

Modern Perspectives on Niosomal Drug Delivery: Technological Progress, Mechanisms of Action, and Biomedical Applications

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Abstract

Niosomal drug delivery systems have become versatile drug nanocarriers because of its structural flexibility, physicochemical stability, cost effectiveness and capacity to encapsulate both hydrophilic and hydrophobic therapeutic agents. It composed of mainly of non-ionic surfactants and cholesterol, niosomes provide controlled release of the drugs, improved bioavailability and better pharmacokinetic profiles as compared to conventional delivery systems. This is a critical analysis of the technological development of niosomes focusing on the most important physicochemical and biopharmaceutical variables that modulate the stability of the vesicle, the loading of the drug, the biodistribution and the therapeutic efficacy of the formulation. Advances in formulation strategies such as one such approach: microfluidic fabrication, surface functionalization, stimuli-responsive designs, and hybrid architectures, have greatly increased their biomedical uses in the fields of oncology, dermatology, infectious diseases, neurological disorders, gene and vaccine delivery. Mechanistic understandings of cellular uptake, barrier penetration, and control release are pointed out. In spite of some significant progress, there are still challenges concerning long term stability, large scale manufacturing, and harmonizing regulations. Future combination of Quality by Design, artificial intelligence, and continuous manufacturing is likely to facilitate clinical translation of niosomal nanomedicines.

Keywords: Niosomes; Nanotechnology; Controlled drug delivery system; Stimuli-responsive systems; Biomedical applications

Introduction

Niosomes, which are self-assembled vesicular nanocarriers mainly composed of non-ionic surfactants and cholesterol have gained great academic interest as versatile carriers for modern drug delivery. Their conceptual genesis is in the late 1970s when investigators were seeking alternatives to phospholipid bilayered liposomes due to the problems of oxidative degradation, high costs of production, and lack of stability. Early studies showed that non-ionic surfactants could spontaneously assemble to form bilayer structures that were capable of encapsulating both hydrophilic and hydrophobic drug molecules, and this realized the fundamental requirement for building a revolutionary drug delivery technology [1].

Over the years, niosomal systems have evolved from multilamellar vesicles and structurally refined and functionally optimised nanocarriers designed for specific and controlled release. Their physicochemical advantages such as improved chemical stability, reduced manufacturing cost, ease of scale up and suitability for a wide range of therapeutic molecules have made niosomes good candidates as alternatives to liposomes, solid lipid nanoparticles and polymeric nanocarriers. Crucially, the flexible choice of surfactants with different hydrophilic-lipophilic balance (HLB), phase transition temperatures and molecular architectures allows well defined control over the vesicle properties (bilayer fluidity, entrapment efficiency and kinetics of release [2].

In recent decades, the growth of niosomal investigation has been driven by the progress in chemical investigation in surfactants, microfluids, materials science, and surface engineering. These technological breakthroughs have been used to fabricate PEGylated, ligand targeted, pH responsive, and magnetically triggered niosomes with superior stability, cellular uptake and biodistribution profiles. Such customized designs have significantly increased their field of application in oncology, dermatology, infectious diseases, neurological diseases, vaccine delivery and nanotheranostics. In addition, the ability of niosomes to protect labile biomolecules and increase transdermal and mucosal permeation, and transport, has also assured their relevance in precision and regenerative medicine.

Notwithstanding these advances, problems related to long term stability, industrial scale up and regulatory standardisation remain open fields of research. Nevertheless, the progressive combination of computational modelling, Quality by Design (QbD) principles and hybrid biomaterial strategies is continuously redefining the parameters of the technology of niosomal [3, 4]. As the field continues to move toward clinical translation, niosomes are on the verge of playing a key role in the development of next generation nanomedicine through providing new opportunities for safe and effective therapeutic use and individualization according to a patient's needs.

Physicochemical and Biopharmaceutical Determinants of Niosomal Performance

The performance, stability and therapeutic efficacy of niosomal drug delivery systems are controlled by a number of interdependent physicochemical and biopharmaceutical parameters. Among the former, the selection of the surfactant is the highest order [5]. Some of the aspects that are different between surfactants are HLB, chain length and phase transition temperature (T_c) which affect the elasticity of bilayers, the integrity of the membrane and the efficiency of entrapment. Cholesterol integration further affects the rigidity of the vesicles and reduces the leakage of encapsulated cargo and increases the stability under physiological conditions [6].

Vesicle size and polydispersity index (PDI) are important factors in the biodistribution, cellular uptake, and clearance of the nanoparticle; the nanosized vesicles (50-200 nm) have better tumor penetration and longer circulations. Surface charge, usually measured by zeta potential, largely controls the stability of the colloidal and determines the interactions with cell membranes, mucus layers and plasma proteins. Biopharmaceutical determinants include, the physicochemical properties of the drug molecule (solubility, lipophilicity, log P, dissociation constant, pKa and molecular weight), which determine the drug molecule localization inside the vesicle, the loading mechanism and release profile [7].

The retention of hydrophobic agents in the phospholipid and the encapsulation of hydrophilic entities in the central aqueous space highlight the importance of the encapsulation strategies on the pharmacokinetics of drugs. Therapeutic efficacy is determined by permeability, enzymatic stability as well as the tendency to be translocated by the efflux transporters. Furthermore, biologic parameters such as immune detection and specific endocytic pathways like clathrin mediated, caveolae dependent, macro pinocytic uptake plays

a significant role in determining *in vivo* performance. The table.1 outlines the physicochemical and biopharmaceutical determinants of niosomal technology [8]. With a mechanistic understanding of these variables, one will be able to design rationally the niosomal carriers that will have an added stability, release profiles, and enhanced pharmacokinetics, as well as bioavailability. This optimization paradigm forms the basis on which niosomal formulations targeted, stimuli-responsive, and with an ability to be translated to clinical use are developed.

Determinant Category	Specific Parameter	Role in Niosomal Behavior	Impact on Therapeutic Performance
Physicochemical	Surfactant type (HLB, Tc, chain length)	Determine bilayer fluidity, membrane integrity and vesicle production	determine stability, entrapment efficiency and kinetics of release.
	Cholesterol ratio	regulates the rigidity and permeability of the bilayers;	Enhances stability, reduces leakage and longevity in circulation.
	Vesicle size & PDI	Control bio-distribution, aggregation-propensity, and cellular internalisation	changing tumour penetration, tumour absorption and pharmacokinetics
Biopharmaceutical	Drug solubility, lipophilicity (log P), pKa	Control spatial subcellular extension: bilayer vs aqueous core	Determines loading strategy, release features, and total bioavailability.
	Endocytic uptake pathway & enzymatic Exposure	Modulate the cellular internalisation pathways and cellular metabolic state	effect on therapeutic activity, intracellular delivery and systemic persistence.

Table 1: Physicochemical and Biopharmaceutical Determinants [9-11].

Historical Evolution of Niosomal Technology

Origins and Conceptual Emergence

The birth of niosomal technology is dated to the end of the 1970s when the limitations of liposomes composed of phospholipids were pointed out by researchers, among them oxidative instability, high manufacturing costs and limited shelf-life. Non-ionic surfactants, which are already used to make formulations for cosmetics, could form stable bilayer vesicles in the presence of cholesterol. Early niosomes showed an enhanced physicochemical stability and cost-effectiveness which make them appealing for pharmaceutical uses [12]. Initial research focused on vesicle formation mechanics, lamellarity, as well as entrapment behaviour based on classical surfactants such as Span 60 and Tween 20. During this time, niosomes were mainly used for topical and transdermal applications because of the ability to increase penetration and the protection of the active molecules from degradation using niosomes into the skin.

Advancement of Formulation Techniques

Significant progress in preparations methods of niosomes characterised this era. Techniques like thin-film hydration, ether injection, reversal of the phase and microfluidisation did enhance uniformity and reproducibility of vesicles formation. A complex understanding of surfactant thermotropic behaviour was used by researchers to modulate the bilateral rigidity and optimise entrapment efficiency. Incorporation of cholesterol and charge inducing agents further improved the stability of the vesicles and controlled the leakage, also affecting the interactions with biological membranes. These advances expanded the therapeutic range of application for niosomal formulations from the dermatological field into the systemic area [13].

Expansion of Therapeutic Applications

By the early 2000s, niosomal technology experienced an uptick, as various applications of the technology were developed for delivery of anticancer drugs, peptides, vaccines, antifungals and antiviral agents. Studies were carried out to examine the effects of vesicle

size, zeta potential and surfactant composition on biodistribution and pharmacokinetics. Ligand mediated targeting concepts came up in the picture which made it possible to deliver selectively to tumor cells, macrophages, and epithelial tissues [14]. The use of biodegradable surfactants and stabilizers contributed to the improvement of the biocompatibility profile of niosomal carriers.

Emergence of Modern Engineering Approaches

The last 10 years saw a paradigm shift by the combination of microfluidics, sophisticated surfactant chemistry and surface functionalization. Microfluidic Assisted Fabrication Produces Monodisperse Vesicles with Exceptional Control of Size and Lamellarity. PEGylation, antibody conjugation and peptide ligands have made it possible for prolonged circulation time and immune evasion and for receptor specific delivery. Concurrently, stimuli (pH, temperature, magnetic fields and enzymes) responsive niosomes (i.e. controlled drug releases) have been developed that introduce precision controlled drug release for oncology, infection and gene therapy [15].

Transition to Hybrid and Next Generation Niosomes

Contemporary research has moved towards hybrid architectures which involve the combination of niosomes with polymers, metallic nanoparticles, hydrogels or dendrimers, which increases their applications in theranostic, imaging and regenerative therapies. The combination of QbD concepts, computational modelling and automated manufacture has ensured improved formulation predictability and scalability [16]. Although regulatory hurdles, long term stability and clinical translation are still difficult, modern niosomes are still evolving as highly adaptive nanocarriers with a lot of potential for use in personalized medicine and next generation therapeutics.

Mechanisms of Action in Niosomal Drug Delivery

Drug Encapsulation and Protection

Niosomes improve the performance of drugs since they can properly encapsulate both hydrophilic and hydrophobic drugs in the bilayer structure. Hydrophobic molecules become incorporated into the surfactant cholesterol bilayer while hydrophilic drugs are concentrated in the aqueous phase and are thus shielded from enzymatic destruction; hydrolysis and early elimination. This protective mechanism also reduces off target toxicity due to drug stability during transport [17, 18].

Modulation of Pharmacokinetics and Biodistribution

Niosomal formulations have a significant effect on the systemic pharmacokinetics by extending circulation time and limiting reticuloendothelial system (RES) uptake. The addition of cholesterol is stabilizing vesicles while PEGylation or functionalization with ligands is increasing the steric shielding and receptor specific targeting. The figure.1 depicts the mechanism of action of niosomal drug delivery. Nanometric vesicle sizes (50 - 200 nm) promote passive tumor accumulation via the enhanced permeation and retention (EPR) effect due to improved site-specific delivery [18].

Controlled and Stimuli Responsive Drug Release

The permeation properties of niosomal bilayers based on the composition of surfactants, rigidity of the membrane, and the cholesterol rate offer controlled drug release and prolonged drug release. Advanced formulations respond in a selective way to physiological findings such as pH gradients, temperature changes, redox conditions or enzymatic activity. These stimuli-responsive systems guarantee accurate dosing as well as lower dosing frequency and superior therapeutic efficacy [19].

Cellular Uptake and Intracellular Delivery

Niosomes internalize into cells by various pathways of endocytosis such as clathrin modulated endocytosis, caveolae and micropinocytosis. Once internalised, pH sensitive or fusogenic niosomes have the ability to destabilize the endosomal membranes which then favor the release of their content into the cytoplasm. This mechanism is particularly useful for delivery of nucleic acids, peptides and drugs that are not easily penetrated [20].

Barrier Penetration and Permeation Enhancement

Niosomes also increase the ability of drugs to penetrate biological barriers such as skin, mucosa and epithelium. Ultra - deformable niosomes (transferosomes) adapt to the micro - curvatures of tight junctions and allow them to penetrate deep into the tissues and provide better transdermal or mucosal drug delivery. This mechanism has the advantage of enhancing onset of action and bioavailability of different therapeutic agents [21].

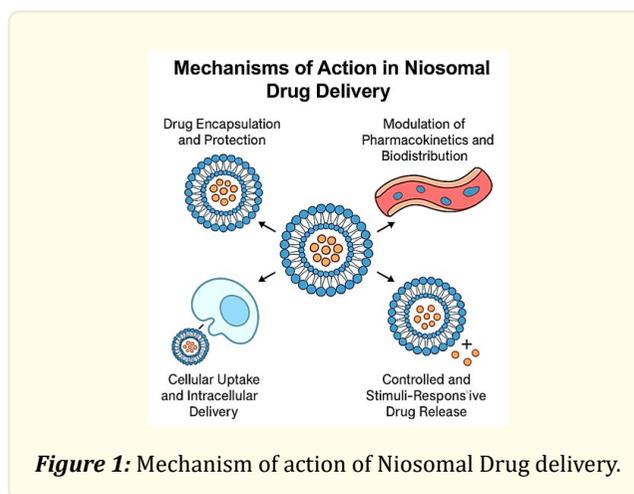


Figure 1: Mechanism of action of Niosomal Drug delivery.

Advanced Formulation and Manufacturing Technologies

Microfluidic Assisted Niosomes Fabrication

Microfluidics has revolutionised production of niosomal by allowing to precisely control mixing conditions, surfactant self assembly and particle size distribution. Continuous flow microfluidic mixers offer the possibility of preparing monodisperse vesicles of well controlled nanometric size with low batch variability and minimal solvent residues [22]. This technology is beneficial for allowing additional scale along with supports for rapid prototyping of optimised formulations.

High Energy and Low Energy Methods

Traditional high energy based techniques such as probe sonication, high pressure homogenisation and microfluidisation are widely used to decrease the vesicle size and increase the uniformity. In contrast, low energy methods, such as ethanol injection, reverse phase evaporation and thin film hydration have made it possible to encapsulate temperature sensitive drugs under less harsh conditions [23]. The method of choice has direct impacts on lamellarity, rigidity of the bilayer, entrapment efficiency and release behaviour.

Surface Engineering and Functionalization

Modern niosomal systems have the use of sophisticated surface modification strategies for improved stability, targeting and circulation time. PEGylation provides steric stabilization and less sonication, ligand conjugation using antibodies, peptides, folates or aptamers for receptor-mediated targeting is possible. Such functionalized niosomes, which have higher cellular uptake and better therapeutic specificity, are possible [24, 25].

Stimuli Responsive and Smart Niosomes

Addition of stimulus sensitive materials has made it possible to produce smart niosomes that can deliver pharmaceutical ingredients upon changes in pH, changes in temperature, redox potential, magnetic or enzymatic activity. Such complex designs also promote site selectivity, minimize systemic toxicity and the therapeutic localization, especially in oncological and gene-delivery situations [26].

Hybrid and Composite Niosomal Systems

Advances in biomaterials have made the development of hybrid niosomes of polymers, lipids, metallic nanoparticles or hydrogels possible. These composite systems provide superior mechanical strength as well as multiple functionalities and release properties. As a result, hybrid niosomes are observed to aid imaging guided therapies, theranostic approaches and regenerative medicine approaches [27].

Quality by Design (QbD) and Scalable Manufacturing

Quality by Design (QbD) has enhanced predictable and strong production of niosomes. The parameters critical to the raw materials, process parameters are streamlined by the implementation of Design of Experiments (DoE). New automated and continuous manufacturing platforms are an additional endorsement of the scale up with the assurance of reliability and regulatory conformity [28].

Biomedical and Clinical Applications

The combination of their structural flexibility, natural biocompatibility, and drug pharmacokinetics modulation properties has resulted in niosomes becoming very versatile nanocarriers with far reaching biomedical and clinical applications. In oncology, chemotherapy delivery is a key objective for niosomal formulations of chemotherapeutics, like doxorubicin, paclitaxel or curcumin, which improve tumor targeting by enhanced permeation and retention effects and by ligand mediated delivery resulting into the reduction of systemic toxicity and the enhancement of the therapeutic index. In dermatology and transdermal therapy are deformable niosomes that enhance dermal penetration to become suitable for anti inflammatory drugs, antifungals, antioxidants and cosmetic actives [29].

Niosomes are also very promising for neurological disorders in which surface engineered vesicles allow transport across the blood brain barrier for delivery of neuroprotective agents and siRNA. In infectious diseases, niosomes are able to improve the intracellular uptake of the antimicrobials leading to improved efficacy against tuberculosis, malaria and viral infections. Besides, vaccine and gene delivery application makes use of cationic niosomes for efficient encapsulation of DNA, mRNA, and peptide antigens for enhanced immune responses and stability.

Emerging theranostic applications combine imaging agents or metallic nanoparticles into niosomal systems allowing for a combination therapy of diagnosis and therapy to be carried out. Collectively these applications highlight the clinical potential of niosomes as versatile nanocarriers that have the potential to meet medical needs that are unmet in the medical fields through the use of diverse therapeutic areas [30].

Safety, Toxicity, and Regulatory Considerations

Niosomal drug delivery systems usually have good safety profiles, the reason being that non ionic surfactants are biocompatible and minimally immunogenic. However, their toxicity depends on the type of surfactant, surfactant concentration, vesicle size, surface charge and route of administration. Rather high concentrations of surfactants or cationic components may cause membrane irritation, hemolysis or cytotoxicity so optimal balanced concentration of formulation is important. In vivo factors such as ultrasonication, biodistribution have an impact on safety results. Comprehensive toxicological evaluation, including hemocompatibility evaluation, acute and chronic toxicity assessment, immunogenicity evaluation, and genotoxicity assessment, are necessary before the clinical translation process [31-33].

Regulatory pathways for niosomes often follow framework for liposomal or nanomedicine. Physiochemical characterization, stability testing and manufacturing variability produces therapeutic benefits for the patient. The growth niosomes based formulations towards the clinical application, harmonized guidelines and high quality standards ensures the key safety and efficacy for its formulation.

Challenges and Limitations

Despite various multiple improvements, niosomal technology is facing several scientific, technical and translational challenges. One of the major limitations is the physical instability of vesicles such as aggregation, fusion, and leakage of drugs during storage, especially for nanosized formulations [34, 35]. Entrapment efficiency may not be as high as desired for highly hydrophilic or unstable biomolecules that can limit their therapeutic use.

Scale up remains challenging, since methods like hydration or sonication developed during the lab scale are often completely insufficient to be reproducible on an industrial level and to comply with the regulations. Additionally, variation in the purity of surfactant and critical packing parameters, and variation from batch to batch can affect the characteristics of vesicles [36].

Some of the biological challenges include high blood clearance which is caused by reticuloendothelial system, surfactants related cytotoxicity danger and in vivo behaviour heterogeneity. Additionally, regulatory barriers exist because of the lack of agreement on guidelines for physicochemical characterization, safety tests, and quality control of manufacturing. These limitations will require joint efforts in terms of developing materials, engineering processes and harmonizing regulations in order to allow further clinical translation of niosomal therapeutics [37].

Future Perspectives

The future of niosomal drug delivery is in the implementation of integrations of advanced materials, precision engineering and personalized medicine strategies. Emerging research is aimed at the development of smart niosomes that respond to stimuli, such as pH, temperature, enzymes or magnetic fields, and release therapeutics in order to achieve highly localized treatment with controlled release. Hybrid architectures based on the combination of niosomes with polymers, lipids, metallic nanoparticles or exosomes, provide new perspectives for multifunctional theranostic applications. Artificial intelligence and machine learning are expected to break the formulation optimization process by predicting critical formulation parameters and biological performance [38].

Microfluidics and continuous manufacturing will increase scale as well as compliance with regulatory requirements. It is expected that both the scale up and regulatory compliance can be improved as the microfluidic technology and continuous manufacturing will be integrated. In clinical therapy, niosomal systems have the potential to be used in oncology, gene editing therapy, cancer vaccines, and regenerative medicine [39-41]. As regulatory environments and more and more interdisciplinary interactions take place, the next generation of niosomes will soon be seen as a revolutionary form of nanomedicine and precision therapeutics.

Conclusion

Niosomal drug delivery vehicles have been developed to replace crude, surfactant driven vesicles, to advanced, multifunction nano-carriers that can offer therapy to a wide range of therapeutic necessities. Their inherent merits such as flexibility in structure, biocompatibility and the ability to entrap hydrophilic as well as hydrophobic agents makes them attractive substitutes to conventional lipid based carriers. Recent developments in surfactants, microfluidics, surface engineering and integration of hybrid materials have enabled the stability, target specific and controlled release to be significantly improved. However, current common problems, including long term stability, complexity of scaling up, and insufficient standardization of regulatory standards, still affect the scale of clinical translation. However, the development of smart systems that react to stimuli or to AI based optimization of formulations as well as continuous manufacturing promises a more predictive and translationally possible niosomal therapeutic development. With the developing field of precision and personalized medicine, niosomes will reshape the definition of drug delivery to provide safer, more effective and highly versatile platforms in a spectrum of biomedical applications.

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