INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Review Paper

Nanoemulsion Future Approach in Faster Routes of Dosage Delivery

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ARTICLE INFO

Published: 13 Jan. 2025
Keywords:
Nano-emulsion, Types of Nano-emulsion
DOI:
10.5281/zenodo.14639589

ABSTRACT

A nano-emulsion drug delivery system has been developed to overcome the drawbacks of traditional drug administration methods. This review summarizes recent advancements in nano-emulsion systems, which are submicron emulsions designed to enhance the distribution of active pharmaceutical ingredients to specific target sites. Nano-emulsions consist of a uniform mixture of lipid and aqueous phases, stabilized by effective emulsifying agents. The droplet sizes range from 50 to 500 nm, distinguishing nano-emulsions from emulsions and micro-emulsions based on their size and distribution characteristics. These systems offer a novel dosage form particularly beneficial for poorly water-soluble drugs, improving their pharmacological activity. Applications for nano-emulsions extend into the cosmetic industry, diagnostic tests, drug treatments, and biotechnology. This review will cover essential information on nano-emulsions, including their advantages, disadvantages, limitations, different types, formulation components, surfactants, preparation techniques, characterization methods, and various pharmaceutical applications, such as in cancer therapy, targeted drug delivery, mucosal vaccines, and transdermal systems.

INTRODUCTION

Nano-emulsions are promising in the pharmaceutical field due to their excellent droplet volumetric fractions, increased bioavailability, and extended shelf life. They represent a unique approach to enhance the bioavailability of poorly soluble drugs by dispersing two immiscible liquids into a stable, isotropic, and transparent nano-emulsion. Nano-emulsions typically consist of oils, surfactants, water, and drugs, with droplet sizes ranging between 50-500 nm, optimizing drug delivery. These systems can significantly enhance drug bioavailability and pharmacological effects while reducing toxicity. Their transparent and stable nature ensures improved formulation of bioactive substances for better absorption.

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Recent studies on both oil-in-water (O/W) and water-in-oil (W/O) nano-emulsion formulations have highlighted varying advantages for pharmaceuticals and cosmetics. These dosage forms are now frequently used for the delivery of biopharmaceuticals, including vaccines, DNA therapies, and antibiotics. The nano-emulsion delivery system offers numerous benefits, such as versatility in administration routes (oral, ocular, and transdermal). In this article, we discuss the various aspects of nano-emulsion production, including emulsifying agents and challenges in developing these systems, while noting their physical stability against sedimentation and creaming caused by Ostwald ripening.

Nanoemulsions are colloidal systems that serve as carriers for drug molecules and are typically found in the submicron size range of 10 to 1,000 nm. These carriers are solid spheres with an amorphous, lipophilic surface that carries a negative charge. The use of magnetic nanoparticles can improve the targeting capabilities of these systems. As a drug delivery mechanism, nanoemulsions enhance the therapeutic effectiveness while reducing side effects and toxic reactions. Their primary applications include treating infections in the reticuloendothelial system (RES), enzyme replacement therapy for liver conditions, cancer treatment, and vaccination. An emulsion consists of two phases, with one phase dispersed as tiny droplets within the other, measuring between 0.1 and 100 μm in diameter. This thermodynamically unstable system can be stabilized with an emulsifying agent (also known as an emulgent or emulsifier). The dispersed phase is referred to as the internal or discontinuous phase, while the surrounding phase is termed the external phase, dispersion medium, or continuous phase. The emulsifying agent can also be called an intermediate or interphase. The term “nanoemulsion” can refer to a type of miniemulsion, specifically a fine dispersion of oil in water or water in oil stabilized by a surfactant film, with droplet sizes ranging from 20 to 600 nm. Due to their small size, nanoemulsions appear transparent. There are three types of nanoemulsions: (a) oil-in-water nanoemulsions where oil is dispersed in an aqueous phase, (b) water-in-oil nanoemulsions where water droplets are dispersed in an oil phase, and (c) bi-continuous nanoemulsions.

Merits

1. Can replace lipid/protein-coated medications and vesicles.
2. Enhances drug bioavailability.
3. Non-toxic and non-irritating.
4. Improved physical stability.
5. Larger surface area for increased absorption.
6. Compatible with various formulations like foams, creams, oils, and sprays.
7. Enhances solubility of lipophilic drugs.
8. Masks unpleasant odors.
9. Requires less energy for preparation.

DISADVANTAGES OF NANO-EMULSION**

1. Necessitates a high ratio of surfactants and co-surfactants to maintain stability.
2. Limited ability to solubilize rapidly melting liquids.
3. Stability can be influenced by environmental factors such as humidity and pH.

LIMITATIONS OF NANO-EMULSION**

1. Production can be costly and technically challenging due to the need for specialized equipment, such as homogenizers and processes like microfluidization and ultrasound.
2. Long-term stability of nano-emulsions can present significant difficulties during formulation.

TYPES OF NANO-EMULSION**

Nano-emulsions are generally classified into three categories: oil in water (O/W), water in oil (W/O), and bi-continuous types.

1. **O/W Nano-emulsion:** Formed by combining water and oil with a surfactant, typically exhibiting a higher volume fraction than the W/O type. In this formulation, the surfactant forms a film that disperses the oily phase in an aqueous phase.
2. **W/O Nano-emulsion:** Characterized by small droplets of liquid surrounded by an oil phase, where surfactant polar heads are in the oil phase and their fatty tails are within water droplets, known as "reverce micelles."
3. **Bi-continuous Nano-emulsion:** Characterized by the interspersing of oil and water micro-domains in the formulation context.

The illustration for preparing the oil-in-water nano-emulsion

Method of Preparation for Nano-emulsion Drug Delivery System

Nano-emulsions are clear and stable emulsions that consist of two immiscible liquids with particle sizes smaller than 100 nm. The preparation methods for nano-emulsion drug delivery systems are outlined below.

****High-Pressure Homogenization****

In this technique, two liquids (the oily and aqueous phases) are combined under extremely high pressure (between 500 and 5000 psi) through a small orifice. This results in the formation of very fine emulsion particles due to the friction and kinetic shear involved. This method effectively separates a lipid-soluble core from the aqueous core. While it yields high-quality emulsions, a significant downside is the substantial increase in temperature and resource consumption during the process.

****Micro-fluidization****

This blending method utilizes a device known as a micro-fluidizer. It requires a high-pressure displacement pump (between 500 and 20000 psi) to generate stress, pushing the material through tiny channels termed "micro-channels." When the material flows past these channel walls into an area of occlusion, it produces submicron-sized particles. In this process, the oily and aqueous phases are combined and then expelled to create a coarse emulsion.

****Ultrasonication****

Numerous studies have explored nano-emulsion formulation using ultrasonic sound to reduce particle size. This involves applying continuous ultrasonic energy at pressures exceeding atmospheric levels. Increased external pressure raises the cavitation threshold of ultrasonic waves and presents smaller bubbles. However, this higher pressure can also enhance the strength of collapsing cavitation bubbles. Thus, this technique produces more vigorous and intense bubble collapses compared to ambient conditions.

****Phase Inversion Method****

This method relies on energy derived from symmetry breaking, which leads to uniform distribution of the emulsion components. By adjusting the rotational speed of the emulsion while controlling internal temperature, a transformation can be achieved.

****Solvent Evaporation Technique (SET)****

This method involves dissolving a drug with its emulsifier in a solvent that is not compatible with the drug. As the solvent evaporates, the drug precipitates out of solution. Crystallization can be managed through the use of a high-speed stirrer, which creates significant shear forces.

****Hydro-gel Method****

The primary distinction in this technique is that the anti-solvent causes the solute to become soluble. Increased shear strengths can influence both crystal growth and Ostwald ripening.

APPLICATION OF NANOEMULSIONS

Encapsulating Drugs for Improving the Bioavailability Recently, poor drug compounds have drawn attention. Tis section gives an overview of research that has increased the bioavailability of drug compounds by encapsulating them in nanoemulsions. Te research

on nanoemulsions created utilizing high- or low-energy techniques is the main em- phasis of this review. Nanoemulsion can be produced at low cost in diferent pharmaceutical dosage forms, such as creams, gels, foams, sprays, and aerosols, and it can also be taken orally, topically, intravenously, intrapulmonary, in- tranasally, and intraocularly. Nanoemulsion is a safe and efective dosage form of subpar medication candidates for increasing bioavailability in the treatment of a variety of conditions, such as hypertension, infammation, and cancer, and lowers the dose-related adverse impact of the drugs. Tere have already been several research conducted as shown in Table 2 that supports the idea that nanoemulsion is an emerging novel technology for improving the bio-availability of drugs. 11. Application of Nanoemulsion in Drug Delivery 11.1. Nanoemulsion and Drug Targeting. Te fascinating application that is currently under the development involves using of nanoemulsion formulations for the delivery of controlled and targeted medication [134]. Teir submicron size makes it simple to target the tumor's location. Aqueous insoluble drugs have historically been delivered by nano-emulsions, but more recently, attention has been focused on colloidal particles as a carrier for the targeted delivery of diferent anticancer medications, photosensitizers, neutron capture therapy agents, or diagnostic agents. A novel method of treating cancer is the production of magnetic nanoemulsions. Tese can spread into tissue layers of the skin with photosensitizers like Foscan®, causing hyper- thermia and the subsequent production of free radicals. Photodynamic therapy, which uses this technology, can be utilized to treat cancer [135]. 11.2. Drug Delivery via Transdermal Nanoemulsions. Tere has been a lot of interest in this area since it is practical to provide medications through the skin to the systemic circulation for a variety of clinical diseases [136, 137]. Te parenteral method has the advantage of continuous drug- controlled distribution over a longer period of time, even when self-administration may not be possible. Te patient can stop taking the medication at any time by simply re- moving the transdermal patch. Nanoemulsions have a pleasant feeling on the skin thanks to their transparency and fuidity. Te complete absence of gastrointestinal ad- verse efects such as irritating gastrointestinal and bowel ulcers, which are typically linked to oral delivery, is an added beneft. For a variety of illnesses and disorders, such as cardiovascular problems, Parkinson's disease, Alzheimer's disease, anxiety, and depression, transdermal medicinal treatments have been produced. Te main drawback to this form of administration is the skin's barrier, which prevents the bioactives from penetrating the body efectively. Te stratum corneum, which severely limits their absorption and bioavailability, the sweat ducts, and hair follicles are the three primary routes through which drugs can enter the skin. Te major objective is to improve drug targeting and pharmacokinetics. Te main skin barriers must be broken down for better medication pharmacokinetics and targeting. Additionally, it is important to manage the redistribution of topically applied medications through the cutaneous blood and lymphatic system. Nano-sized emulsions can quickly enter the systemic circulation and pass through the skin's pores, channeling the substance for efcient distribution [138]. By oral administration, cafeine has been utilized to treat a variety of cancers. Cafeine nanoemulsions in water- in-oil have been created for transdermal medication de- livery. Tese and aqueous cafeine solutions' in vitro skin permeation profles were compared, and the nanoemulsion- loaded medicines' permeability parameters signifcantly increased [139]. 11.3. Drug Delivery via Pulmonary Nanoemulsions. Very little research has been published in this feld, and the nanoemulsion method has not yet been completely

utilized for pulmonary drug administration [140]. As an alternative to liposomes as a gene transfer vector, emulsion systems have been developed [141]. Other researches on emulsion for gene administration (nonpulmonary route) indicated that the emulsion or DNA combination had a strong afnity than liposomal carriers [142]. Genes were administered more efectively using this stable emulsion approach compared with liposomes [143]. According to Bivas-Benita et al. [144], cationic submicron emulsions are promising DNA vaccine delivery systems to the lung because they can transfect pulmonary epithelial cells, which may result in cross- priming of antigen-presenting cells and direct activation of dendritic cells, stimulating antigen-specifc T cells. As a result, the nebulization of submicron emulsions will be a new and developing research in the feld of pharmaceutical sciences. However, due to the potential negative efects of oil and Emulsifers on lung alveolar function, more research is required to formulate the inhalable submicron emulsion as a successful route of pulmonary administration (adverse interactions with lung emulsifer)Delivery of Parenteral Drugs Using Nanoemulsions. Tis is one of the most common and efcient drug delivery methods, and it is typically used for active ingredients with low bioavailability and limited remedial indices. Because of the ability to dissolve large amounts of hydrophobics, mutual compatibility, and the potential to protect medicines from enzymatic degradation and hydrolysis, nanoemulsions are ideal carriers for parenteral administration. Further- more, because these emulsions ensure that medications are released continuously and consistently over long periods of time, the injection dosage and their frequency can be re- duced throughout the period of drug therapy. In this context, the lack of focculation, creaming, and sedimen- tation, as well as the high surface area and free energy, provide clear benefts over emulsions with larger particle sizes. Furthermore, because these emulsions ensure that pharmaceuticals are released continuously and under con- trol over long periods of time, the frequency and dosage of injections can be reduced during the course of drug therapy. Te absence of focculation, creaming, and sedimentation, combined with the high surface area and free energy, clearly outperforms emulsions with larger particle sizes in this situation. It was loaded into parenteral emulsions made using the high-energy ultrasonication method to study its pharmacokinetics and anticancer activity. Tis nano- emulsion treatment for colon adenocarcinoma in mice re- sults in the suppression of higher tumors rather than a plain solution of drug treatment, indicating that drug-loaded emulsion may be a useful vehicle for medication trans- port in treating cancer [145]. Tere was no parenteral treatment available for patients due to carbamazepine's limited water solubility, a common anticonvulsant medi- cation. Kuo et al. [77] elaborated a nanoemulsion with good in vitro release kinetics for intravenous administration. 11.5. Delivery of Ophthalmic Drugs Using Nanoemulsions. A wide range of diseases are categorized as ophthalmic ailments, including glaucoma, cataracts, dry eye syndrome, and numerous ocular infections. Due to the defensive sys- tems of the eye, including tear flm dynamics and the blood- ocular barrier, it is frequently difcult to deliver medications to the eye successfully. By encapsulating medications into nanoscale droplets, nanoemulsions are able to effectively penetrate the ocular surface and maintain a longer residence duration. Ophthalmic nanoemulsions have a number of significant uses, including the treatment of glaucoma, a major contributor to permanent blindness. Antiglaucoma medications' ocular bioavailability can be improved using nanoemulsions, enabling lower dosages and less systemic adverse effects. Furthermore, nanoemulsions are adaptable carriers

for a variety of therapeutic agents utilized in ophthalmology because they may include both hydrophilic and hydrophobic medicines. Additionally, because they are more tolerable and cause less discomfort, nanoemulsion-based ophthalmic formulations can increase patient compliance. These formulations address a prevalent problem with conventional ophthalmic therapies by being frequently less viscous and easier for patients to administer [146]. 11.6. Delivery of Intranasal Drugs Using Nanoemulsions. In addition to oral and parenteral administration routes, intranasal drug delivery systems are now recognized as an effective route for the administration of dosage forms. Te nasal mucosa has been shown to be a therapeutically effective route for systemic medication administration and an effective strategy for circumventing barriers that prevent direct drug entry into the target-oriented site. Tis method was also painless, tolerable, and non-invasive. Due to less enzymatic activity, more immunoactive sites, and permeable epithelium layer, the nasal cavity is one of the most effective places for the delivery of drug [147]. Targeting medications for the brain poses several challenges, especially for hydrophilic and large molecular-weight medications. Tis is due to the impermeable properties of the endothelium, which separates the systemic circulation and acts as a blood- brain barrier [148]. Te nasal mucosa's olfactory region serves as a direct link between the nose and the brain, and ailments such as Alzheimer's disease, migraine, depression, schizophrenia, Parkinson's disease, and meningitis are treated with medication-loaded Nano emulsions [149, 150]. There have been reports of reserpine Nano emulsions being developed for nasal administration [150, 151]. It is implied that this emulsion works better when taken orally rather than intravenously. Another therapeutic application for intranasal drug delivery systems is vaccine development. Immunity is produced as a result of mucosal antigen de- livery, and the frst intranasal vaccine is now available on the market. One of the potential delivery methods is the use of nanocarriers, which shows considerable excellence in protecting biomolecules, fostering nanocarrier interaction with mucosae, and directing antigens to lymphoid tissues. The use of nanoemulsion technology in intranasal drug delivery systems is expected to produce significant results in treating central nervous system disorders by effectively targeting medications to the brain. Future Prospective Since its creation, nanoemulsion has proven to be a versatile and effective new medication delivery technology. Because they have a limited capacity for solubilizing nonpolar active chemicals, nanoemulsions are being proposed for a variety of uses in pharmacies as drug delivery methods.

Future applications of nanoemulsion in various therapeutic disciplines or in the creation of cosmetics for the skin or hair are quite bright. Nanoemulsions have a wide range of uses, including medication delivery, where they serve as effective carriers for bioactive and make a variety of administration methods possible. Their parenteral delivery has been used to meet nutritional needs, manage drug release, deliver vaccines, and target drugs to certain locations. Their are many benefts and uses for oral medication administration using these vehicles, where the size of the droplets affects how well they are absorbed in the GIT. Te application of nano- emulsions in ocular delivery, where pharmaceutical medi- cines are better maintained than their corresponding solutions, has also been researched. Other efective ad- ministration methods for nanoemulsifed delivery systems include pulmonary and transdermal routes. Although there have not been many reports of nanoemulsion uses in other domains, these subjects have a lot of potential, including engineering, agriculture, and the chemical and

physical sciences. Te price of making nanoemulsions will go down as new equipment for high-pressure homogenization be- comes available and manufacturers begin to compete with one another. Optimized emulsifer systems and more ef- cient emulsifer utilization will result from the fundamental study into the function of emulsifers in the process of producing nanoemulsions. Te ability to modify nano-emulsions for targeted distribution holds great promise in treating malignancies and in delivering drugs to the brain in the feld of oncology.

****Parenteral Delivery****

Nano-emulsions have been utilized for intravenous administration, requiring the formation of droplets smaller than 1 micrometer for effective use. This method serves various nutritional purposes, delivering fats, carbohydrates, and vitamins.

****Oral Delivery****

Nano-emulsion systems present multiple benefits over conventional formulations for oral delivery, including enhanced absorption, improved therapeutic efficacy, and reduced toxicity.

****Topical Delivery****

Topical medication delivery offers advantages over other methods by minimizing hepatic first-pass metabolism and potential side effects. This approach involves administering medication directly to the affected skin or ocular areas.

****Ocular Delivery****

Topically delivered nano-emulsions are employed to treat eye disorders, aiding in the dissolution of poorly soluble drugs, enhancing absorption, and achieving prolonged release profiles.

****Cosmetic Industry****

The aesthetic qualities of nano-emulsions, such as low viscosity and transparent properties due to droplet sizes below 200 nm, facilitate the effective transfer of active substances to the skin, making them particularly appealing for cosmetic applications. They can be used to create oil-in-water mini-emulsions that help retain moisture and enhance skin safety.

****Cancer Treatment****

In chemotherapy, niosomes serve as carriers to extend drug release and improve the delivery of anti-cancer therapies through the skin by enhancing lymphatic penetration.

****Gene Delivery Vector****

Emulsion systems have been developed as potential platforms for genetic manipulation using liposomes. Studies suggest that the retention of emulsion/DNA complexes is superior to that of simply encapsulated transmitters, improving gene delivery efficiency compared to microcapsules.

****Nasal Drug Delivery to the Brain****

Nasal drug administration has emerged as a non-invasive and efficient method for delivering medicine to the brain, addressing challenges posed by aqueous and larger molecular drugs. This route facilitates quick access to the targeted site, providing a painless method of administration. The nasal mucosa is recognized for its effectiveness in delivering high molecular weight drugs due to its reduced enzymatic activity and extensive absorption.

CONCLUSION AND DISCUSSION

An advanced drug delivery system has been created to address the significant limitations of traditional drug delivery methods. This review provides an in-depth overview of nanoemulsion systems, which are small-scale emulsions designed to enhance the delivery of active pharmaceutical ingredients. These systems are thermodynamically stable and isotropic, created by mixing two immiscible liquids into a single phase using an emulsifying agent, such as a surfactant and co-surfactant. Typically, the droplet size of nanoemulsions ranges from 20 to 200 nm. The key distinction between emulsions and nanoemulsions lies in the size and shape of the particles dispersed within the continuous phase. This review focuses on the formulation,

preparation methods, characterization techniques, evaluation criteria, and various applications of nanoemulsions.

The nano-emulsion drug delivery system has found extensive application in the pharmaceutical field, offering numerous advantages for drug and biochemical delivery. Its versatility across multiple routes underscores its potential in various domains. This innovative technology addresses challenges in delivering poorly soluble drugs and serves as a means for specific drug categories, such as anti-cancer agents and photo-sensitizers. Overall, nano-emulsion formulations are effective, safe, and patient-friendly options for pharmaceutical distribution, with anticipated advancements in future research.

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HOW TO CITE: Sonali Bhagat, Anup Kendre, Shubhangi Dorle, Vaishnavi Khandre, Nanoemulsion Future Approach in Faster Routes of Dosage Delivery, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 1, 1026-1035. https://doi.org/10.5281/zenodo.14639589