REVIEW ARTICLE

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Nanoemulsions - A Review

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ABSTRACT

This review explores advancements in drug delivery systems, focusing specially on Nanoemulsions as a solution to the limitations of conventional methods. nanoemulusions, defined as stable emulsions with nano-sized particles, are engineered to improve the delivery of active pharmaceuticals ingredient. These systems achieve stability through the use of surfactants and co-surfactants to combine two unmixable liquids. Nanoemulusions typically have droplet sizes ranging from 20 to 200nm, distinguishing them from conventional emulsions based on particle size and shape in the continuous phase. The review provides an overview of nanoemulsion preparation techniques, various applications.

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Introduction

In recent years, the application of nanoemulusions has surged across the pharmaceutical cosmetic, and food industries due to their distinct benefits over traditional ranging from 20-200 nanometre, offer notable improvements in stability. Appearance, release properties, and bioavailability of various ingredients.

In the food sector nanoemulsion are increasingly utilized to enhance product quality and longevity. They contribute to the stability and visual appeal of emulsified products such as beverages, dressings, sauces and desserts. Additionally, materials to extend the shelf life of food items. their ability to boost the bioavailability of vitamins and nutraceuticals as well as to improve the dispersion and compatibility of hydrophobic components like oil-soluble antioxidants, antimicrobials, colours, and, flavours highlight their significant role in this industry (Mushtaq A et al., 2023).

In the cosmetic industry, nanoemulusions are employed to enhance the delivery and preparation of active ingredients into the skin. Their diminutive particle size allows for improved efficacy and performance of skincare formulation.

Similarly, the pharmaceutical industry benefits from nanoemulsion through enhanced drug solubility and bioavailability. This is particularly advantageous for delivering poorly water –soluble drugs, offering more effective treatment options this review provides an in – depth exploration of nanoemulsion formulation and production methods. It also examines their recent applications in the food, pharmaceutical and cosmetic five years. Through this review, readers will gain a thorough understanding of the evolving role of nanoemulusions and their impact across these industries.

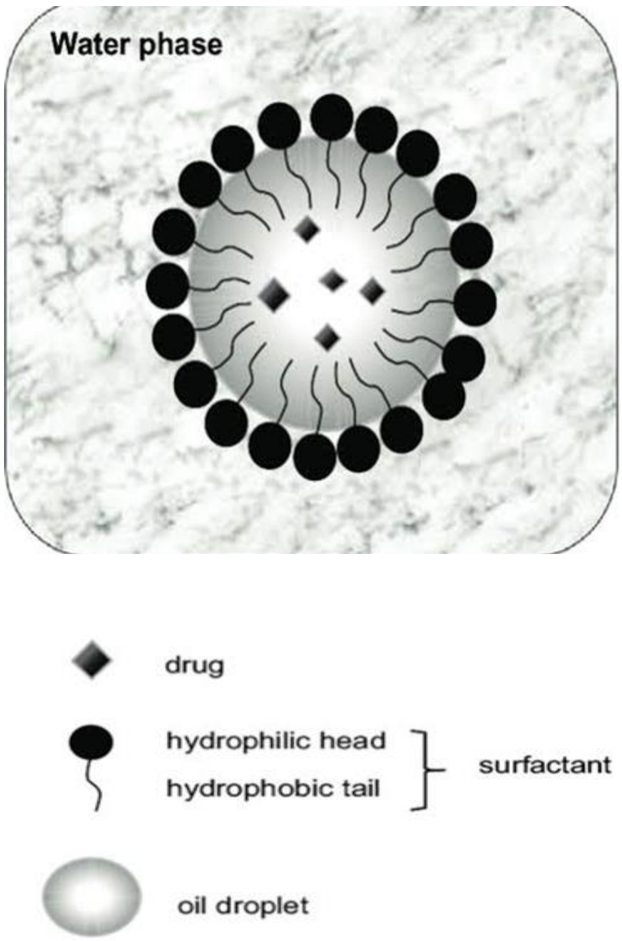

Figure 1. Structure of Nanoemulsion.

Nanoemulsions are colloidal dispersion of oil and water stabilized by surfactants and sometimes co-surfactants, forming droplets typically in the size range of 20-200nm.

Selection of ingredients: for nanoemulsion formulation, the choice of ingredients is crucial typically, safe and natural components that are generally recognized as safe (GRAS) are preferred. These can include surfactants like tweens and spans, which are commonly used due to their low toxicity and ability to stabilize the emulsion (Shukla P et al., 2023).

1. **Methods for Increasing Stabilty:** chemical stability of Nanoemulsions can be enhanced through several methods (McClements D et al., 2023).
2. **Incorporation of Antioxidants or Chelating Agents:** this helps in preventing oxidation of oils and maintaining stability (Liu Q et al., 2019).
3. **Manipulation of interfacial characteristics:** Adjusting factors like surface charge, interfacial thickness, and chemical reactivity can improve stability (Cai Z et al., 2023)
4. **Materials used for Preparation:** different materials can be used in Nanoemulsions preparation, each with specific properties. These materials often include lipids (oils), proteins, polysaccharides, or composites thereof. Each material choice can influence the stability, viscosity, and functionality of the nanoemulsion (Pavoni L et al., 2020).

Formation of Nanoemulsions:

Nano-emulsions are non-equilibrium systems that cannot form spontaneously and require an external energy input to overcome the energy barrier associated with droplet formation and stabilization. This energy is typically introduced through high-energy emulsification techniques, which involve mechanical devices designed to deliver intense forces to the emulsion system. The primary methods include:

1) **High energy methods:**

A) High-Shear Stirring: Generally, Nanoemulsions produced using 'high-energy' methods necessitate specific devices to deliver sufficient energy for increasing the water/ oil interfacial area, thereby generating submicronic droplets. High-energy mechanical processes—such as stirring, pressure, micro fluidization, high-pressure homogenization, or sonication—break up macroscopic droplets into smaller ones. Nanoemulsions created via these dispersion or high-energy emulsification techniques are well-documented in the literature. These methods typically involve two key steps: (i) deforming and disrupting large droplets into smaller ones, and (ii) ensuring surfactant adsorption at the droplet interface for steric stabilization. It has been observed that equipment providing energy most rapidly and generating the most uniform flow also produces the smallest particulate sizes. To formulate nanoemulsions, the applied force must greatly exceed the interfacial energy to achieve large interfacial areas necessary for nanoscale emulsification. Under such extreme forces, larger droplets are broken into smaller ones due to the generated fluid stresses, which overcome the interfacial tension between the immiscible liquids (Ricaurte L et al., 2016).

b) High-Pressure Homogenization: In this technique, the emulsion is forced through a narrow gap or valve under extremely high pressure. This process induces high shear and cavitation forces, which effectively reduce droplet size to the nanoscale and improve the uniformity of the emulsion. High-pressure homogenizers are known for their ability to produce very stable and consistent nano-emulsions due to the controlled application of energy. High pressure homogenization (HPH) is the most popular method for preparation of nanoemulsions. The technique relies on the powerful cavitation phenomenon to disrupt and produce smaller sizes oil droplets. Other factors such as homogenisation pressure and number of cycles can profoundly influence the mean droplet size and particle distributions. A high-pressure homogenizer is used to produce high pressure over the mixture of oil phase, aqueous phase and surfactant or co-

c) Ultrasound Generators:

The preparation of nanoemulsions via ultrasonication is increasingly favoured by formulators due to its remarkable energy efficiency, minimal equipment requirements, ease of system manipulation, and notably low production costs. Ultrasonic emulsification disperses one liquid into another immiscible liquid using acoustic fields. The key mechanism is cavitation, where vapor bubbles rapidly form and collapse in the liquid under reduced pressure at ambient temperature. This bubble collapse generates pressurized shock waves, creating intense localized turbulence and significant shear forces that propagate through the liquid, resulting in high-velocity liquid jets. These effects enhance the mixing of the emulsion near the collapsing bubbles and disrupt the droplets.

Ultrasonic waves efficiently disperse the oil phase into the water phase, forming monodisperse droplets with diameters under 100 nm. According to Canselier et al., the process involves a two-step mechanism: initially, interfacial waves and system instability cause the dispersed phase droplets to explode into the continuous phase; subsequently, cavitation near the interface further breaks down these droplets. However, despite its potential, this method is currently limited to small batch sizes and remains primarily suitable for laboratory research rather than industrial-scale production (harma N et al., 2013).

2) Low-Energy Methods:

a) Phase Inversion Temperature: : These methods involve changing the emulsification conditions, such as temperature or the addition of surfactants, to induce a phase inversion. For example, the phase inversion temperature (PIT) method uses temperature changes to trigger the inversion of the emulsion from oil-in-water to water-in-oil or vice versa, resulting in nano-sized droplets (Banker GS et al., 2002).

b) Spontaneous Emulsification: This technique relies on the chemical potential difference between the components to create emulsions. By mixing specific surfactants and solvents, the system naturally forms nano-sized droplets without the need for extensive mechanical energy input (Guilleme J et al., 2016).

c) Microfluidic Devices: Utilize microchannels to precisely control the flow of fluids and induce the formation of nano-sized droplets through hydrodynamic focusing or other microfluidic phenomena. This method allows for fine control over droplet size and distribution with relatively low energy input compared to traditional high-energy methods Studies have shown that the apparatus providing the energy input most efficiently and rapidly—while maintaining precise control over the process—tends to produce nano-emulsions with superior stability, smaller droplet sizes, and greater uniformity. This method allows for fine control over droplet size and distribution with relatively low energy input compared to traditional high-energy methods Studies have shown that the apparatus providing the energy input most efficiently and rapidly—while maintaining precise control over the process—tends to produce nano-emulsions with superior stability, smaller droplet sizes, and greater uniformity. The choice of method and equipment can significantly impact the final characteristics of the nanoemulsion, including its stability, appearance, and performance in various applications such as pharmaceuticals, cosmetics, and food products (Von Corswant C et al., 1998).

Properties of Nanoemulsions:

- Nanoemulsions offer a larger surface area, and their free energy enhances their effectiveness in transportation.
- Due to their small droplet size, nanoemulsions do not experience creaming, sedimentation, flocculation, or coalescence over time.
- Nanoemulsions are therapeutically valuable as they are non-damaging to human and animal cells.
- Their small droplet sizes facilitate transdermal penetration.
- Compared to microemulsions, Nanoemulsions require a smaller number of surfactants.
- The very small droplet sizes prevent flocculation in nanoemulsions, allowing them to remain uniformly dispersed in the system (Floyd AG et al., 1999).

Biphasic Nanoemulsions:

- Water-in-Oil (W/O): The water droplets are dispersed in a continuous oil phase.
- Oil-in-Water (O/W): The oil droplets are dispersed in a continuous water phase.
- Multiple Nanoemulsions: These involve more complex structures with multiple layers or phases (Sole I et al., 2010).

Phase Volume Ratio:

- This ratio indicates the proportion of the internal phase (dispersed droplets) to the continuous phase. It affects the stability and droplet quantity of the nano emulsion.
- The phase present in a larger volume usually becomes the continuous (external) phase of the nano emulsion.
- Phase inversion refers to the physical process where an emulsion changes from oil-in-water (o/w) to water-in-oil (w/o), or vice versa. This change can be induced by adjusting the phase volume ratio, adding electrolytes, or altering the temperature (Sharma SN et al., 1985).

Role of Emulsifiers:

The type of emulsifier used (hydrophilic or lipophilic) influences the type of nanoemulsion formed.

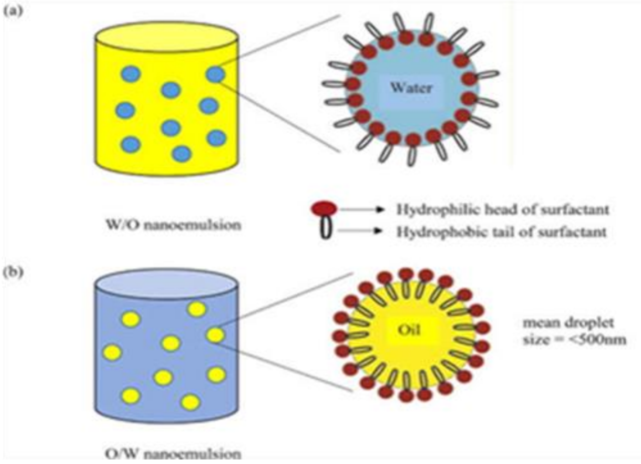

Figure 2. Types of Nanoemulsions

Lipophilic Emulsifiers: Favor W/O emulsions.

Hydrophilic Emulsifiers: Favor O/W emulsions.

The emulsifier's polar region generally acts as a better barrier to droplet coalescence compared to its hydrocarbon region. In essence, the type of nanoemulsion you get depends on the balance of phases and the nature of the emulsifier used. The emulsifier's characteristics help determine whether the final nanoemulsion will be oil-in-water, water-in-oil, or more complex, and also influence its stability and performance (Preeti S et al., 2023).

Applications

Nanoemulsion in Drug Delivery:

Nanoemulsions have found diverse applications in drug delivery, including topical, ocular, intravenous, intranasal, and oral routes. Their versatility arises from their ability to solvate water-insoluble drugs due to their lipophilic nature and to formulate aqueous solutions with tuneable charge and rheology, facilitating easy administration (Thakur N et al., 2012).

A. Nanoemulsion and Drug Targeting:

Nanoemulsions are emerging as promising carriers for controlled and targeted drug delivery, especially in oncology. Their submicron size facilitates precise targeting to tumor sites, improving the effectiveness of treatments. Historically used for delivering aqueous-insoluble drugs, nanoemulsions are now being explored for a variety of applications including anticancer drugs, photosensitizers, neutron capture therapy agents, and diagnostic tools. A particularly innovative approach involves magnetic nanoemulsions, which, when combined with photosensitizers like Foscan®, can induce hyperthermia and produce free radicals for photodynamic therapy. This technology holds potential for enhanced treatment through localized and controlled action in breast cancer (Primo FL et al., 2007).

B. Drug Delivery via Transdermal Nanoemulsions:

Transdermal delivery provides a convenient drug administration method, enabling controlled drug release with minimal side effects and enhancing patient compliance. Unlike oral routes, it avoids first-pass metabolism and gastrointestinal side effects such as diarrhoea and nausea, as well as drug degradation in the gut. However, the Stratum corneum, the outermost layer of the skin composed of flattened, anucleated keratinocytes (corneocytes), poses a barrier to the entry of hydrophilic drugs. This layer significantly impedes the penetration of both xenobiotics and therapeutic agents. Therefore, the skin's permeability to drugs, which is influenced by their pKa and oil-in-water partition coefficient, is a key factor affecting their bioavailability through transdermal delivery (Souto EB et al., 2020).

C. Drug Delivery via Pulmonary Nanoemulsions:

The application of nanoemulsions in pulmonary drug delivery is still in its infancy but shows promise, particularly as alternatives to liposomes for gene transfer. Submicron emulsions have demonstrated the ability to transfect pulmonary epithelial cells effectively, which can stimulate antigen-specific T cells and potentially enhance vaccine efficacy. However, challenges remain, including potential adverse effects on lung function from the oils and emulsifiers used. Further research is needed to address these issues and optimize formulations for safe and effective pulmonary administration (Bivas-Benita M et al., 2004).

D. Delivery of Parenteral Drugs Using Nanoemulsions:

Nanoemulsions are well-suited for parenteral drug delivery, especially for drugs with low bioavailability or stability issues. They can solubilize large amounts of hydrophobic drugs, protect them from degradation, and provide sustained, controlled release. This results in reduced injection frequency and improved patient compliance. Studies have shown that nanoemulsion formulations can enhance the pharmacokinetics and anticancer activity of drugs, such as in the case of colon adenocarcinoma treatment in mice. Additionally, nanoemulsions have been developed for intravenous administration of drugs like carbamazepine, demonstrating their versatility and effectiveness in overcoming solubility challenges (Ganta S et al., 2010).

E. Delivery of Ophthalmic Drugs Using Nanoemulsions:

Ophthalmic drug delivery using nanoemulsions offers significant advantages due to their ability to penetrate the ocular surface and prolong drug residence time. They improve the bioavailability of drugs for conditions such as glaucoma, allowing for lower doses and reduced systemic side effects. Nanoemulsions are versatile carriers capable of including both hydrophilic and hydrophobic drugs, making them suitable for a wide range of ocular conditions. Their lower viscosity compared to traditional formulations enhances patient comfort and compliance (Dhahir RK et al., 2021).

F. Delivery of Intranasal Drugs Using Nanoemulsions

Intranasal drug delivery using nanoemulsions is emerging as a non-invasive and effective route for systemic drug administration. The nasal mucosa offers a direct pathway to the brain, making it an attractive option for treating central nervous system disorders like Alzheimer's, Parkinson's, and depression. Nanoemulsions can enhance drug delivery through the nasal cavity, bypassing the blood-brain barrier and providing targeted treatment. Additionally, they show promise in vaccine delivery by protecting antigens and facilitating their interaction with mucosal surfaces and lymphoid tissues (Kumar M et al., 2008).

G. **Topical Delivery**

Topical drug delivery presents several advantages over oral administration, including bypassing first-pass metabolism, avoiding drug degradation in the gastrointestinal tract, preventing gastric irritation, eliminating unpleasant taste or administration difficulties, and removing the need for disintegration and dissolution steps. However, a major challenge is the skin barrier, which hinders drug absorption into systemic circulation. Nanoemulsion-based topical drug delivery can significantly overcome this barrier. Drugs generally penetrate the skin through three main routes: hair follicles, sweat ducts, and directly through the stratum corneum. Nanoemulsions enhance this process by combining hydrophobic and hydrophilic components that aid penetration through both the hydrophobic stratum corneum and the hydrophilic sweat ducts. For example, ropinirole, a drug with low oral bioavailability and frequent dosing requirements, shows improved skin penetration and extended release when delivered as a nanoemulsion gel. This formulation has been found to increase the relative bioavailability of ropinirole by more than twofold compared to conventional gels (Azeem A et al., 2011).

H. Oral Delivery

Nanoemulsions are employed in oral drug delivery to improve the solubility and bioavailability of poorly soluble drugs. Formulations are tested under conditions that mimic the small intestine environment to evaluate absorption efficiency (Prakash UR et al., 2011).

I. Imaging and Therapy

Beyond drug delivery, Nanoemulsions are also used as ultrasound imaging agents. For example, Kaneda et al. developed Nanoemulsions with perfluorocarbons for quantitative molecular imaging and targeted therapeutics. Gianella et al. created a multifunctional nanoemulsion platform for imaging-guided therapy. In their study, oil-in-water Nanoemulsions were designed to carry iron oxide nanocrystals for MRI, the fluorescent dye Cy7 for near-infrared fluorescence (NIRF) imaging, and the hydrophobic glucocorticoid prednisolone acetate valerate for therapeutic purposes. This approach was evaluated in a colon cancer mouse model,

demonstrating the potential for combined imaging and therapeutic applications (Gianella A et al., 2011).

Overall, nanoemulsions Nanoemulsions represent a promising tool in pharmaceutical and medical applications due to their ability to enhance drug solubility, stability, and delivery across various routes, as well as their potential in advanced imaging and targeted therapies.

Recent Advances of Nanoemulsions:

Recent advances in nanoemulsions have led to their increased use in drug delivery systems, particularly in skin care. Here are some of the ways nanoemulsions are being utilized:

- **Improved skin penetration:** Nanoemulsions are being used to improve the penetration of drugs through the skin, which is especially useful for hydrophilic drugs.
- **Increased bioavailability:** Nanoemulsions are being used to increase the bioavailability of lipophilic drugs, which are often difficult for the body to absorb.
- **Targeted drug delivery:** Nanoemulsions are being used to target specific areas of the body, reducing side effects and improving efficacy.
- **Improved stability**: Nanoemulsions are being used to improve the stability of drugs, which can degrade quickly when exposed to light, temperature, or other environmental factors.
- **Increased patient compliance:** Nanoemulsions are being used to improve patient compliance, as they can be formulated to be more comfortable and easier to use (Chime SA et at., 2014).

Future Perspective of Nanoemulsions:

The future perspective of nanoemulsions is promising, with potential applications in:

1. Personalized medicine: Nanoemulsions can be tailored to individual patient needs, improving treatment outcomes.

2. Cancer therapy: Targeted nanoemulsions can enhance drug delivery to tumors, reducing side effects (Singh R et al., 2020).

3. Gene therapy: Nanoemulsions can efficiently deliver genetic material to cells, potentially treating genetic diseases (Rao SSM et al., 2013).

4. Vaccine development: Nanoemulsions can improve vaccine efficacy and stability, enabling widespread use Infectious viral diseases and outbreaks are evolving global threats, and managing them remains challenging due to the rapid genetic mutations of viruses. For instance, COVID-19, caused by SARS-CoV-2, quickly became a global pandemic following its emergence in December 2019. Despite ongoing global efforts to develop effective treatments and vaccines, COVID-19 continues to cause significant health, social, and economic disruptions. Nanoemulsions (NEs), which are stable mixtures of oil and water stabilized by surfactants, offer a promising solution. Their droplets range from 10 to 1000 nm and are stabilized by surfactants that prevent coalescence and phase separation. Although NEs are thermodynamically unstable, careful selection of their components can enhance their stability and shelf life, which is crucial for effective medical applications (Tayeb HH et al., 2021).

5. Topical and transdermal delivery: Nanoemulsions can enhance skin penetration, improving treatment of skin conditions Brownian movement, which is common in some pharmacological systems, facilitates diffusion through the skin. Nanoemulsions, with their notable Brownian motion, are expected to enhance skin penetration due to their high kinetic activity. This makes them especially effective for delivering drugs that have poor solubility in both water and lipids (Anissimov YG et al., 2012).

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6. Food and beverage industry: Nanoemulsions can improve nutritional supplement delivery and food product stability they also play a vital role in flavour enhancement Flavors give food its unique taste and aroma. However, because many flavour compounds are structurally unstable, encapsulation offers a promising method to preserve their distinct characteristics. Using nanoemulsion systems for flavour encapsulation enhances their stability by increasing the surface area, which promotes rapid dissociation and improved reactivity this approach also helps reduce gravitational separation and enhances physical stability during aggregation The combination of gelatin and Tween 20 improved the stability of citral in acidic conditions, making it an effective emulsifier for protecting citral from degradation in acidic environments within the food industry (Tian H et al., 2017).

7. Cosmetics and personal care: Nanoemulsions can enhance product stability, efficacy, and by rising demands for enhanced product efficacy have blurred the lines between cosmetics and topical pharmaceuticals, making it harder to distinguish between the two. 'Cosmeceuticals' attract significant consumer interest as they occupy the intermediary space between cosmetics and pharmaceuticals (Katz LM et at., 2015).

8. Wound healing: Nanoemulsions can deliver growth factors and antimicrobials to promote wound healing antimicrobial nanoemulsions are oil-in-water (o/w) emulsion systems stabilized by surfactants and alcohols, which act as co-surfactants. These nanoemulsions, with particle sizes between 200 and 600 nm, are effective against various bacteria, including S. aureus, E. coli, and Salmonella (Patra vale VB et al., 2009).

9. Ophthalmic delivery: Nanoemulsions can improve drug delivery to the eye, treating ocular diseases unlike soft colloidal nanomaterials such as liposomes, solid nanomaterials applied to the eye may aggregate either upon contact with tear fluid or after penetrating the corneal barrier, potentially impacting their in vivo performance. This necessitates the use of advanced biological models to thoroughly evaluate the effectiveness of these formulations in living systems. Additionally, the lack of comprehensive regulatory guidelines and the complexities associated with scaling up production can drive up the development costs of new formulations (Khiev D et at., 2021).

10. Brain targeting: Nanoemulsions can potentially deliver drugs across the blood-brain barrier, treating neurological disorders, where a mucoadhesive nanoemulsion (NE) of risperidone was prepared by adding 0.50% (w/w) chitosan and stirring the dispersion for 1 hour. In vivo studies conducted on Swiss albino rats assessed drug distribution in the blood and brain following both intranasal and intravenous administration of the NEs and risperidone solutions, using technetium-99m (99mTc) labelling. The results demonstrated that intranasal administration of the chitosan-containing mucoadhesive NEs resulted in faster and more extensive drug transport into the central nervous system compared to nasal and intravenous NEs and solutions. Similar findings were reported for drug-loaded NEs containing olanzapine, a second-generation antipsychotic with broad efficacy (Kumar M et al., 2010).

Conclusion

In conclusion, Nanoemulsions have emerged as a cutting-edge drug delivery system, offering unprecedented opportunities for improving the efficacy, safety, and patient compliance of various therapeutic agents. Recent advances in nanoemulsion technology have enabled the development of optimized formulations with enhanced solubility, stability, and bioavailability. These systems have demonstrated remarkable potential in delivering a wide range of drugs, including hydrophobic and hydrophilic molecules, proteins, and nucleic acids.

The latest drug delivery nanoemulsions have shown remarkable advantages, including:

- Improved solubility and bioavailability of poorly water-soluble drugs
- Enhanced penetration and retention in targeted tissues
- Reduced toxicity and side effects
- Improved patient compliance due to ease of administration
- Flexibility in route of administration (oral, parenteral, topical, etc.)

Nanoemulsions offer multiple benefits, including precise drug release rates, extended therapeutic efficacy, reduced side effects, and protection against enzymatic and oxidative degradation. They also provide flexibility in manufacturing by accommodating various components. However, the application of nanoemulsions for brain tumor treatment is still evolving. Several critical issues need to be addressed before they can be used clinically for this purpose.

The brain's intricate structure poses significant challenges for effective targeting and delivery. To ensure safety and efficacy, extensive toxicological studies are necessary to evaluate potential adverse effects on brain tissue and overall health. This includes assessing the biocompatibility of nanoemulsions, understanding their interactions with neural tissue, and monitoring long-term effects. Moreover, research must focus on improving the precision of nanoemulsion targeting to ensure that drugs reach tumor sites effectively while minimizing off-target effects. Advanced imaging techniques and molecular profiling could aid in developing better-targeted formulations. Additionally, the stability and release kinetics of nanoemulsions need to be optimized to ensure consistent performance within the challenging environment of the brain. Addressing these challenges requires interdisciplinary collaboration, integrating insights from pharmacology, nanotechnology, and neuroscience. Rigorous preclinical and clinical evaluations will be crucial for advancing nanoemulsions from experimental to therapeutic applications in brain tumor treatment.

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