

A COMPREHENSIVE REVIEW ON NIOSOMES IN MODERN PHARMACEUTICS AS ADVANCED VESICULAR CARRIERS: FROM MOLECULAR DESIGN TO CLINICAL POTENTIAL

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ABSTRACT

Niosomes are advanced non-ionic surfactant-based vesicular nanocarriers that have gained significant attention in modern pharmaceuticals due to their ability to improve drug solubility, stability, bioavailability, and therapeutic efficiency. These vesicles consist mainly of non-ionic surfactants and cholesterol, forming a bilayer structure capable of encapsulating hydrophilic, hydrophobic, and amphiphilic drugs. Their advantages, including improved chemical stability, low cost, ease of preparation, and controlled drug release, make them attractive alternatives to conventional drug delivery systems. Recent advances in molecular design, formulation optimization, and surface modification have expanded their applications in ocular, transdermal, topical, oral, anticancer, vaccine, and targeted drug delivery. Different preparation approaches allow control over vesicle size, drug loading, and release behaviour, while advanced characterization techniques ensure evaluation of formulation quality and stability. Despite promising pharmaceutical applications, challenges related to large-scale manufacturing, stability, regulatory approval, and clinical translation remain. This review highlights recent developments in niosomal technology, focusing on molecular design, formulation components, preparation methods, characterization approaches, therapeutic applications, and future perspectives in modern drug delivery.

KEYWORDS: Niosomes; Non-ionic surfactant vesicles; Nanocarriers; Vesicular drug delivery; Controlled release; Targeted delivery; Pharmaceuticals.

1. INTRODUCTION

The development of efficient drug delivery systems is an important area of pharmaceutical research due to limitations associated with conventional dosage forms, including poor aqueous solubility, low bioavailability, rapid degradation, and lack of site-specific drug delivery. Nanotechnology-based approaches have provided promising solutions by improving drug stability, enhancing therapeutic activity, and enabling controlled release of active pharmaceutical ingredients.^[1,2]

Among various nanocarriers, vesicular systems such as liposomes, niosomes, transfersomes, and ethosomes have attracted considerable interest because of their ability to encapsulate a wide range of therapeutic molecules.^[3] Niosomes are closed bilayer vesicles composed mainly of non-ionic surfactants, cholesterol, and an aqueous phase, formed by the self-assembly of amphiphilic molecules.^[1]

The unique structure of niosomes consists of a hydrophilic aqueous core surrounded by a hydrophobic bilayer, allowing incorporation of both water-soluble and lipid-soluble drugs. This property makes niosomes suitable carriers for antibiotics, anticancer drugs, proteins, peptides, and other therapeutic molecules.^[2]

Niosomes are classified based on vesicle structure, composition, and preparation approaches, including conventional niosomes, proniosomes, and advanced surface-modified niosomal systems. Recent advances have expanded their role in controlled and targeted drug delivery applications.^[8]

Compared with liposomes, niosomes offer advantages such as better chemical stability, reduced susceptibility to oxidation, lower production cost, and greater flexibility in formulation design due to the use of non-ionic surfactants.^[3,4]

The performance of niosomes depends on various formulation factors, including surfactant type, hydrophilic–lipophilic balance (HLB), phase transition temperature, cholesterol concentration, and preparation method. These variables influence vesicle size, membrane rigidity, entrapment efficiency, and drug release behaviour.^[1]

Niosomes have shown significant potential in ocular drug delivery by improving drug retention, enhancing corneal penetration, and providing prolonged release of ophthalmic drugs.^[7] They have also been investigated for transdermal delivery, where their flexible vesicular structure improves penetration through the skin barrier and enhances drug deposition.^[5]

In cancer therapy, niosomes provide an effective platform for improving the delivery of anticancer agents by enhancing drug accumulation at target sites, reducing systemic toxicity, and providing controlled release.^[6]

Although niosomes demonstrate remarkable potential, challenges such as physical instability, drug leakage, scale-up difficulties, batch-to-batch variation, and regulatory issues remain major barriers for clinical translation.^[11]

Therefore, continuous research is required to optimize formulation strategies, improve stability, and establish standardized manufacturing approaches for successful clinical application of niosomal systems.

2. Molecular Design Of Niosomes

The molecular design of niosomes plays a crucial role in determining their physicochemical characteristics, stability, drug encapsulation efficiency, and biological performance. The formation and properties of niosomes are mainly influenced by the type of non-ionic surfactant, cholesterol content, surfactant-to-cholesterol ratio, surface charge, and preparation conditions.^[1,3]

Niosomes are formed through the self-assembly of amphiphilic non-ionic surfactant molecules in an aqueous environment. The hydrophilic head groups orient toward the aqueous phase, while the hydrophobic tails associate inward to form a bilayer structure.^[1] The incorporation of cholesterol between surfactant molecules improves membrane rigidity, reduces permeability, and enhances vesicle stability.^[2] The selection of surfactant is one of the most important molecular design parameters. Non-ionic surfactants such as Span and Tween series are commonly used because they provide good biocompatibility and flexibility in controlling vesicle characteristics.^[3] Surfactants with suitable hydrophilic–lipophilic balance (HLB) values promote stable bilayer formation and influence drug entrapment and release behaviour.^[12]

The molecular packing of surfactants, critical packing parameter, and interaction between surfactant and cholesterol determine vesicle morphology, membrane fluidity, and drug retention properties. Optimization of these parameters is essential for developing stable niosomal formulations.^[20]

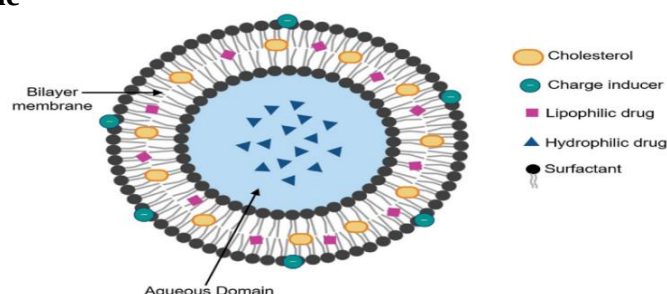
The phase transition temperature (T_c) of the surfactant affects membrane fluidity and vesicle stability. Surfactants with higher phase transition temperatures generally produce more rigid vesicles with slower drug release, whereas lower transition temperature surfactants form more flexible membranes.^[1,3]

Cholesterol acts as a membrane stabilizer by filling gaps between surfactant molecules. It improves mechanical strength, prevents leakage of encapsulated drug, and regulates membrane permeability. However, excessive cholesterol concentration may reduce drug entrapment by decreasing available space within the bilayer.^[2,4]

Surface charge modification is another important strategy in niosomal design. Charge-inducing agents such as dicetyl phosphate (negative charge) or stearylamine (positive charge) can be incorporated to increase electrostatic repulsion between vesicles and reduce aggregation.^[4]

Advanced molecular designs include surface-modified and targeted niosomes. Attachment of ligands, polymers, antibodies, or other targeting molecules can enhance tissue-specific delivery and improve therapeutic outcomes.^[15,17]

Structure of niosome



3. Components Of Niosomes

Niosomes are primarily composed of non-ionic surfactants, cholesterol, charge-inducing agents, and an aqueous hydration medium. Each component contributes to vesicle formation, stability, drug loading, and release characteristics.

S. no.	Component	Examples	Function
1	Non-ionic surfactants	Span 20, Span 60, Span 80, Tween 20, Tween 60, Tween 80	Formation of bilayer structure and vesicle formation
2	Cholesterol	Cholesterol	Improves membrane rigidity and stability
3	Charge-inducing agents	Dicetyl phosphate, Stearylamine	Enhances zeta potential & prevents aggregation
4	Hydration medium	Water, PBS	Provides aqueous environment for vesicle formation
5	Targeting molecules	Ligands, antibodies, polymers	Improves site-specific drug delivery

4. Preparation Methods Of Niosomes

The preparation method strongly influences the physicochemical characteristics of niosomes, including vesicle size, morphology, drug entrapment efficiency, lamellarity, and stability. Selection of an appropriate preparation technique depends on the nature of the drug, surfactant properties, desired vesicle size, and intended route of administration.^[1,2]

In the preparation of niosomes, formulation optimization using statistical experimental designs such as Box–Behnken design and response surface methodology helps evaluate the influence of formulation variables, including surfactant concentration, cholesterol ratio, and processing conditions, on critical quality attributes.^[14]

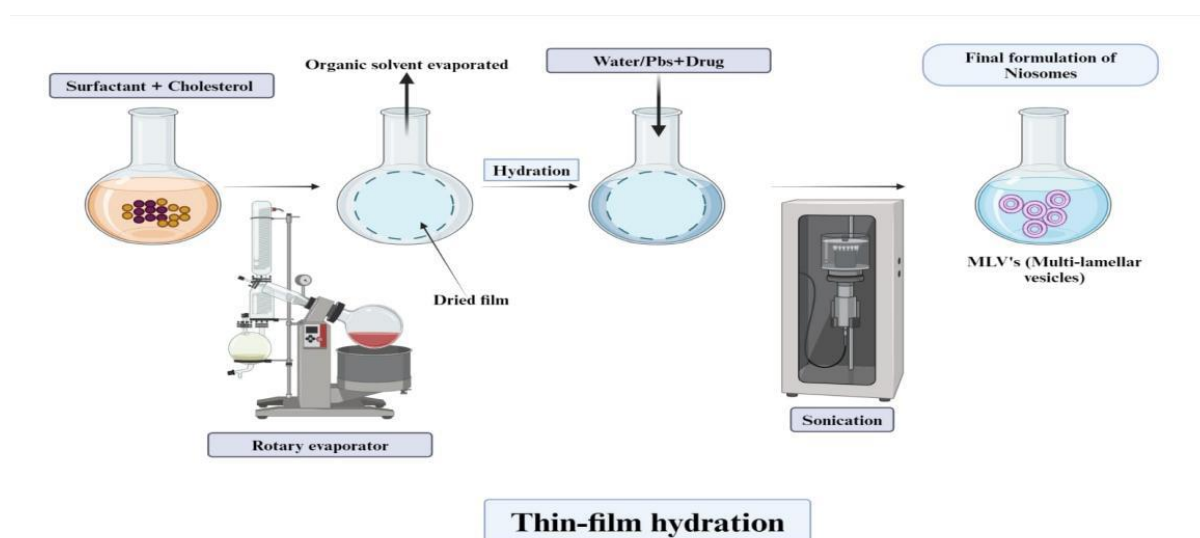
Several conventional and advanced techniques have been developed for niosome preparation, including thin-film hydration, reverse-phase evaporation, ether injection, sonication, microfluidization, and proniosome-based methods.^[1]

4.1 Thin Film Hydration Method

Thin-film hydration is one of the most widely used methods for preparing niosomes, especially in pharmaceutical research. In this technique, surfactant and cholesterol are dissolved in an organic solvent such as chloroform or methanol. The organic solvent is evaporated under reduced pressure using a rotary evaporator, producing a thin lipid film. The dried film is then hydrated with an aqueous phase containing the drug, resulting in formation of multilamellar niosomal vesicles.^[1,2]

Thin film hydration remains one of the most widely adopted methods due to its simplicity and ability to produce multilamellar vesicles; however, additional size reduction techniques are often required to obtain nanosized vesicles.^[21]

Further size reduction can be achieved using sonication or extrusion techniques. The method provides good drug entrapment and is suitable for both hydrophilic and hydrophobic drugs.^[1]

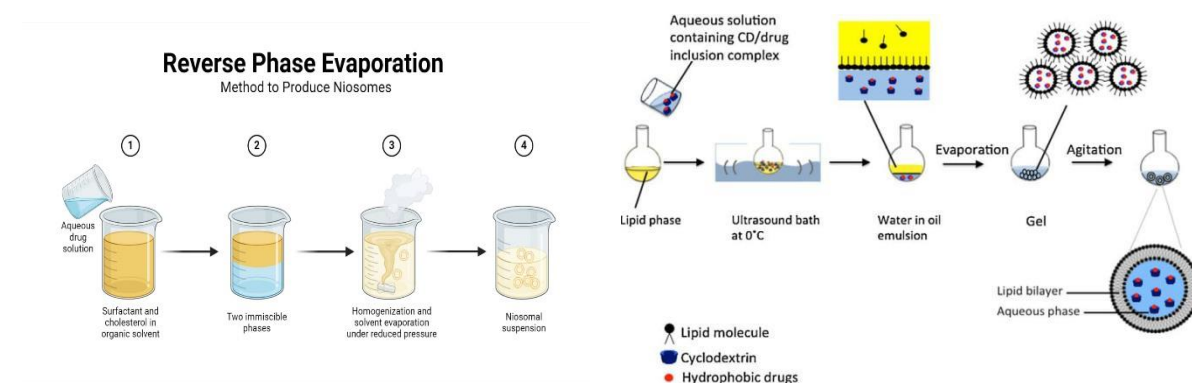


4.2 Reverse Phase Evaporation Method

Reverse-phase evaporation produces large unilamellar vesicles with higher aqueous volume entrapment. In this method, surfactant and cholesterol are dissolved in an organic solvent, followed by addition of an aqueous drug solution to form a water-in-oil emulsion. Removal of the organic solvent results in formation of niosomal vesicles.^[1,3]

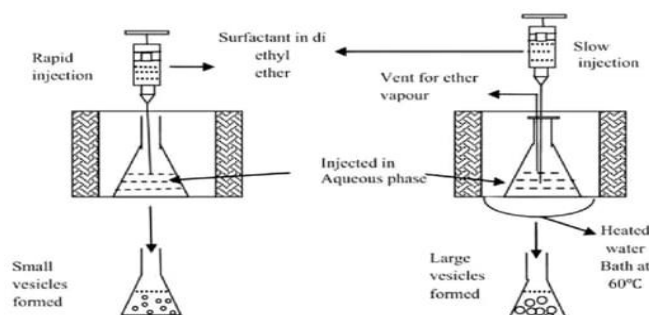
Reverse phase evaporation is advantageous for encapsulation of hydrophilic molecules because of the large aqueous volume available inside vesicles.^[22]

This method is particularly useful for encapsulating hydrophilic drugs, peptides, and proteins because of the increased aqueous space available inside vesicles.^[2]



4.3 Ether Injection Method

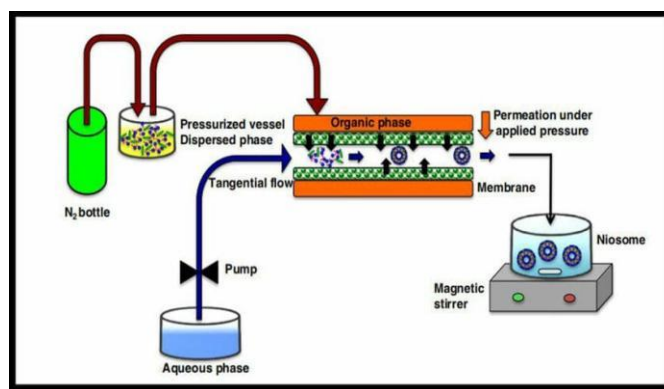
In the ether injection method, surfactant and cholesterol are dissolved in diethyl ether and slowly injected into a heated aqueous phase. Evaporation of ether leads to formation of niosomal vesicles.^[1]



The size of vesicles depends on: Injection rate, Temperature, Surfactant concentration.

4.4 Sonication Method

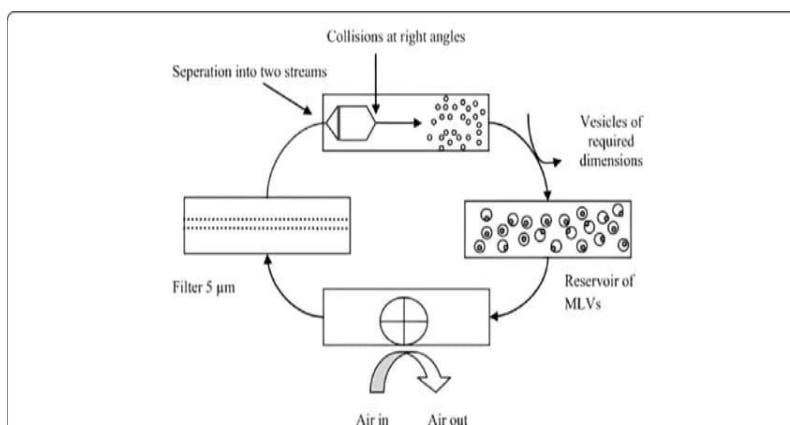
Sonication is used for reducing vesicle size and obtaining smaller niosomes. The prepared niosomal dispersion is subjected to ultrasonic energy using bath or probe sonication, which reduces particle size by disrupting larger vesicles.^[1,3]



4.5 Microfluidization Method

Microfluidization is an advanced preparation technique where surfactant and aqueous phases are passed through microchannels under high pressure. The intense mixing forces produce uniform nanosized vesicles with narrow size distribution.^[1]

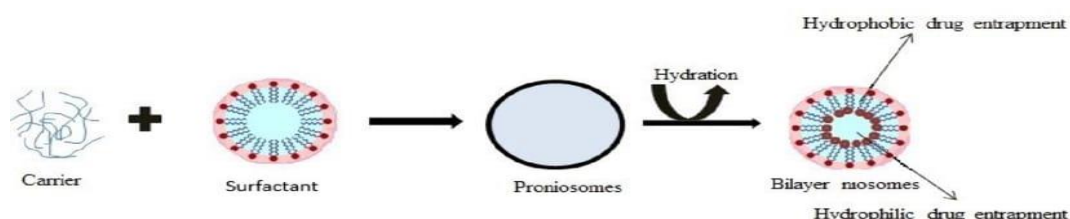
This method provides better control over particle size and reproducibility compared with conventional techniques. Recent studies highlight microfluidics and related technologies as promising approaches for industrial-scale niosome production.^[1]



4.6 Proniosome Method

Proniosomes are dry formulations containing non-ionic surfactants and other components that form niosomes upon hydration. They improve stability by reducing problems associated with aqueous niosomal dispersions, such as aggregation and drug leakage.^[5]

Proniosomes are considered promising alternatives for improving storage stability and large-scale manufacturing of niosomal systems.^[5]



5. Characterization of Niosomes

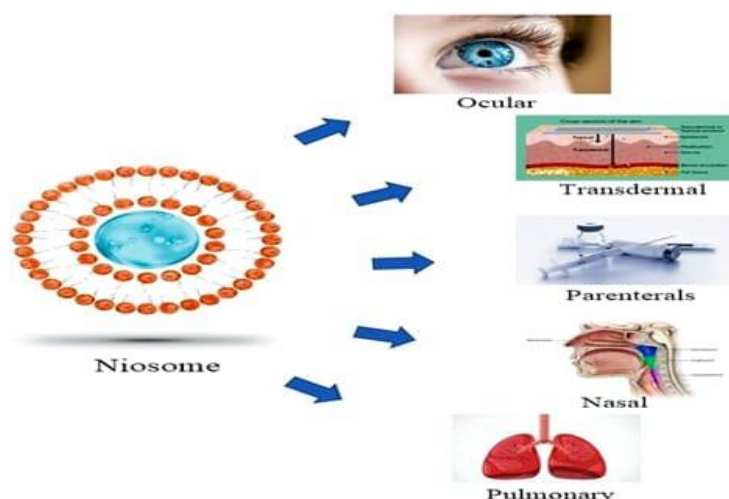
Characterization of niosomes is essential to evaluate their physicochemical properties, stability, drug-loading capacity, and suitability as vesicular drug delivery systems. The major characterization parameters include particle size, polydispersity index (PDI), zeta potential, morphology, entrapment efficiency, vesicle structure, drug–excipient compatibility, in vitro drug release, and stability studies. These parameters influence drug delivery performance, bioavailability, and therapeutic efficacy of niosomal formulations.^[29]

Particle size and polydispersity index are critical quality attributes because they influence stability, cellular uptake, tissue penetration, and drug release behaviour.^[23]

Optimization of niosomal formulations requires systematic evaluation of particle size, polydispersity index, entrapment efficiency, and drug release behaviour to establish the relationship between formulation variables and performance characteristics.^[1]

S.no	Parameter	Instrument	Significance
1	Vesicle size	Dynamic light scattering	Determines particle size and predicts drug delivery behaviour
2	Size distribution	PDI measurement by DLS	Evaluates uniformity of vesicle population
3	Zeta potential	Zeta potential analyser	Determines surface charge and physical stability
4	Morphology	TEM, SEM	Confirms vesicle shape, structure, and integrity
5	Entrapment efficiency	Centrifugation, dialysis, ultrafiltration	Determines amount of drug incorporated inside vesicles
6	Drug loading	UV spectroscopy/HPLC	Measures drug content in formulation
7	Drug release	Dialysis membrane/Franz diffusion cell	Evaluates sustained and controlled release
8	Release kinetics	Mathematical modelling	Determines mechanism of drug release
9	FTIR analysis	Fourier transform infrared Spectroscopy	Evaluates drug-excipient compatibility
10	DSC analysis	Differential scanning calorimetry	Studies thermal behaviour and molecular interactions
11	Stability study	Storage under different conditions	Determines shelf life and formulation stability

6. Therapeutic Applications Of Niosomes



6.1 Ocular Drug Delivery

Ocular drug delivery is challenging because of physiological barriers such as tear dilution, blinking, nasolacrimal drainage, and limited corneal permeability, which result in poor drug bioavailability from conventional eye drops.^[7]

Niosomes provide an effective approach for ocular delivery by increasing precorneal residence time, improving drug penetration, and enabling sustained release of ophthalmic drugs.^[7,13,24]

6.2 Transdermal Drug Delivery

The stratum corneum acts as a major barrier limiting penetration of many therapeutic agents through the skin. Niosomes improve transdermal delivery by enhancing drug partitioning into skin layers and acting as penetration-enhancing vesicular carriers.^[5,10,25]

6.3 Topical Drug Delivery

Topical delivery aims to achieve localized drug action while minimizing systemic exposure. Niosomes incorporated into gels and creams improve drug deposition within skin layers and provide prolonged drug release.^[2,5]

6.4 Oral Drug Delivery

Oral administration remains the preferred route due to convenience and patient compliance; however, poor solubility, enzymatic degradation, and gastrointestinal barriers limit the bioavailability of many drugs.^[2]

Niosomes can improve oral drug delivery by protecting drugs from degradation, enhancing intestinal absorption, and providing sustained release.^[1,2]

6.5 Cancer Drug Delivery

Cancer therapy is one of the most explored applications of niosomes because conventional chemotherapy often suffers from poor selectivity and systemic toxicity.^[6,19]

6.6 Vaccine Delivery

Niosomes have gained interest as vaccine delivery carriers because they can protect antigens from degradation and enhance immune responses.^[2]

6.7 Gene and Biological Molecule Delivery

Recent research has expanded niosomal applications toward delivery of biological molecules such as DNA, RNA, peptides, and proteins.^[2,17] Niosomes protect genetic materials from enzymatic degradation and improve cellular uptake through vesicular transport mechanisms.^[17,26]

7. Clinical Potential of Niosomes

Niosomes have demonstrated significant potential as advanced pharmaceutical carriers due to their versatility, biocompatibility, and ability to improve therapeutic performance of various drugs. Their capability to encapsulate both hydrophilic and hydrophobic molecules makes them suitable for delivery of small molecules, proteins, peptides, and genetic materials.^[1,2]

The controlled release characteristics of niosomes can improve drug residence time, reduce dosing frequency, and enhance patient compliance compared with conventional formulations. Their ability to modify surface properties also provides opportunities for targeted and site-specific drug delivery.^[15,17]

Niosomal formulations have shown promising outcomes in preclinical studies for ocular, transdermal, topical, and anticancer applications. Ocular niosomes improve drug retention and penetration, whereas cancer-targeted niosomes enhance therapeutic efficacy by improving drug accumulation at tumour sites.^[6,7]

The development of multifunctional niosomes, including ligand-modified and stimuli-responsive systems, has expanded their potential in precision medicine and advanced therapeutic delivery.^[2,15]

8. Challenges Associated with Niosomal Drug Delivery

Although niosomes offer several advantages, certain challenges limit their clinical translation.

8.1 Physical and Chemical Stability

A major limitation of conventional niosomal dispersions is instability during storage. Vesicles may undergo: Aggregation, Fusion, Drug leakage, Changes in vesicle size.

These changes may reduce therapeutic effectiveness and affect product quality.^[1,11]

Strategies such as cholesterol optimization, surface modification, and development of proniosomal systems have been explored to improve stability.^[5,27]

8.2 Scale-Up and Manufacturing Challenges

Most niosomal formulations are developed at laboratory scale, and transferring these processes to industrial production remains challenging.

Major scale-up issues include: Maintaining uniform particle size, Achieving batch-to-batch reproducibility, Controlling production parameters, Reducing manufacturing cost, Advanced techniques such as microfluidization may improve large-scale production and reproducibility.^[1,28]

8.3 Drug Loading and Release Limitations

Some drugs show low entrapment efficiency due to their physicochemical properties, including poor solubility and limited interaction with the vesicle membrane. Optimization of surfactant type, cholesterol concentration, and formulation conditions is required to improve drug loading.^[1,3]

8.4 Safety and Regulatory Concerns

Although non-ionic surfactants generally possess good biocompatibility, detailed evaluation of long-term toxicity, biodegradation, immunogenicity, and safety is necessary before clinical approval.^[11]

Standardized regulatory guidelines for characterization, quality control, and manufacturing of niosomal products are still developing.^[18]

9. Future Perspectives

Current research is focused on developing advanced niosomal systems with improved targeting ability, multifunctional properties, and optimized formulation strategies for clinical translation.^[9]

9.1 Surface-Modified and Targeted Niosomes

Surface modification using ligands, antibodies, peptides, and polymers can improve selective drug delivery to specific cells or tissues. These approaches are particularly promising for cancer therapy and targeted delivery applications.^[15,17]

9.2 Stimuli-Responsive Niosomes

Stimuli-responsive niosomes are designed to release drugs in response to specific biological conditions such as:

pH changes

Temperature variations

Enzymatic activity

External stimuli

These systems provide improved control over drug release and may enhance therapeutic outcomes.^[2]

9.3 Combination with Emerging Nanotechnologies

Integration of niosomes with other nanotechnology platforms may provide multifunctional delivery systems with improved targeting, imaging capability, and therapeutic efficiency. Such hybrid systems may contribute to the development of next-generation personalized medicine approaches.^[2,17]

9.4 Clinical Translation and Commercial Development

For successful commercialization, future research should focus on:

Scalable manufacturing methods

Long-term stability studies

Standardized characterization protocols

Clinical safety evaluation

Regulatory approval pathways

These improvements will support the transition of niosomal systems from experimental research to clinically available pharmaceutical products.^[1,11]

10. CONCLUSION

Niosomes represent a promising and versatile vesicular drug delivery platform with considerable potential in modern pharmaceuticals. Their unique molecular structure enables efficient encapsulation of a wide range of therapeutic molecules while improving drug stability, bioavailability, and controlled release properties.

Advances in surfactant selection, formulation optimization, surface modification, and characterization techniques have expanded their applications in ocular, transdermal, topical, oral, anticancer, vaccine, and targeted drug delivery systems.

Despite their advantages, challenges related to stability, large-scale production, regulatory requirements, and clinical translation must be addressed. Continuous advancements in nanotechnology and pharmaceutical formulation strategies are expected to enhance the clinical acceptance of niosomes and establish them as important carriers for future drug delivery applications.

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