REVIEW ARTICLE

Niosomes: Best Approach for Novel Drug Delivery and Future Aspects

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Abstract

When hydrated with synthetic non-ionic surfactants, niosomes-vesicles of non-ionic surfactants-are formed, either with or without the inclusion of cholesterol or other lipids. Niosomes are effective and non-ionic for the distribution of drugs; it is less harmful and increases the drug therapeutic index by limiting its impact to target cells. Niosomes gain growing scientific attention in nanotechnology because they are exceptional in their versatility as valuable drug delivery mechanisms for a range of therapeutic applications. Niosomes were prepared by various methods like sonication, microfluidization, the handshaking approach, reverse-phase evaporation, and the ether injection method. Two separate conditions, commonly 4±1° and 25±2°, are used for storing niosomes. Niosomes have various applications in neoplasia, Leishmaniasis, peptide drug delivery, and immunological disorders.

Key words: Cholesterol, lipophilic, niosomes, proniosomes, vesicles

INTRODUCTION

Niosomes are vesicles made of non-ionic surfactants that are generated by hydrating synthetic non-ionic surfactants, either with or without the addition of lipids such as cholesterol. Handjani-Vila *et al*. introduced this class of vesicles.[1,2] Niosomes, also known as non-ionic surfactant vesicles, are tiny lamellar structures that are created when cholesterol and non-ionic surfactant belonging to the alkyl or dialkyl polyglycerol ether class are mixed together and then hydrated in aqueous conditions.[3,4]

In the field of nanotechnology, niosomes are gaining increasing scientific interest as useful drug delivery systems for several therapeutic applications due to their unique versatility. Niosomes are vesicular nanocarriers made up of non-ionic surfactants, developed by scientists as the best alternative to liposomes. Niosomes and liposomes are both amphiphilic carriers with similar physicochemical properties, pharmaceutical applications, and, also, equal in vivo Behavior.[1] Despite these comparable features, niosomes differ in the chemical composition of the bilayer, and this offers several advantages over liposomes. Liposomes are based on phospholipids, whereas niosomes are made of surfactants with improved physical, chemical, and biological stability. Furthermore, higher drug entrapment can be achieved by modulating the composition of niosome bilayers, and their industrial manufacture is less expensive because it does not require special handling methods or storage conditions due to the higher stability. Most of the published papers focused on niosomes, highlighting their optimal skin permeation potential, sustained release characteristics, long shelf life, and high drug photo-protective activity as compared to liposomes.[5,6] Niosome production was first reported in the 70s in the cosmetic industry, but then potential applications of niosomes were expanded for the delivery of several pharmacological agents such as anticancer, antioxidants, anti-inflammatory, antiasthma, antimicrobial, antiviral, antibacterial molecules, and oligonucleotides. At the present state of the art, most of the publications in scientific literature and the first clinical trials about niosomes highlight the great potential of these systems in dermal and transdermal applications but also show the niosomal potentialities as oral formulations for blood glucose lowering, antihypertensive, or analgesic drugs.[7,8]

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ORIGIN OF NIOSOMES

The first niosome formulations were developed and patented by L'Oreal in 1975. The developed niosome formulations were capable of altering the pharmacokinetic profile, organ distribution, and metabolism of methotrexate in mice. Niosomes are versatile in structure, morphology, and size; they can entrap hydrophilic drugs in aqueous compartments or lipophilic drugs by partitioning these molecules into bilayer domains. Furthermore, they can be formulated as unilamellar, oligolamellar, or multilamellar vesicles. Niosomes also possess good physical stability, are cost-effective, and are relatively straight-forward for routine and large-scale production.[9]

STRUCTURE OF NIOSOME

A typical niosome vesicle would consist of a vesicle-forming amphiphile [Table 1].[10]

COMPOSITIONS OF NIOSOMES[11-13]

The two major components used for the preparation of niosomes are:

Advantages of niosomes[14,15]

- The vesicle suspension, being water-based, offers greater patient compliance over oil-based systems.
- Since the structure of the niosome offers a place to accommodate hydrophilic, lipophilic, and amphiphilic drug moieties, they can be used for a variety of drugs.

Disadvantages of niosomes[3,14,16,17]

- Physical instability
- Aggregation
- Fusion
- Leaking of an entrapped drug
- Hydrolysis of encapsulated drugs, which limits the shelf life of the dispersion.

METHODS OF PREPARATION

Niosomes are prepared by various methods, and they are

Preparation of small unilamellar vesicles

Micro fluidization

The submerged jet principle is adopted for niosome formulation. Via a microchannel inside the interaction chamber, a fluidized stream of medication and surfactant are permitted to interact at extremely high speeds. The thin liquid sheet impingement along a common front is organized so that the energy used by the system stays in the region where niosome production occurs. The method results in the formation of niosomes of greater uniformity, smaller size, and better reproducibility.[18]

Sonication

This method involves the addition of surfactant or cholesterol in organic solvent and a drug in an aqueous solution. This aqueous solution of the drug is mixed with a surfactant solution and further homogenized for 3 min at a temperature of 60°C.[19]

Preparation of multilamellar vesicles

Handshaking method (thin film hydration technique)

This process entails the rota developing a thin, dry coating. This process involves dissolving cholesterol and surfactant in an organic solution. In order to create a thin coating on the inside wall of the ask, both solutions are combined and then evaporated at a specific temperature while under reduced pressure. Following evaporation, niosomes are formed by sonication-based hydration.

CHARACTERIZATION OF NIOSOMES

Vesicle diameter

Niosomes range in size from 20 nm to 50 nm and have a spherical form. With light microscopy, the vesicular shape and size distribution can be ascertained. Another method used for determination of the diameter and size of the niosome is freeze-fracture electron microscopy.[20]

Vesicle charge

Vesicle charge is determined by measuring zeta potential. Hence, during the preparation, charged vehicles like diacetyl phosphate are added to the surfactant/cholesterol mixture.[21]

Table 1: Differences between niosomes and liposomes

Property	Niosomes	Liposomes
Components	Surfactants	Phospholipids
Component availability	High	Low
Component purity	Good	Variable
Stability	Very good	Low
Cost	Low	High
Preparation and storage	No special conditions required	Inert atmosphere and low temperature

Bilayer formation and number of lamellae

The bilayer formation of niosomes is characterized by X-cross formation. NMR spectroscopy, electron microscopy, and small-angle X-ray scattering are used to characterize the number of lamellae.

Membrane rigidity and homogeneity

The rigidity of the membrane affects the biodegradation and biodistribution of niosomes. The determination of the rigidity of the niosomal suspension is done by a fluorescence probe as a function of temperature. P-NMR, differential scanning calorimetry, Fourier transform infrared spectroscopy, and fluorescence resonance energy transfer are used to determine the membrane homogeneity.[22]

Encapsulation efficiency

It can be done by separating the unentrapped drug from the niosomal dispersion by using various methods such as centrifugation, gel filtration, and dialysis. Another method of separation includes complete disruption of the vesicle using 50% n-propanol or 0.1% Triton ×-100. Then, the required disrupted vesicle is analyzed for drug content and, hence, entrapment efficiency.[23]

Entrapment efficiency (EF) = (Amount entrapped/total amount) ×100

In-vitro drug release

In-vitro drug release of niosomes can be characterized by the following methods: (a) dialysis; (b) Franz diffusion cell.

Stability of niosomes

Niosomes are typically stored at two distinct temperatures: 4 ± 1° and 25 ± 2°. The stability of niosomes is indicated by the continuous concentration of the drug encapsulated and the constant size of the particle. The stability of niosomes is also influenced by the type and concentration of cholesterol and surfactants. The particle size of the niosomes was found to be in the range of 135-223 nm.

Number of niosomes per cubic mm = Total number of niosomes × dilution factor × 400/Total number of small squares counted.

DIFFERENCES BETWEEN NIOSOMES AND LIPOSOMES[24,25]

Table 1.

In vivo behavior of niosomes

The size of niosomes is very impressive on tissue distribution or accumulation. The large size niosomes stick to alveoli and will stop in the lungs, whereas the smaller size can easily pass through fenestrations in the liver sinusoidal epithelium and thus have better access to the spleen. Due to the structural similarity between liposomes and niosomes, it can be predicted that both obey the same mechanisms to face with cells; niosomes behave *in vivo* like liposomes. The interaction of cells and niosomes may be described by five mechanisms.[26,27]

Intermembrane transfer

Intermembrane transfer to components that are between the two layers can be done without destroying the structure of niosomes. Interactions between niosomes and lipoproteins may continue to demolish whole vesicles.

Contact release

Contact release of niosomes occurs when contact vesicles with the cell increase the permeability of the niosome membrane. This leads to the release of a high concentration of water-soluble components in the area adjacent to the cell. In fact, it is an effective way to release the active ingredient without destroying the structure of all niosomes.

Endocytosis

The niosome is enveloped by the cell, and lysozyme digests and destroys the bilayer structure of niosomes. In this way, the entrapped material is released into the medium.

Fusion

In some cases, the property of the niosomal membrane allows the noisome to stick firmly to the cell; this fusion can cause niosomes to easily transfer their contents into the cytoplasm of the cell.

Adsorption

Adsorption can result from the interaction of physical forces between the cell surface and niosomes or the result of specific binding ligands on the surface of the niosomes and receptors in the cell.

APPLICATIONS

- Peptide medications typically have stability issues, making it challenging to manufacture them as parenteral tablets. Thus, the stability of peptide medications can be increased by employing niosomes as drug carriers.[28,29]
- When anticancer medications like 5-FU cancer therapy are administered, niosomes can be a good drug delivery method. It is also utilized to incorporate the medicine

into niosomes, which increases its efficacy.[30] Niosomal suspension can be utilized as a hemoglobin carrier because it exhibits a visible spectrum that can be superimposed onto that of free hemoglobin.[31]

- Drugs with a low therapeutic index and low water solubility can be encapsulated by the niosomal system, allowing for continuous release action in the circulation. The majority of leishmaniasis cases are treated with compounds of antimony. At greater amounts, it can have adverse consequences that affect the kidneys, liver, and heart. Niosomes can be used as a medication carrier to get around these negative effects at larger concentrations.
- Antimonials encapsulated within niosomes are taken up by mononuclear cells, resulting in the localization of the drug, an increase in potency, and hence a decrease both in dose and toxicity.[32,33] The evolution of niosomal drug delivery technology is still at an infancy stage, but this type of drug delivery system has shown promise in cancer chemotherapy and anti-leishmanial therapy.
- Niosomes: A superior drug delivery system compared with liposomes

Niosomes possess a bilayer structure, which is similar to liposomes. However, the materials used to prepare niosomes confer better stability on them.[34]

Niosomes are cost-effective for industrial manufacture and do not require special storage conditions, which are essential while manufacturing liposomes. The cost of liposome preparation is high because of the unstable chemical ingredients (phospholipids), which undergo oxidative degradation.[5] Niosomes possess a longer shelf life than liposomes.[35] They prolong the circulation of encapsulated drugs and increase metabolic stability in an emulsified form, whereas liposomes have a limited shelf life because of the rancidification of their lipid components.[36-39]

EXPERT OPINION ON NIOSOMES

Are certainly a great and innovative promise for drug delivery, and their near future could be very bright with several pharmacological therapies and other applications. Considering the abovementioned properties of niosomes as drug carriers, they can represent a valid alternative to liposomes. The pioneer topic formulation was launched into the market by Lancome in 1987, and the benefits of these systems in the cosmetic field are largely validated. However, niosomal nanotechnology is still pre-mature, and a lot of work is still needed to guide its future applications in different clinical fields. Effectively, niosomes are young systems, and few papers in the literature have focused on these carriers. Since their birth, as evidenced by the Scopus database, only 4896 scientific reports focus on niosomes in drug delivery, against 95705 ones dealing with liposomes. In most of these works, the pharmaceutical researches have taken advantage of the versatility and adaptability of easily modified and functionalized non-ionic surfactants to obtain specific targeting tools or those with intrinsic stimuli-responsive properties. The versatility of their constituents has led researchers to study their behavior as anticancer carriers or for applications in gene therapy. These reports and our experience in the pharmaceutical fields underline the importance of creativity and innovation to tailor-made the niosomes suitable for various therapeutic purposes. Furthermore, multi-functional niosomes have been proposed as a further evolution of the traditional 'magic bullet' and the way to open new possibilities to achieve personalized therapies.[40,41] These strategies were also extensively explored for liposomes, but the incorporation of non-ionic surfactants in the composition of lipid-based vesicular systems was largely reported in many studies as the main reason to improve their major limitations of phospholipids. Then, why do not replace fully phospholipids in vesicular bilayers after seeing their important drawbacks? The niosome potentiality is already recognized in dermatological therapy; indeed, clinical trials for treatment of acne,[42] psoriasis,[43] leishmaniasis,[44] wart,[45] and oromucosal ulcers[46] are currently ongoing, but it would be desirable that the same interest be directed to different applications, such as diagnostics or therapeutics or also theranostics devices. Therefore, it is essential to focus on the discovery of novel and innovative surfactants able to form niosomal formulations adequate for pre-clinical studies and switch after to clinical studies. The niosomes, despite their similarity to liposomes, have peculiar characteristics worth to be considered in order to increase the availability of pharmaceutical formulations that are more efficacy and less expensive. The real opportunities of these vesicular systems should be effectively considered, and, in the near future, it will be important to spend more financial resources on their studies.

RECENT DEVELOPMENTS NIOSOMES

Numerous investigations have been conducted concerning niosomes. An investigation found that the created niosome demonstrated increased release and improved permeability across the animal intestinal membrane compared to plain drug formulations and commercialized formulations, indicating that efforts were made to improve the oral bioavailability of Cefdinir through niosome incorporation.[47] Studies conducted to improve the solubility of the BCS class II medication valproic acid by entrapping it in niosomal gel found that the gel with entrapped niosomal particles exhibited superior release across the animal nasal membrane in vitro, making it a viable option for valproic acid delivery.[48] Niosomes of oxcarbazepine were synthesized and assessed for potential superiority over traditional dosage forms. Oxcarbazepine niosomes have been demonstrated in pharmacokinetic experiments to have a greater elimination half-life and an area under the curve than pure oxcarbazepine.[49] This supports their potential to improve the drug's safety and efficacy.

CONCLUSION

Niosomes have great drug delivery potential for targeted delivery of anti- cancer, anti-infective agents. Niosome appears to be a well preferred drug delivery system over liposome as noisome being stable and economic. Niosomes represent a promising drug delivery module. They presents a structure similar to liposome and hence they can represent alternative vesicular systems with respect to liposomes, due to the niosome ability to encapsulate different type of drugs within their multi environmental structure.

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