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Review Article

A Review on Advances of Nanoemulsions in Drug Delivery and Therapeutics

Dasa Mani Deepika*, M. Sunitha Reddy, K. Anie Vijetha

Centre for Pharmaceutical Sciences, UCESTH, Jawaharlal Nehru Technological University, Hyderabad, Kukatpally, Telangana, India 500085

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ABSTRACT

Nanoemulsions have emerged as a cutting-edge drug delivery system, offering improved solubility, bioavailability, and targeted drug release. Their unique physicochemical properties make them highly suitable for oral, parenteral, transdermal, and nasal drug formulations. The pharmaceutical industry has increasingly adopted nanoemulsion-based therapeutics for oncology, neurology, infectious diseases, and vaccine delivery. This review explores recent advancements in nanoemulsion formulations, regulatory challenges, and novel manufacturing techniques. The study highlights the role of lipid-based nanoemulsions in enhancing drug absorption through lymphatic transport, mucoadhesive nanoemulsions for intranasal and ocular applications, and stimuli-responsive nanoemulsions for controlled drug release. Regulatory agencies such as the FDA and EMA require extensive characterization, including particle size distribution, zeta potential, and stability assessments to ensure nanoemulsion safety and efficacy. Despite challenges in stability, toxicity, and large-scale production, nanoemulsions are expected to reshape modern drug delivery. Future directions include the development of smart nanoemulsions, biodegradable surfactants, and AI-powered drug design, positioning nanoemulsions as a pivotal technology in personalized medicine and advanced therapeutics.

INTRODUCTION

1. The Market Need for Pharmaceutical Nanoemulsions

Nanoemulsions have emerged as a transformative drug delivery system in the pharmaceutical industry, addressing key challenges such as poor solubility, low bioavailability, and inefficient drug targeting. With the increasing demand for patient-friendly, efficient, and targeted therapeutics,

***Corresponding Author:** Dasa Mani Deepika
Address: *Centre for Pharmaceutical Sciences, UCESTH, Jawaharlal Nehru Technological University, Hyderabad, Kukatpally, Telangana, India 500085*
Email : manideepikadasa@gmail.com
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nanoemulsions are gaining prominence across various pharmaceutical sectors. Their ability to enhance drug solubility, improve permeability, provide controlled release, and enable site-specific delivery has led to their widespread adoption in oral, injectable, transdermal, and nasal formulations[1,2].

1.1. The Rise of Nanoemulsions in the Pharmaceutical Industry

Nanoemulsions are submicron-sized emulsions (20–200 nm) with a thermodynamically stable nature, making them superior to conventional emulsions. Their rise in the pharmaceutical industry is attributed to:

1. **Improved Drug Solubility and Bioavailability–** Nearly 40% of new chemical entities (NCEs) suffer from poor aqueous solubility. Nanoemulsions enhance the solubility of Biopharmaceutical Classification System (BCS) Class II and IV drugs, leading to improved absorption and bioavailability.

2. **Versatile Drug Delivery Applications–** Nanoemulsions can be used in oral, parenteral, ophthalmic, pulmonary, transdermal, and nasal drug delivery, making them highly adaptable to different pharmaceutical formulations.

3. **Compatibility with Both Hydrophilic and Lipophilic Drugs–** Nanoemulsions allow the encapsulation of both water-soluble and oil-soluble drugs, broadening their applicability.

4. **High Stability–** Unlike conventional emulsions, nanoemulsions resist coalescence, flocculation, and Ostwald ripening, ensuring longer shelf-life and stability in pharmaceutical formulations.

5. **Enhanced Targeted Drug Delivery–** Functionalized nanoemulsions (e.g., ligand-conjugated or polymer-coated) allow precise targeting of disease sites, especially in cancer and neurodegenerative disorders.

The global pharmaceutical industry has increasingly embraced nanoemulsions, with major pharmaceutical companies investing in their development for oncology, infectious diseases, neurodegenerative disorders, and vaccine formulations[3,4].

1.2. Market Drivers: Bioavailability, Solubility, and Targeted Drug Delivery

Several market forces are driving the growth of nanoemulsion- based pharmaceuticals, primarily focusing on solubility enhancement, bioavailability improvement, and precision drug delivery:

1. Bioavailability Enhancement

A major challenge in drug development is the poor oral bioavailability of many drugs. Nanoemulsions enhance gastrointestinal absorption through lymphatic transport, bypassing first-pass metabolism (e.g., lipophilic drugs like curcumin and cannabinoids)[4].

Example: Lovaza® (Omega-3 acid ethyl esters), an FDA-approved nanoemulsion formulation, enhances fatty acid bioavailability for cardiovascular diseases.

2. Solubility Enhancement

Nanoemulsions can solubilize highly hydrophobic drugs within their oil phase, overcoming solubility limitations.

Example: Sandimmune® (cyclosporine nanoemulsion) increases the oral absorption of the immunosuppressant drug in transplant patients[4].

3. **Targeted Drug Delivery for Precision Medicine**

Nanoemulsions offer site-specific targeting through surface functionalization with ligands, antibodies, or peptides.

They enable targeted drug delivery in cancer therapy (e.g., tumor-targeting nanoemulsions) and brain-targeted drugs crossing the blood-brain barrier (BBB)[5].

Example: Nanoemulsion-based CBD formulations for neurodegenerative disorders like Alzheimer's and epilepsy.

4. **Consumer Preference for Novel Drug Forms**

The rise of self-administrable, needle-free, and patient-friendly formulations has increased the demand for transdermal and nasal nanoemulsions[6].

Example: Nasal nanoemulsions for migraine (sumatriptan nanoemulsion) and intranasal COVID-19 vaccines.

5. **Regulatory Push Towards Advanced Drug Delivery**

Regulatory agencies like the FDA and EMA are promoting nano-enabled drug formulations for improved therapeutic efficacy[7].

Pharma giants are focusing on GRAS (Generally Recognized as Safe) excipients and biodegradable components for regulatory compliance.

1.3. Key Pharma Sectors Benefiting from Nanoemulsion Technology

Several therapeutic areas are witnessing high adoption of nanoemulsions, particularly in oncology, neurology, infectious diseases, and vaccine formulations.

1. **Oncology (Cancer Treatment)**

Nanoemulsions improve the bioavailability of hydrophobic anticancer drugs (e.g., Paclitaxel, Curcumin)[8].

Example: Docetaxel-loaded nanoemulsions for metastatic breast cancer.

2. **Neurological Disorders (Brain-Targeted Drug Delivery)**

Nanoemulsions help cross the Blood-Brain Barrier (BBB), enabling delivery of drugs for Alzheimer's, Parkinson's, and epilepsy[9].

Example: CBD-based nanoemulsions for epilepsy and neurodegenerative disorders.

3. **Infectious Diseases and Vaccines**

Nanoemulsions serve as vaccine adjuvants, increasing the immunogenicity of antigen formulations[10].

Example: Nanoemulsion-based intranasal flu and COVID-19 vaccines.

4. **Pulmonary and Respiratory Drug Delivery**

Nebulized nanoemulsions enhance lung drug deposition, benefiting asthma, COPD, and tuberculosis patients[11].

Example: Nanoemulsions for liposomal amphotericin B delivery in fungal lung infections.

5. **Transdermal and Topical Nanoemulsions**

Used in pain relief, wound healing, and dermatological treatments[12].

Example: Diclofenac nanoemulsion gel for arthritis pain management.

6. Ophthalmic Drug Delivery

Nanoemulsions improve ocular drug absorption and reduce side effects in glaucoma and dry eye treatment[13].

Example: Restasis® (cyclosporine nanoemulsion) for chronic dry eye.

2. Pharmaceutical-Grade Nanoemulsions: Formulation Trends

2.1. Lipid-Based Nanoemulsions for Oral and Parenteral Use

Lipid-based nanoemulsions have gained significant attention due to their ability to enhance the solubility and bioavailability of poorly water-soluble drugs (BCS Class II and IV drugs). These nanoemulsions are classified based on their administration route:

A. Oral Lipid-Based Nanoemulsions

- Designed to improve gastrointestinal absorption by utilizing lymphatic transport mechanisms, bypassing first-pass metabolism.
- Suitable for lipophilic drugs, improving bioavailability and sustained plasma levels[14].
- Example: Cyclosporine A nanoemulsion (Sandimmune®) for immunosuppression.

B. Parenteral Lipid-Based Nanoemulsions

- Used for intravenous (IV), intramuscular (IM), and subcutaneous (SC) delivery, ensuring rapid drug absorption and systemic circulation.
- Ideal for anticancer, antiviral, and anti-inflammatory drugs requiring high plasma drug concentrations[14].
- Example: Propofol nanoemulsion (Diprivan®) used as an anesthetic in surgery.

C. Self-Nanoemulsifying Drug Delivery Systems (SNEDDS)

- A specialized oral lipid-based system that spontaneously forms nanoemulsions in the gastrointestinal tract upon dilution with gastric fluids[15].
- Example: Lipid-based formulations of Itraconazole and Ritonavir.

Key Excipients Used in Lipid-Based Nanoemulsions:

- Medium-chain triglycerides (MCTs)
- Phospholipids(Lecithin, Phosphatidylcholine)
- Surfactants (Tween 80, Poloxamers)

2.2. Mucoadhesive and Intranasal Nanoemulsions for Enhanced Bioavailability

Mucoadhesive and intranasal nanoemulsions are being developed to overcome gastrointestinal and hepatic metabolism issues, providing rapid drug absorption and brain-targeted delivery.

A. Intranasal Nanoemulsions for Brain and Systemic Delivery

- **Bypassing the Blood-Brain Barrier (BBB):**

Drugs that struggle to penetrate the BBB (e.g., Alzheimer's, Parkinson's, and epilepsy drugs) can be efficiently delivered via the nasal route[16].

Example: Intranasal Rivastigmine nanoemulsion for Alzheimer's disease.

- **Faster Onset of Action:**

Used for migraine relief, pain management, and emergency medications.

Example: Sumatriptan nanoemulsion nasal spray for migraine treatment.

- **COVID-19 and Flu Vaccines:**

Nanoemulsion-based intranasal vaccines enhance mucosal immunity, leading to long-term immune response.

Example: Intranasal NanoVax® influenza vaccine.

B. Mucoadhesive Nanoemulsions for Enhanced Absorption

Mucoadhesive properties in nanoemulsions improve retention time at the absorption site, ensuring prolonged drug release[16].

Common Formulation Strategies:

- Chitosan-Coated Nanoemulsions – Improves nasal mucosal adherence.
- Hyaluronic Acid-Based Nanoemulsions – Enhances ocular and transdermal drug absorption.
- Example: Mucoadhesive nanoemulsions for intranasal insulin delivery in diabetes treatment.

2.3. Nanoemulsions in Controlled and Sustained Drug Release Systems

One of the major formulation trends in nanoemulsions is their use in controlled and sustained drug release, reducing dosing frequency, improving patient compliance, and minimizing side effects[17-18].

A. Controlled-Release Nanoemulsions

Designed to slowly release the drug over time, providing prolonged therapeutic effects.

Example: Injectable curcumin-loaded nanoemulsion for sustained anti-inflammatory effects.

B. Stimuli-Responsive Nanoemulsions

These nanoemulsions release drugs in response to external stimuli such as pH, temperature, or enzymes.

Example: pH-sensitive nanoemulsions for cancer therapy, ensuring drug release only in tumor microenvironments.

C. Lipid-Polymer Hybrid Nanoemulsions for Long-Term Drug Release

Combination of nanoemulsions with polymeric nanoparticles provides extended drug retention in the bloodstream.

Example: Paclitaxel-loaded hybrid nanoemulsion for chemotherapy.

D. Transdermal Nanoemulsions for Sustained Drug Release

Lipophilic drugs struggle with poor skin penetration, and nanoemulsions enhance transdermal drug absorption through their nano-sized droplets and surfactant action.

Example: Nanoemulsion diclofenac gel for sustained pain relief in arthritis.

3. Regulatory Landscape and Challenges

3.1. US FDA and EMA Guidelines for Nanoemulsion-Based Drug Approvals

Both FDA (U.S.) and EMA (European Union) classify nanoemulsions under

"nanopharmaceuticals" or "complex drug formulations", meaning they require detailed characterization, rigorous safety studies, and specialized clinical trials[20-21].

1. **Nanoemulsions as New Drug Products (NDA Pathway)**

- Requires full clinical trials (Phase I–III).
- Detailed studies on pharmacokinetics (PK), pharmacodynamics (PD), and toxicity.
- FDA nano-specific characterization data:
- Particle size distribution
- Zeta potential and stability
- Encapsulation efficiency
- Polydispersity index (PDI)
- Long-term safety profiling

2. **Nanoemulsions as Generic Drug Products (ANDA Pathway)**

Applicable for nanoemulsions of existing drugs with bioequivalence studies.

Example: Cyclosporine nanoemulsions (generic versions of Sandimmune® and Restasis®).

3. **Regulatory Requirements for Injectable and Inhalable Nanoemulsions**

Sterility assurance: Must meet USP <71> sterility standards.

Endotoxin testing: To prevent pyrogenic reactions.

4. Formulations require particle size <100 nm to avoid embolism risks.

Example of FDA- Approved Nanoemulsion:

- Propofol (Diprivan®) – FDA-approved intravenous anesthetic nanoemulsion.

A. EMA Guidelines on Nanoemulsion-Based Pharmaceuticals

The European Medicines Agency (EMA) regulates nanoemulsions under[19]:

1. **Quality of Nanomedicines (ICH Q8, Q9, Q10)**

Covers formulation strategies, stability assessments, and impurity profiling.

2. **Guidelines on Non-Clinical & Clinical Requirements**

EMA emphasizes comparative studies with non-nano drug versions to prove therapeutic superiority.

Requires long-term stability testing at multiple temperatures.

3. **Biopharmaceutical and Pharmacokinetic Considerations**

EMA mandates detailed bioavailability and systemic exposure studies for oral and parenteral nanoemulsions.

Example: Cyclosporine nanoemulsions require AUC (Area Under Curve) and Cmax (Maximum Concentration) comparisons.

Example of EMA-Approved Nanoemulsion:
✓ Restasis® (Cyclosporine nanoemulsion for dry eye syndrome) – EMA-approved ophthalmic nanoemulsion

4. Stability, Toxicity, and Pharmacokinetic Challenges in Market Authorization

Despite their pharmaceutical advantages, nanoemulsions face regulatory and scientific challenges related to long-term stability, toxicity risks, and pharmacokinetic variability.

A. Stability Concerns in Nanoemulsions3

Nanoemulsions are thermodynamically unstable, requiring surfactants and stabilizers to maintain long-term homogeneity. Regulatory bodies require extensive stability testing under ICH guidelines:

1. **Common Instabilities:**

- Phase separation and coalescence – Leads to drug leakage.
- Ostwald ripening – Gradual growth of large droplets, reducing stability.
- Degradation of surfactants and lipids – Affects drug loading efficiency.

2. **Regulatory Stability Tests for Nanoe33mulsions (ICH Q1A Guidelines)**

- Accelerated stability testing (40°C ± 2°C, 75% RH) for at least 6 months.
- Long-term stability testing (25°C ± 2°C, 60% RH) for 12–24 months.
- Freeze-thaw cycling tests for parenteral formulations.

Solution: Use of PEGylated lipids, poloxamers, and hybrid lipid-polymer stabilizers to extend nanoemulsion shelf-life.

B. Toxicity Challenges in Nanoemulsions

1. **Nanotoxicity Risks**

- Potential immunogenic responses – Some surfactants trigger inflammatory reactions.
- Long-term accumulation of nanoparticles in organs (liver, spleen, lungs).

2. **Regulatory Toxicity Tests Required**

- In vitro cytotoxicity studies (MTT assays on human cell lines).
- In vivo acute and chronic toxicity (animal models, histopathological analysis).
- Hemolysis studies for IV nanoemulsions to prevent red blood cell damage.

Solution: Using GRAS (Generally Recognized as Safe) excipients for regulatory approval. Example: Lecithin-based nanoemulsions (safe and biodegradable for systemic use).

5. Emerging Nanoemulsion-Based Pharmaceutical Products

Approved and Marketed Nanoemulsion Drugs: Case Studies

Several nanoemulsion-based drugs have received regulatory approval, underscoring their therapeutic efficacy and commercial viability. Notable examples include:

1. **Diprivan® (Propofol Nanoemulsion)**

- Indication: Induction and maintenance of anesthesia[22].
- Description: An oil-in-water nanoemulsion formulation of propofol, providing rapid onset and recovery from anesthesia with reduced pain upon injection.
- Approval: FDA-approved and widely used in clinical settings.

2. **Restasis® (Cyclosporine A Nanoemulsion)**

- Indication: Chronic dry eye disease (keratoconjunctivitis sicca).
- Description: An ophthalmic nanoemulsion that enhances the solubility and ocular penetration of cyclosporine A, leading to increased tear production.
- Approval: FDA-approved for improving tear production in patients with dry eye disease[23].

3. **Ontak® (Denileukin Diftitox)**

- Indication: Persistent or recurrent cutaneous T-cell lymphoma.
- Description: A recombinant fusion protein formulated in a nanoemulsion to target malignant cells expressing the IL-2 receptor.
- Approval: FDA-approved for specific types of lymphoma[24].

Clinical Trials and Pipeline Products: What's Coming Next?

The pipeline for nanoemulsion-based therapeutics is robust, with numerous clinical trials exploring their potential across various medical conditions:

1. **Clopidogrel Nanoemulsion (Intravenous Formulation)**

- Indication: Antiplatelet therapy for patients unable to take oral medication.
- Development: Ascendia Pharmaceuticals developed a novel nanoemulsion IV formulation for clopidogrel, which received Investigational New Drug (IND) approval from the FDA[25].

2. **Nanoemulsion-Based Vaccines**

- Indication: Enhanced immunogenicity for various infectious diseases.
- Development: Clinical trials are underway to evaluate nanoemulsion-adjuvanted vaccines for influenza and other viral infections, aiming to improve immune responses and vaccine stability[26].
- Pharmaceutical Partnerships and Mergers in Nanoemulsion R&D

Strategic collaborations have been instrumental in advancing nanoemulsion technologies:

1. **Ascendia Pharmaceuticals and AcuteBio, LLC**

Collaboration: Developed a novel nanoemulsion IV formulation for clopidogrel, leveraging Ascendia's EmulSol® nanotechnology platform[26].

2. **MIT and Industry Partners**

Collaboration: Researchers at MIT developed nanoemulsion gels capable of delivering drugs through the skin, utilizing FDA-approved components, and are exploring partnerships for clinical translation[27].

3. **L'Oréal and Nestlé**

Joint Venture: Established Galderma, focusing on dermatological applications, including nanoemulsion-based skincare products, blending pharmaceutical and cosmetic expertise[28].

6. Advanced Manufacturing Technologies in Pharmaceutical Nanoemulsions

Microfluidic Technologies in Nanoemulsion Production

Microfluidics involves manipulating fluids at the microscale, offering precise control over nanoemulsion characteristics such as droplet size and distribution. This precision is crucial for ensuring consistent product quality and efficacy. Recent studies have demonstrated the use of microfluidic platforms to produce uniform oil-in-water nanoemulsions through spontaneous self-assembly, highlighting their potential in scalable manufacturing processes[29,32,34].

Role of Artificial Intelligence in Formulation

Artificial Intelligence (AI) is revolutionizing nanoemulsion formulation by enabling rapid optimization and innovation. Machine learning algorithms can predict the effects of various formulation parameters, streamlining the development process. A comprehensive review

analyzed the transformative impact of AI technologies on sustainable manufacturing, focusing on critical applications such as energy optimization and waste reduction[30,31,33].

Green and Sustainable Manufacturing Approaches

The nanoemulsion manufacturing industry is increasingly adopting green methodologies to minimize environmental impact. For instance, membrane-assisted techniques have been employed for the sustainable production of nanoemulsions, offering eco-friendly alternatives to traditional methods[30,31,33].

AI's Contribution to Sustainability

AI plays a pivotal role in promoting eco-friendly manufacturing practices. By analyzing production processes, AI identifies opportunities for reducing emissions, optimizing resource utilization, and enhancing overall sustainability. Insights from the World Economic Forum indicate that AI-driven Environmental, Social, and Governance (ESG) data can bridge gaps between manufacturers and stakeholders, fostering sustainable change[30,31,33].

7. Investment Landscape and Future Market Opportunities

Big Pharma's Interest in Nanoemulsions: Funding and Collaborations

Pharmaceutical giants are increasingly investing in nanoemulsion-based drug delivery due to their advantages in enhancing bioavailability, stability, and targeted drug delivery. Major funding sources include:

- **R&D Grants and Government Funding –** Agencies like the National Institutes of Health (NIH), European Commission (Horizon Europe), and FDA Orphan Drug Grants are supporting research into nanoemulsion-based therapeutics for diseases such as cancer, neurodegenerative disorders, and infectious diseases.
- **Venture Capital and Biotech Partnerships** – Big Pharma is actively acquiring biotech startups with nanoemulsion technologies to accelerate drug development.
- **University-Industry Collaborations** – Many pharmaceutical companies are partnering with academic research institutions to develop novel nanoemulsion-based drugs and vaccines[29,35].

Key Collaborations in Nanoemulsion Research

1. **Pfizer and BioNTech –** Worked on lipid-based nanoemulsions for mRNA vaccine delivery, leading to the successful COVID-19 vaccine rollout.

2. **Novartis and MIT** – Collaborated on nanoemulsion formulations for ophthalmic drug delivery, improving treatment efficacy for glaucoma and macular degeneration.

3. **GSK (GlaxoSmithKline) and CureVac** – Jointly developing nanoemulsion-based vaccines to enhance immune response and antigen stability.

4. **Johnson & Johnson and NanoBio Corporation** – Focused on intranasal nanoemulsion vaccines for influenza and respiratory infections.

CONCLUSION

Pharmaceutical nanoemulsions are revolutionizing drug delivery by enhancing bioavailability, stability, and targeted release. Despite their potential, regulatory complexity, scale-up challenges, and high production costs remain key hurdles. AI-driven formulation development and

microfluidic continuous manufacturing are streamlining production. Big Pharma is investing heavily in nanoemulsion-based vaccines, cancer therapies, and gene delivery. Startups can leverage orphan drug markets and personalized medicine to enter the space. Regulatory agencies are working toward standardized approval pathways for faster commercialization. The future lies in smart nanoemulsions, green manufacturing, and AI-optimized drug delivery.

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