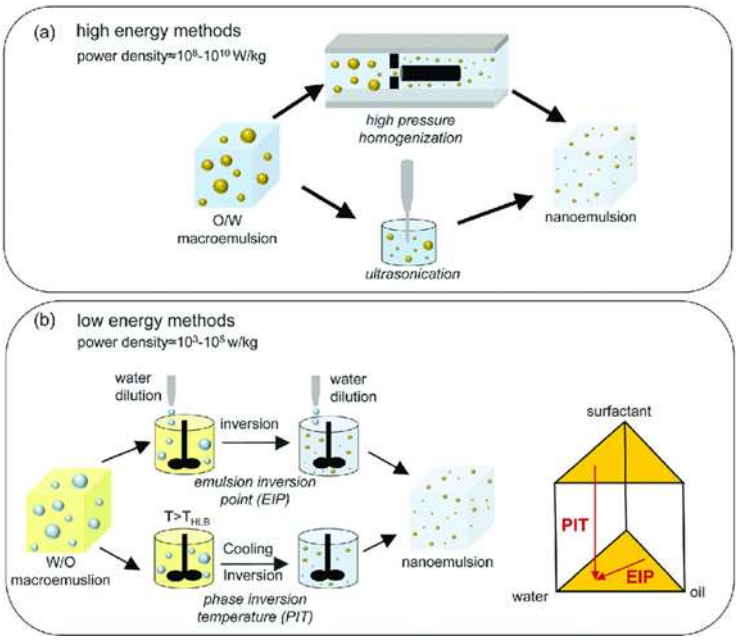

Figure 2.1. High-energy vs. low-energy preparation techniques for nanoemulsions.

3.3 Excipients and Optimization

The choice of excipients determines stability, drug loading, and release profile. Oils such as MCTs enhance solubility [40], surfactants stabilize droplets [46], and co-surfactants provide interfacial flexibility [47]. Additives extend shelf

life [50]. Recent studies have applied Quality by Design (QbD) approaches and artificial intelligence (AI)-based predictive modeling to optimize formulations [21].

4. Characterization Techniques

Comprehensive characterization ensures reproducibility and stability of nanoemulsions [52].

4.1 Droplet Size and Polydispersity Index (PDI)

Measured by dynamic light scattering (DLS). A PDI < 0.3 indicates a uniform distribution [55].

4.2 Zeta Potential

Represents surface charge and predicts stability. Values above ±30 mV suggest good stability due to electrostatic repulsion [57].

4.3 Morphology

Transmission electron microscopy (TEM), Cryo-TEM, and atomic force microscopy (AFM) reveal droplet shape and distribution [55].

4.4 Viscosity and Refractive Index

Measured to assess consistency and isotropy of formulations [57].

4.5 Stability Testing

Centrifugation, freeze–thaw cycles, and long-term storage studies are used to evaluate phase separation and robustness [19].

Table 2. Characterization Parameters and Instruments Used

Parameter	Instrument/ Method	Significance
Droplet size, PDI	DLS, PCS	Size distribution, stability
Morphology	TEM, Cryo-TEM, AFM	Visual confirmation of nanoscale droplets
Zeta Potential	Zeta Analyzer	Surface charge, colloidal stability
Drug content	HPLC, UV-Vis	Quantification of drug loading
Viscosity	Brookfield viscometer	Flow and application behavior
pH & Refractive Index	pH meter, refractometer	Physiological compatibility
Stability	Centrifugation, Freeze–thaw	Resistance to aggregation or creaming
Drug release	In vitro models, PK studies	Release kinetics and bioavailability

5. Mechanism of Enhanced Solubility and Bioavailability

Nanoemulsions improve solubility and absorption through multiple mechanisms [16,34]:

- Increased surface area enhances dissolution rate.
- Surfactants improve drug wettability and permeability [46].
- Facilitation of lymphatic uptake avoids hepatic first-pass metabolism [38].
- Enhanced protection of labile drugs improves bioavailability [36].
- Modulation of efflux transporters can further improve absorption [35].

6. Applications in Drug Delivery

6.1 Oral Delivery

Oral nanoemulsions improve solubilization in gastrointestinal fluids and enhance lymphatic transport [17,23]. Drugs such as cyclosporine and curcumin have shown improved bioavailability with oral nanoemulsions [29].

6.2 Parenteral Delivery

Parenteral nanoemulsions provide rapid and sustained drug release with reduced toxicity [3]. Lipid-based intravenous nanoemulsions have been applied in cancer therapy and anesthesia.

6.3 Topical and Transdermal Delivery

Nanoemulsions enhance skin penetration due to small droplet size and surfactant-mediated disruption of the stratum corneum [25]. They are widely explored for antifungal, anti-inflammatory, and cosmetic applications [30].

6.4 Ophthalmic Delivery

Nanoemulsions increase corneal residence time and improve ocular bioavailability [24]. FDA-approved formulations such as Restasis® demonstrate clinical translation.

6.5 Nasal/Brain Targeting

Nanoemulsions bypass the blood–brain barrier through intranasal administration, enhancing drug delivery to the central nervous system [26].

6.6 Vaccine Adjuvants

Nanoemulsion-based adjuvants such as MF59 have been successfully used in influenza vaccines [27]. They enhance immune responses through antigen uptake and presentation [11].

6.7 Theranostics and Cancer Therapy

Theranostic nanoemulsions integrate imaging and therapy, enabling real-time monitoring of drug delivery [15,33]. Surface-modified nanoemulsions provide targeted delivery and reduced systemic toxicity [7,37].

7. Non-Pharmaceutical Applications

7.1 Food Industry

Nanoemulsions are employed to encapsulate bioactives such as vitamins, polyphenols, and curcumin, enhancing stability and bioaccessibility [12,28,29].

7.2 Cosmetics

Nanoemulsions improve skin hydration, penetration of actives, and stability of cosmetic formulations [13,30]. They are widely used in sunscreens, moisturizers, and anti-aging creams.

7.3 Agriculture

Nanoemulsions offer eco-friendly delivery of pesticides and bioactives, reducing environmental toxicity [14,31,32]. Neem oil nanoemulsions demonstrate sustainable pest control [32].

8. Advances in Nanoemulsion Research

8.1 Surface Modification and Targeting

Ligand-conjugated nanoemulsions provide site-specific delivery and enhanced therapeutic index [7,37].

8.2 Stimuli-Responsive Nanoemulsions

pH-, enzyme-, and temperature-responsive systems enable controlled release [20].

8.3 Smart and Hybrid Systems

Bicontinuous nanoemulsions allow co-delivery of hydrophilic and lipophilic drugs [10]. Hybrid systems integrate polymers for improved stability [54].

8.4 Artificial Intelligence and Predictive Modeling

AI has been applied in formulation optimization, predicting droplet size, stability, and release patterns [21].

9. Regulatory and Stability Challenges

Despite promising applications, nanoemulsions face challenges in regulatory approval due to safety and scale-up concerns [19]. Issues include:

- Stability under stress conditions.
- Variability in excipient selection.
- Toxicity of surfactants and co-surfactants.
- Lack of standardized regulatory guidelines.

10. Future Prospects

The future of nanoemulsions lies in personalized medicine, AI-driven formulation design, and clinical translation. Focus will be on:

- Targeted and stimuli-responsive systems.
- Safer and biodegradable excipients.
- Large-scale manufacturing optimization.
- Integration with nanotheranostics for precision therapy [20,21].

CONCLUSION

Nanoemulsions represent a versatile and promising platform for delivering poorly soluble drugs. They overcome solubility barriers, enhance permeability, protect unstable drugs, and enable targeted delivery across multiple routes of administration. Their applications span pharmaceuticals, food, cosmetics, and agriculture, highlighting their multifunctional potential. While challenges related to stability, toxicity, and regulatory approval remain, emerging technologies such as AI-based optimization and stimuli-responsive formulations provide a strong foundation for future development. Continued interdisciplinary research is essential to translate nanoemulsion-based systems into safe, effective, and commercially viable therapeutics.

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