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Review Paper

Niosomes: An Advanced Drug Delivery System

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ABSTRACT

Niosomes are vesicles composed of non-ionic surfactants, which are biodegradable, relatively nontoxic, more stable, and inexpensive, serving as an alternative to liposomes. They are also known as vesicular nanocarriers, which are self-assembled by the hydration of a non-ionic surfactant, cholesterol, or other molecules. In novel drug delivery, it has applications in the treatment of cancer, used as a carrier in hemoglobin delivery of peptide drugs through the oral route, in the treatment of leishmaniasis, in ophthalmic delivery, and as a carrier in dermal drug delivery. This review article focuses on the composition, advantages, types of niosomes, preparation methods, characterization, and application of the vesicular system.

INTRODUCTION

Niosomes are non-ionic surfactant-based vesicles. They were originally developed as an alternative controlled drug delivery system to liposomes to overcome the problems associated with sterilization, large-scale production, and stability (Azmin et al., 1985, 1986; El Maghraby & Williams, 2009). The hydration of a film, comprising a mixture of a single or double-alkyl chain and cholesterol, leads to the formation of vesicular dispersion. These dispersions were termed niosomes (Baillie et al., 1985). These vesicles do not form spontaneously. Thermodynamically stable vesicles form only in the presence of proper mixtures of surfactants and

a membrane stabilizing agent (cholesterol), at a temperature above the gel/liquid transition of the main lipid-forming vesicles (Azmin et al., 1985, 1986; Sahin, 2007). The first niosome formulations were developed and patented by L'Oreal in 1975 (Sahin, 2007). Niosomes were first utilized in drug delivery for anticancer drugs (Azmin et al., 1985, 1986). The developed niosome formulations could alter the pharmacokinetic profile, organ distribution, and metabolism of methotrexate in mice (Azmin et al., 1985, 1986). 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

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domains. Furthermore, they can be formulated as unilamellar, oligolamellar, or multilamellar vesicles. Niosomes also possess good physical stability, are cost-effective, and are relatively

straightforward for routine and large-scale production (Baillie et al., 1985; Uchegbu & Florence, 1995; Uchegbu & Vyas, 1998).

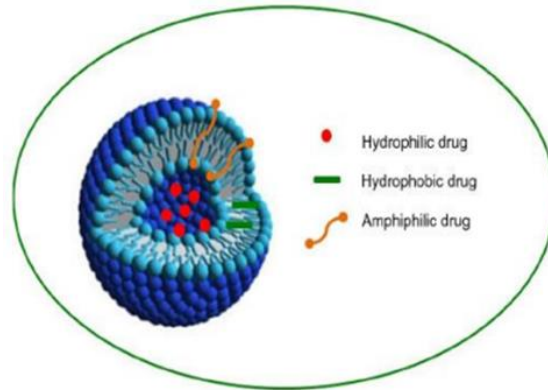


Figure 1 Typical structure of niosomes

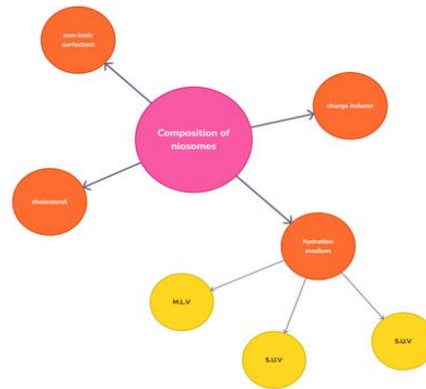


Figure 2.Composition of Niosomes

Advantages of niosomes:

1. Patient compliance is higher than with alternative administration systems.
2. Minimized adverse effects and maximal duration of action.
3. Only a tiny amount of the medication is needed to get the desired outcome.
4. The bilayer surrounding the active component of the preparation protects it from internal and external environmental influences.
5. Serve as a depot formulation to enable regulated medication release.
6. The drug is designed to resist breakdown in the gastrointestinal tract and first-pass metabolism.
7. An emulsion possesses a stable structure Even in the form of an emulsion.

8. Niosomes can be administered parenterally, topically, or orally.

- Please remember the following points:
 - Surfactants do not require any special conditions for handling and storage.
 - They enable controlled and targeted drug delivery.
 - They are stable and osmotically active.
 - They enhance dermal penetration and oral bioavailability, improving drugs' therapeutic effect.
 - Niosomes, being water-based, offer better patient compliance compared to greasy dosage forms.

Disadvantages Of Niosomes:

Niosomes' aqueous suspensions have a limited shelf life because they tend to fuse, aggregate, leak entrapped drugs, and undergo hydrolysis of encapsulated drugs.

1. Creating multilamellar vesicles using the extrusion and sonication method is time-consuming and requires specialized equipment for processing.

2. It is a time-consuming process and requires specialized equipment for processing.

3. Limited shelf life due to:

a) Fusion

b) Aggregation

c) Leakage of entrapped drugs

d) Hydrolysis of encapsulated drugs.

Here are different methods of preparation:

1. Thin film hydration technique for handshaking method

2. Microfluidization

3. Reverse Phase Evaporation (REV)

4. Ether Injection Method

5. Trans-membrane pH-gradient (inside acidic)

6. The Bubble Method

7. Sonication

8. Multiple extrusion method

9. Niosomes formation from proniosomes

1 Thin film hydration technique for the handshaking method: The non-ionic surfactant and cholesterol are dissolved in a volatile organic solvent (such as diethyl ether, chloroform, or methanol) in a round-bottom flask used in the hand-shaking technique. At room temperature (20°C), the organic solvent is eliminated using a rotary evaporator, leaving behind a thin coating of solid mixture that is deposited on the flask wall. When the drug-containing aqueous phase is heated to between 50 and 60 degrees Celsius, the dry surfactant film is gently stirred. Multilamellar niosomes are created in this way.

- Benefits of thin-film hydration for the handshaking technique :

- Easy to use and reasonably priced

- appropriate for both small and large-scale manufacturing.

Drawbacksof thin-film hydration for the handshaking technique :

- frequently leads to more varied and big vesicle sizes.

➤ requires a size-reduction step to be done after preparation, such as sonication or extrusion.

2)Micro-fluidization: The science and technology of microfluidics deals with devices that use channels of sizes ranging from one to hundreds of micro-meters to process or control tiny volumes of fluids (microliter to attoliter). This area's goal, mostly driven by technology applications, is to create whole labs inside of chips. Micro-fluidization is a technique in which unilamellar vesicles of defined size distribution are prepared.

It is based on the submerged jet principle in which two fluidized streams interact at ultra-high velocities (100 ml/min), in precisely defined micro channels within the interaction chamber. The impingement of a thin liquid sheet along a common front is arranged in such a way that the energy supplied to the system remains within the area where niosomes are formed. Niosomes formed by this method have greater uniformity, smaller size, and better reproducibility

- Benefits of Micro-fluidization:

- High repeatability and scalability

- consistent and tiny vesicle sizes produced

- Drawback of micro-fluidization:

- Expensive equipment is required,

- the process is limited to specific formulas due to shear forces.

3. Reverse Phase Evaporation (REV)

The ratio of surfactant to cholesterol is 1:1 during reverse-phase evaporation. The combination mentioned above dissolves in a mixture of ether and chloroform. The drug dissolves in the water phase. Sonication is applied to both mixtures at 4-6°C. Niosomes are produced by diluting the niosome suspension in PBS at 60°C for ten



minutes using a water bath. The resulting product is again mixed with PBS and sonicated at low pressure while maintaining a temperature of 40–45°C, which removes the organic phase. To produce niosomes, the resulting solution is diluted with PBS and boiled in water at 60°C for 10 minutes.

- Benefits of reverse phase evaporation:
- Large uni-lamellar vesicles may be produced.
- High encapsulation efficiency for hydrophilic pharmaceuticals in general.
- Drawbacks of reverse phase evaporation
- The process can be time-consuming.
- When using organic solvents with sensitive medications, there may be some issues.

4. Ether Injection Method:

The niosomes are made using the ether injection process, which involves adding a surfactant solution mixed in volatile organic solvent diethyl ether to warm water kept at 60°C. Using a 14-gauge needle, the surfactant combination in ether is injected into an aqueous solution of the substance. Ether vapourization produces single-layered vesicles (volatile organic solvent)

- Benefits of ether injection method:
- Good control over vesicle size
- produces smaller vesicles than other techniques.
- Drawbacks of the ether injection method:
- the use of volatile organic solvents
- the danger of solvent contamination from leftovers.

5) Trans-membrane pH-gradient (inside acidic)

This process involves mixing or blending the cholesterol and surfactant in a round-bottom flask and then dissolving them in chloroform. The chloroform evaporates at low pressure, leaving behind a thin layer on the flask wall. The film is hydrated by vortex mixing 300 mM (pH 4.0) citric acid. An aqueous solution containing 10 mg/ml of the medication is added to the niosomal

suspension mentioned earlier, and it is vortexed. After adding 1M disodium phosphate, the sample's pH is brought to 7.0–7.2. The mixture is then heated for 10 minutes at 60°C. Using this technique, multilamellar vesicles are created.

- Benefits of trans-membrane pH-gradient:
- Excellent drug loading performance. The capacity to regulate medication release in response to pH variations.
- Drawbacks of trans-membrane pH-gradient:
- Needs certain tools and circumstances.
- Some sensitive medications may be deteriorated by a pH gradient.

6. The Bubble Method

An innovative approach for producing niosomes without the use of organic solvents is the bubble method. This approach uses the bubbling unit. The temperature is regulated by three necks on a round-bottom flask that is submerged in a water bath. First neck is used for water-cooled reflux; the second neck is used for thermometers; and third neck is used for nitrogen passage. In a buffer solution (pH-7.4), cholesterol and surfactant are combined at 70 degrees Celsius. After mixing the mixture for 15 seconds with a high shear homogenizer, nitrogen gas is utilized to instantly cause the mixture to bubble at 70°C.

- Benefits of the bubble method:
- Doesn't need the use of organic solvents.
- Suitable for substances that are sensitive to temperature.
- drawback of the bubble method:
- the low encapsulation efficiency.
- often produces a wide range of sizes.

7. Sonication One of the traditional methods for niosome preparation is sonication. This approach involves dissolving the medication in the buffer to create the drug solution. Next, the non-ionic surfactant combination is added to this buffer drug solution at an ideal ratio. Sonicating the combination at a certain frequency, temperature,

and duration yields the required niosomes. It's one of the simplest ways to regulate the niosomes' particle size. Niosomes having a limited size distribution can have their diameters reduced using this technique. Probe sonicators are another option, although they require a lot of energy. As a result, there is an abrupt rise in temperature and titanium ejection.

- **Benefits of sonication:**

- Generates homogeneous, tiny vesicles.
- Easy and efficient way to reduce size.

- **Drawbacks of sonication:**

- Heat generation may cause sensitive medications to degrade.
- Post-processing is required to eliminate any metal contamination on the probe.

8) Multiple extrusion method

This process involves mixing diacetyl phosphate, cholesterol, and surfactant in chloroform. To create a thin film, this chloroform combination is then evaporated. A polycarbonate drug membrane that is aqueous is used to hydrate thin films. The solution and the resulting suspension are forced through the eight channels in this membrane. This approach also yields the requisite size of the niosomes.

- Benefits of multiple extrusion method:
 - Generates vesicles with a limited range of sizes.
 - Ideal for both tiny and big quantities.
- Drawbacks of multiple extrusion method:
- Takes a lot of time.
 - needs certain equipment

9. Niosomes formation from proniosomes

The generation of niosomes occurs with brief agitation at a temperature higher than the surfactant's typical transition phase temperature. T_m where T_m = Mean Phase Transition Temperature and T = Temperature

Preniosomes based on maltodextrin were used to formulate niosomes, as reported by Blazek-Walsh A.I. et al. With this formulation, niosomes may be

quickly reconstituted with the least amount of leftover carrier. Drying the mixture of maltodextrin and surfactant produced a free-flowing powder that could be rehydrated by adding warm water.

- Benefits Niosomes formation from proteasomes:
- Easy storage and excellent stability.
- A straightforward hydration procedure forms niosomes
- drawbacks of Niosomes formation from proteasomes :
- Needs extra steps to complete the conversion.
- restricted to specific combinations.

Distance From Untrapped Drug:

Dialysis: Phosphate buffer, glucose solution, or regular saline are used to dialyze the aqueous niosomal suspension in dialysis tubing.

2) The process of gel filtration

Phosphate buffered saline or regular saline is used for elution after gel filtration employing a Sephadex-G-50 column to extract the medicine that was not encapsulated in the niosomal solution.

3) Centrifugation

The niosomal suspension is centrifuged and the liquid supernatant is separated during the centrifugation process. Washing the particle and the resuspended solution yields a niosomal suspension devoid of untrapped medication.

Liposomes and niosomes are nearly identical in their molecular makeup. If niosomes are composed of non-ionic surfactants, they are stable in nature, but the phospholipids employed in liposomes are not. Liposomes are made from double-chain phospholipids, while niosomes are made from unaltered single-chain non-ionic surfactants. Liposomes are less than 10-300 nm, while niosomes are between 10 and 100 nm in size. When compared to liposomes, niosomes are more cost-effective.

The following variables affect niosomal formulation:



- surfactant nature;
- surfactant structure;
- membrane composition;
- nature of encapsulated medication;
- temperature of hydration Charge;
- Cholesterol content;
- Adaptability to osmotic stress;

1. Surfactant Nature

A single alkyl hydrophobic tail on an ether-type surfactant makes it more hazardous than a dialkyl ether chain. Due to the increased likelihood of esterases breaking down ester linkage into fatty acids and triglycerides, ester-based surfactants are chemically less stable than ether-type surfactants. Compared to ester-based surfactants, ether-type surfactants are more hazardous. The mean size of niosomes increases when the HLB value of surfactants increases because the hydrophobicity of the surfactant increases and surface free energy decreases. Niosome bilayers can be in a liquid or gel condition at any one time. It is dependent on the surfactant type, temperature, and cholesterol. In the gel state, alkyl chains are well-organized, while in the liquid state, they are disorganized.

For example, span 60 with a higher TC shows superior entrapment. Surfactants with an HLB value of 14–17 are not appropriate for use in niosomal preparations. The entrapment efficiency is reduced when the HLB value of surfactants drops from 8.6 to 1.7; the maximum entrapment efficiency is achieved when the HLB value is 8.6. The alkyl chain lengths of C12–C18 surfactants are appropriate for niosome production.

2. Surfactant Structure

The vesicle's shape is influenced by the critical packing parameter of the surfactant structure. Critical packing parameters (CPP) provide a prediction for the vesicle's shape. 37. If the CPP is less than $\frac{1}{2}$, then round micelles $\frac{1}{2} CPP < 1 \Rightarrow$ dual-layer micelles

Inverted Micelles: $CPP > 1$ To find the critical packing parameter (CPP), use the following

formula. $CPP = \frac{V}{lc \cdot a_0}$. Where Critical packing parameters, or CPP Critical hydrophobic group length (lc) equals V , the hydrophobic group volume. Area of the hydrophilic head group, or a_0

3: Membrane Composition: To stabilize the niosomes, several chemicals are added to the medication and surfactant. The addition of cholesterol increases the membrane's stiffness and decreases medication leakage. The polyhedral niosomes generated from C16G2 do not aggregate when a small quantity of solution C24 (cholesteryl poly-24-oxy ethylene ether) is added. This is because steric hindrance is prevented from developing.

4. Nature Of Encapsulated Medication: The physicochemical characteristics of the medication contained have a significant impact on the charge and stiffness of the niosomal bilayer. Entrapment of medication happens by interacting with the surfactant head groups leading to the increased charge and producing mutual repulsion of the surfactant bilayer and therefore increasing vesicle size 38. The level of entrapment is influenced by the drug's HLB.

5. Temperature Of Hydration Charge: The niosome's size and shape are influenced by the hydration temperature. The gel liquid phase transition temperature should be higher than the hydration temperature. Temperature variations have an impact on surfactant vesicle assembly and vesicle shape change. The alteration is also explained by the hydration medium's amount and duration. Fragile niosomes and drug leakage issues may occur from choosing the hydration temperature, duration, and medium volume incorrectly.

viii. Cholesterol content: The entrapment effectiveness and hydro-dynamic diameter of niosomes are enhanced by the incorporation of cholesterol. Cholesterol functions in two ways 39: it either increases or decreases the chain order of bilayers in the liquid state.

An increase in cholesterol content results in stiffer bilayers and a slower rate of encapsulated substance release.

viii. Adaptability to osmotic stress

Vesicle diameter decreases upon the addition of hypertonic solution. Because of the mechanical vesicle structural loosening brought on by osmotic stress, inhibition of fluid eluting from vesicles in hypotonic solution first causes a sluggish release, which is then followed by a rapid release.

CONCLUSION: The creation of innovative medication delivery systems has undergone a significant revolution in the last several decades. Niosome technology as a viable medication delivery mechanism is still in its early stages of development. Niosomes have demonstrated a strong effect in focusing on specific tissues and organs. Niosomes can be used as more effective transdermal, nasal, ocular, and vaccine delivery methods, as well as superior diagnostic and tumor-targeting agents. Niosomal compositions that are sold commercially need a great deal of research.

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