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Review Article

Nanoemulsion For Drug Delivery System: A Detailed Review

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ABSTRACT

This review explores nanoemulsions, thermodynamically stable systems with nano-sized droplets (20-200 nm), enhancing delivery of active pharmaceutical ingredients. We discuss formulation, preparation methods, characterization techniques, evaluation parameters, and applications of nanoemulsions, highlighting their potential in overcoming limitations of conventional drug delivery systems.

INTRODUCTION

Nanoemulsions are colloidal systems with submicron-sized particles (10-1,000 nm) that serve as carriers for drug molecules, enhancing therapeutic efficacy and minimizing adverse effects. These systems are thermodynamically stable and can be formulated as oil-in-water, water-in-oil, or bi-continuous nanoemulsions. Nanoemulsions are stabilized by surfactants and have a droplet size range of 20-200 nm, making them transparent due to their small size. With applications in cancer treatment, enzyme replacement therapy, and vaccination, nanoemulsions offer a promising approach to targeted drug delivery. Unlike traditional emulsions (with droplet sizes in the micrometer range), nanoemulsions have unique optical, rheological, and physicochemical properties that make them highly advantageous in various applications, such as drug delivery, cosmetics, food processing, and agrochemicals.

Advantages of Nanoemulsions[2]

- **Enhanced Bioavailability:** Nano-sized droplets increase surface area, improving absorption of poorly soluble drugs or nutrients.
- **Improved Drug Solubilization:** Can solubilize lipophilic drugs in aqueous environments, ideal for oral, topical, or injectable delivery.

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- **Controlled and Targeted Delivery:** Enables sustained or targeted release, reducing dosage frequency and side effects.
- **Physical Stability**: More stable against sedimentation and creaming than macroemulsions.
- **Versatility:** Useful in pharmaceuticals, cosmetics, and food systems for encapsulating Flavors, vitamins, or drugs.
- **Non-toxic and Biocompatible:** Often made using GRAS (Generally Recognized As Safe) ingredients, especially for food and topical uses.

Disadvantages of Nanoemulsions[2]

- **High Energy Input for Preparation:** Ultrasonication or high-pressure homogenization is energy-intensive and may increase production costs.
- **Stability Issues:** Susceptible to Ostwald ripening (growth of larger droplets at the expense of smaller ones), especially with low oil-phase solubility.
- **Short Shelf-life for Some Formulations:** May require refrigeration or stabilizers to maintain integrity over time.
- **Limited Drug Loading:** Small droplet size limits the amount of active ingredient that can be encapsulated.
- **Toxicity of Surfactants:** Some surfactants used in nanoemulsions can cause irritation or toxicity, especially in parenteral or ocular delivery.
- **Regulatory Challenges:** Nano-sized systems face stricter scrutiny in terms of safety, efficacy, and environmental impact.

Composition of nanoemulsion

1. Oil Phase (Lipophilic Phase)[3]

Role: The oil phase is responsible for encapsulating hydrophobic active ingredients such as drugs, vitamins, or essential oils. This phase is generally non-polar and forms the dispersed phase in oil-in-water (O/W) nanoemulsions or water-in-oil (W/O) nanoemulsions, depending on the formulation.

Types of Oils Used:

Vegetable oils: Soybean oil, sunflower oil, and olive oil are commonly used due to their availability and biocompatibility.

Medium-chain triglycerides (MCTs): These oils (e.g., caprylic/capric triglyceride) are favored because of their low viscosity and favorable absorption properties, making them ideal for pharmaceutical and cosmetic formulations.

Essential oils: Used for their therapeutic or cosmetic properties, such as lavender or peppermint oil.

Synthetic oils: In some industrial formulations, synthetic oils like isopropyl myristate may be used.

2. Aqueous Phase (Hydrophilic Phase)[4]

Role: The aqueous phase is the continuous phase in an oil-in-water nanoemulsion. It helps disperse surfactants and stabilizes the oil droplets. It can be pure water or aqueous solutions such as saline or buffer solutions.

Types:

Water: Typically deionized or distilled water.

Aqueous Solutions: For certain formulations, additional ingredients such as electrolytes, salts, or buffers (like phosphate-buffered saline, PBS) are included for stability.

3. Surfactants (Emulsifiers)[5]

Role: Surfactants are essential in reducing the interfacial tension between the oil and water phases. They stabilize the fine droplets in the nanoemulsion by forming a protective layer around them, preventing coalescence and aggregation.

Types of Surfactants:

Non-ionic Surfactants: These are the most commonly used in nanoemulsions because they are biocompatible, less toxic, and work effectively to reduce interfacial tension.

Examples:

- Polysorbates (Tween 20, Tween 80): Widely used in pharmaceutical formulations.
- Cetyl alcohol and sorbitan esters (Span series): Used to adjust the hydrophilic-lipophilic balance (HLB).
- Polyethylene glycol (PEG) derivatives: PEG-40 castor oil is another popular non-ionic surfactant.

Anionic Surfactants: These are less commonly used in nanoemulsions because of their charge, which can cause instability. However, they can be used in certain systems that require a charge for stability.

Example: Sodium dodecyl sulfate (SDS).

Cationic Surfactants: Rarely used, except when electrostatic stability is required, but they can be incorporated for specific applications.

Surfactant Concentration: The concentration of surfactant typically ranges from 1-10% of the total formulation, depending on the oil-to-water ratio and the desired droplet size. A higher surfactant concentration helps create smaller droplets, but excessive surfactant can lead to irritation or toxicity, especially in pharmaceutical and cosmetic products.

4. Co-Surfactants (Optional)[6]

Role: Co-surfactants enhance the efficiency of the surfactant by reducing the interfacial tension even further, making it easier to form fine droplets. Co-surfactants can also improve the solubilizing capacity of surfactants and help in achieving stable nanoemulsions.

Types of Co-Surfactants:

Short-chain alcohols: Ethanol, isopropyl alcohol, or butanol can be added as co-surfactants. They help to lower the viscosity of the oil phase and make emulsification easier, leading to smaller droplet sizes.

Caprylic/capric triglycerides: These are sometimes used as co-surfactants in lipid-based nanoemulsions.

5. Active Ingredients or Drugs (Optional)[7]

Role: In pharmaceutical, nutraceutical, and cosmetic nanoemulsion formulations, the oil phase is often used to encapsulate bioactive compounds. Nanoemulsions are particularly useful for enhancing the solubility, stability, and bioavailability of poorly water-soluble drugs.

Types of Active Ingredients:

Hydrophobic Drugs: Many drugs with low solubility in water, like curcumin, paclitaxel, or cannabinoids, are effectively delivered in nanoemulsions.

Vitamins: Lipophilic vitamins such as Vitamin E, A, and D can be encapsulated in the oil phase.

Essential Oils: Often used for their antimicrobial, antioxidant, or anti-inflammatory properties in cosmetics or therapeutic formulations.

6. Stabilizers (Optional)[8]

Role: Stabilizers help improve the long-term stability of the nanoemulsion, particularly in preventing droplet coalescence, flocculation, or phase separation. Stabilizers can be used to increase the viscosity of the system or to create a more robust interface around the droplets.

Types of Stabilizers:

Viscosity Enhancers: Agents like xanthan gum, carbomers, or hydroxyethyl cellulose can be used to improve stability, particularly in topical formulations.

Antioxidants: Vitamin E, ascorbic acid, or other antioxidants may be included in formulations to prevent oxidation of the oil phase, which can degrade the active ingredients.

Methods of preparation of nanoemulsion

High-Energy Emulsification

High-energy emulsification is a top-down method widely used to prepare nanoemulsions by applying intense mechanical force to break large droplets into nanoscale droplets (typically 20–200 nm). It is preferred when precise control of droplet size, long-term stability, and industrial scalability are required.

1. High-Pressure Homogenization (HPH)[9]

Principle:

A pre-emulsion is forced through a narrow valve or orifice at very high pressure (500–1500 bar). The resulting shear, turbulence, and cavitation break down the oil droplets.

Process Steps:

- Form a coarse emulsion using mild stirring.
- Pass the mixture through a high-pressure homogenizer.
- Repeat the cycle 3–10 times depending on desired droplet size.

Advantages:

- Produces very fine and uniform droplets.
- Scalable for industrial production.
- Suitable for both O/W and W/O emulsions.

Limitations:

- Generates heat (may degrade thermolabile drugs).
- Requires high capital investment.

Applications:

- Pharmaceuticals, cosmetics, food emulsions, vaccines.

2. Ultrasonication (Acoustic Cavitation)[10]

Principle:

High-frequency sound waves (typically 20–40 kHz) create alternating high- and low-pressure cycles, forming microscopic cavitation bubbles.

These collapse violently, creating shockwaves that break oil droplets.

Process Steps:

- Mix oil, surfactant, and water to form a coarse emulsion.
- Sonicate using a probe sonicator at specific amplitude and time (e.g., 50% amplitude for 10 minutes).
- Cool the mixture to prevent overheating.

Advantages:

- Effective for heat-sensitive drugs.
- Easy to use at lab scale.

Limitations:

- Not ideal for large-scale production.
- Risk of metal contamination from the probe tip.

Applications:

- Lab-scale formulation of nanoemulsions for drug delivery and cosmetics.

3. Microfluidization (High-Shear Fluid Processing)[1]

Principle:

A pre-emulsion is pumped through micro-channels at high pressure (up to 30,000 psi). Two fluid streams collide at high velocity, causing intense shear and impact, breaking droplets into nano-size.

Process Steps:

- Form a coarse emulsion.
- Pass it through the microfluidizer 3–10 times.
- Collect the final nanoemulsion.

Advantages:

- Produces highly monodisperse emulsions.
- Good reproducibility and scalability.
- Suitable for sterile preparations.

Limitations:

- High equipment and maintenance cost.
- Requires cleaning to avoid contamination.

Applications:

- Injectable emulsions, protein and vaccine delivery, cosmetics.

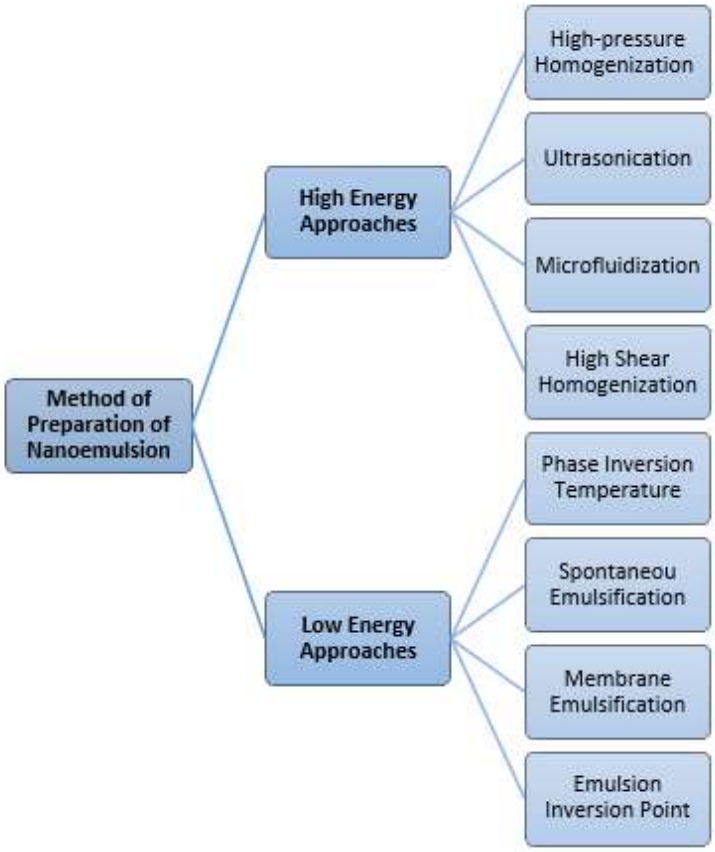

Fig.1.Method of preparation of nanoemulsion

Low-Energy Emulsification

Low-energy emulsification relies on spontaneous changes in system composition or temperature to reduce interfacial tension and form nano-sized droplets. These methods are typically thermodynamically or kinetically driven, not mechanically forced.

1. Spontaneous Emulsification (SE)[12]

(also known as self-emulsifying or solvent diffusion method)

Principle:

Spontaneous formation of nanoemulsions occurs when an organic phase (oil + surfactant + co-solvent) is added to an aqueous phase, leading to interfacial turbulence and droplet formation.

Procedure:

- Prepare oil phase (oil + surfactant + co-solvent like ethanol).
- Slowly add oil phase into water under gentle stirring.
- Nanoemulsion forms spontaneously without external force.

Advantages:

- Simple and energy-efficient.
- Ideal for poorly soluble drugs (e.g., oral drug delivery).

Limitations:

- Limited to specific surfactant and oil systems.

- May require organic solvents.

Applications:

- Self-emulsifying drug delivery systems (SEDDS), lipid-based formulations.

2. Phase Inversion Temperature (PIT) Method[11]

Principle:

Uses non-ionic surfactants (like polyoxyethylene-based types) whose solubility changes with temperature. At a certain PIT, the surfactant becomes equally soluble in water and oil, causing phase inversion and droplet size reduction.

Procedure:

- Mix oil, surfactant, and water.
- Heat the mixture above the PIT (~70–80°C).
- Rapidly cool the system to room temperature with stirring.
- Nano-sized droplets get fixed in O/W form.

Advantages:

- No need for high-pressure equipment.
- Fine droplet size (~100 nm) can be achieved.

Limitations:

- Not suitable for heat-sensitive drugs.
- Requires precise temperature control.

Applications:

- Cosmetics, food emulsions, pharmaceutical emulsions.

3. Emulsion Phase Inversion Composition (EPI) Method[1]

Principle:

Changing the composition, especially the water-to-oil ratio, causes the emulsion to invert from W/O to O/W. During the inversion, high shear is generated at the interface, forming fine droplets.

Procedure:

- Mix surfactant and oil to create a W/O pre-emulsion.
- Slowly add water under continuous stirring.
- At a critical water content, phase inversion occurs, forming a stable nanoemulsion.

Advantages:

- No heating needed (ideal for temperature-sensitive APIs).
- Simple stirring is sufficient.

Limitations:

- Sensitive to formulation ratios.
- Limited reproducibility if parameters are not controlled.

Applications:

- Topical and oral nanoemulsion formulations.

Evaluation of nanoemulsion

1. Physicochemical Characterization[13]

- **Droplet Size and Distribution:** Measured using dynamic light scattering (DLS). Nanoemulsions typically have droplet sizes ranging from 20–200 nm.

- **Zeta Potential:** Indicates surface charge and predicts stability. High zeta potential (±30 mV) suggests good stability.
- **Viscosity and Refractive Index:** These parameters affect the flow and optical properties.
- **pH:** Important for skin compatibility or drug stability.

2. Stability Studies[14]

- **Physical Stability**: Resistance to phase separation, coalescence, flocculation, and Ostwald ripening.
- **Thermal and Centrifugation Tests:** Assess kinetic stability under stress conditions.
- **Shelf-life:** Long-term stability at various temperatures.

3. Drug Delivery and Bioavailability[1]

- **Encapsulation Efficiency:** How effectively the drug is loaded within the droplets.
- **Controlled Release:** Assessed via in vitro release studies.
- **Enhanced Bioavailability:** Compared to conventional formulations due to increased surface area and absorption.

4. Toxicological Evaluation[15]

- **Cytotoxicity Tests:** Using cell lines to ensure biocompatibility.
- **In vivo Studies:** Evaluation in animal models for safety and systemic effects.

5. Application-Specific Evaluations[2]

- **Pharmaceutical**: Drug solubilization and sustained delivery.
- **Cosmetic:** Skin penetration, moisturization.
- **Food:** Flavour encapsulation, nutrient delivery.

Formulations available of nanoemulsion[16]

1. Skincare & Cosmetics Nanoemulsions

- **Skin Caviar (La Prairie):** Contains caviar extract & peptides; promises firming, smoothing, and hydration within 15 min—achieved via enhanced nanoemulsion penetration.
- **Bepanthol Facial Cream Ultra Protect (Bayer):** 5% provitamin B5 nanoemulsion with antioxidants; supports moisture retention and skin barrier in eczema, psoriasis.
- **Nanovital VITANICS Crystal Moisture Cream (Vitacos):** Niacinamide, arbutin, vitamin C; white & firm skin with nanoemulsion-mediated stability and delivery.
- **Nano Emulsion Multi-Peptide Moisturizer (Hanacure):** Peptides, squalene, sodium hyaluronate; improves tone, texture, hydration via nano-droplets.
- **Olïvenol Anti Falten Pflegekonzentrat Cream (Dr. Theiss):** Olive oil + acacia; anti-aging cream with nanoemulsion for enhanced bioavailability.
- **The Kemira nano-gel** is a patented nanoemulsion gel system designed to improve skin feel and boost active penetration, particularly in moisturizers and sunscreens.

2. Hair & Body Care

- **Korres Red Vine Hair Sun Protection Spray:** Uses nanoemulsion to deliver UV filters and polyphenols, protecting hair from sun damage.

- **Coco Mademoiselle Fresh Moisture Mist (Chanel):** A fine, airy body mist with moisturizing benefits derived from nanoemulsion technology.

3. **Ocular Nanoemulsions**

- **Cationorm (Laboratoires Théa/Bioglan, formerly Novagali):** Cationic oil-in-water nanoemulsion with cetalkonium chloride; effective for dry eye therapy. Marketed since 2008, it binds to ocular surfaces, reducing irritation and enhancing drug delivery.

4. **Herbal & Lipid-Based Nanoemulsions**

- Higher activity stability and ingredient solubility

- Improved stratum corneum penetration and skin hydration

- Lowered need for alcohol, oils, or occlusive agents

Challenges in manufacturing nanoemulsions[17]

1. High Equipment & Energy Costs

- Advanced equipment—such as high-pressure homogenizers, microfluidizers, ultrasonicators, rotor–stator mixers—is essential to reduce droplet size to nano-scale. These machines are expensive to acquire and maintain, especially at industrial scale .

- Energy-intensive processes, particularly high-pressure homogenization (20–100 MPa) and ultrasonication, drive substantial operational costs and generate heat that may degrade sensitive actives.

2. Formulation Complexity & Surfactant Selection

- Precise surfactant/co-surfactant systems are required to reduce interfacial tension. Overuse may lead to toxicity, underuse to instability.

- Low-energy methods (e.g., PIT, PIC) offer energy savings but demand tight control of temperature, composition, and HLB balance, limiting robustness.

3. Stability Concerns

- Ostwald ripening remains a major issue: small droplets dissolve and redeposit on larger ones, causing polydispersity and instability over time .

- Other physical instabilities such as coalescence, flocculation, creaming, phase separation, and chemical degradation (e.g., oil oxidation, ingredient breakdown) often occur during storage or stress conditions (temperature, pH, ionic strength, light).

4. Scale-Up & Reproducibility

- Transitioning from lab to industrial scale introduces variability: equipment differences, batch-to-batch inconsistency, and changes in droplet size distribution can impact performance.

- Characterization tools like dynamic light scattering and electron microscopy are costly and may not be easily accessible for routine quality control.

5. Drug Loading & Carrier Compatibility

- For drug delivery especially, limited drug-loading capacity in oil phase restricts therapeutic efficacy for poorly soluble drugs.

- Compatibility between drug, oil, surfactant, and any co-solvent requires extensive screening, which is time-consuming and resource-intensive.

Future prospects of nanoemulsion[18]

1. Market Growth & Segment Expansion

- The nanoemulsion market is forecasted to grow from approximately USD 8–8.2 billion in 2024 to around USD 17–20 billion by 2030–2035, with an annual growth rate of 6–7% CAGR.

- Key sectors driving growth include pharmaceuticals, cosmetics, food & beverages, nutraceuticals, agriculture, industrial coatings, and emerging areas like CBD products and antimicrobial agents.

- The pharma and cosmetics sectors dominate: pharma (~60–70%) and cosmetics (~25–30%) share nearly 90% of the market.

2. Advanced Therapeutic & Delivery Applications

- Parenteral nanoemulsions are projected to lead growth (~CAGR 6.5%), leveraged for targeted delivery of antibiotics, NSAIDs, immunosuppressants, steroids, and vaccine platforms.

- Recent regulatory trends show 14 new nanoemulsion drug approvals in North America (2023–24), making the U.S. a leading therapeutic hub.

3. Expandable Consumer Product Applications

- In cosmetics, nanoemulsions continue to improve skin penetration, texture, and efficacy for anti-aging, sunscreens, and hair care.

- In food and nutraceuticals, they enable better flavoring, stabilization, and bioavailability of vitamins, omega-3s, antioxidants, and functional ingredients in beverages and edible coatings.

4. Technological & Sustainable Innovation

- Formulation technologies like high-pressure homogenization, micro fluidization, low-energy self-emulsification, and Pickering emulsions using nanocellulose stabilizers are gaining traction—for greater control, eco-impact reduction, and cost savings.

- The shift toward natural, biodegradable, and plant-based surfactants and oils is aligned with rising consumer and regulatory demand for greener products.

5. Next-Gen Smart & Active Emulsions

- Intelligent emulsions (e.g., Pickering-type with nanocellulose, active/self-propelled droplets) are at the research cusp. They hold promise for targeted drug delivery, self-healing coatings, and active food packaging .

- Growing collaborations among industry, academia, and regulatory bodies are fueling development of novel excipients and clinically advanced formulations, including large biomolecules like proteins and oligonucleotides .

6. Regional Dynamics & Regulatory Trends

- The Asia-Pacific region, notably India, China, and Japan, is witnessing the fastest adoption—with nutraceutical, cosmetic, and therapeutic

nanoemulsion launches increasing by 20–30% in 2024.

- Europe and North America continue to lead in regulatory approvals and technology investments, especially in vaccine, parenteral nutrition, and sustainable cosmetics .

CONCLUSION

Nanoemulsions have revolutionized pharmaceutical systems, offering numerous benefits, including enhanced drug delivery, protection of sensitive molecules, and improved patient compliance. Their versatility in masking unpleasant tastes, protecting against hydrolysis and oxidation, and providing targeted and prolonged release of medicaments makes them an attractive platform. With ongoing research and development, nanoemulsions are expected to play an increasingly important role in advancing pharmaceutical applications, ultimately leading to more effective, safe, and bioavailable treatments.

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