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Review Article

Niosomes – A Promising Carrier for Drug Delivery

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ABSTRACT: Niosomes are non-ionic surfactant based multilamellar or unilamellar vesicles in which an aqueous solution of solute is entirely enclosed by a membrane resulting from the organization of surfactant macromolecules as bilayer. The term "Niosomes" is named as because vesicle is composed of a bilayer of non-ionic surface-active agents (non-ionic surfactants). Niosomes are a novel drug delivery system, in which the medication is encapsulated in a vesicle. The ionic drug carriers are relatively toxic and unsuitable whereas niosomal carriers are safer. Also handling and storage of niosomes require no special conditions. Niosomes proved to be a promising drug carrier and has potential to reduce the side effects of drugs and increased therapeutic effectiveness in various diseases. Niosomes tackle the problem of insolubility, instability, low bioavailability and rapid degradation of drugs. Present review article deals with advantages, preparations, evaluation and pharmaceutical applications of niosomes.

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INTRODUCTION

Niosomes are non-ionic surfactants with multilameller vesicles obtained on hydration of synthetic nonionic surfactants, with or without incorporation of sterol such as cholesterol or other lipids [1]. Niosomes are microscopic lamellar structures of size range between 10 to 1000 nm and consists of biodegradable, non-immunogenic and biocompatible surfactants. In niosomes, the vesicles forming amphiphile is a non-ionic surfactant which is usually stabilized by addition of cholesterol and small amount of anionic surfactant such as dicetyl phosphate, which helps in stabilizing the vesicle [2].

Niosomes possess an infrastructure consisting of hydrophilic and hydrophobic moieties together, and as a result, can accommodate drug molecules with a wide range of solubilities [3]. Various types of drug deliveries can be possible using niosomes like targeting, ophthalmic, topical, parental etc. Niosomes proved to be a promising drug carrier and has potential to reduce the side effects of drugs and increased therapeutic effectiveness in various diseases.

Advantages

1. Niosomes are osmotically active and stable, chemically stable [4].
2. They are biodegradable and non-immunogenic.
3. Their surface formation and modification are very easy.
4. Niosomes possess infrastructure consisting of hydrophilic and hydrophobic mostly together and so accommodate the drug molecules with a wide range of solubility [5].
5. Niosomes can improve oral bioavailability of poorly absorbed drugs.
6. They exhibit flexibility in their structural characteristics and can be designed according to the desired situation [6].

7. They have high compatibility with biological systems and low toxicity.

8. Niosomes can enhance the skin penetration of drugs.

9. Niosomes prolong the circulation of entrapped drug and altering its organ distribution and metabolic stability [7].

10. They act as a depot for short acting peptide drugs and release the drug in a controlled rate.

Disadvantages

1. The aqueous suspensions of niosomes may have limited shelf life due to fusion, aggregation, leaking of entrapped drugs, and hydrolysis of encapsulated drugs [8].

2. The methods of preparation of multilamellar vesicles such as extrusion, sonication is time consuming and may require specialized equipments for processing.

3. Such type of drug delivery system has high cost.

4. Sometimes phospholipid undergoes oxidation and hydrolysis.

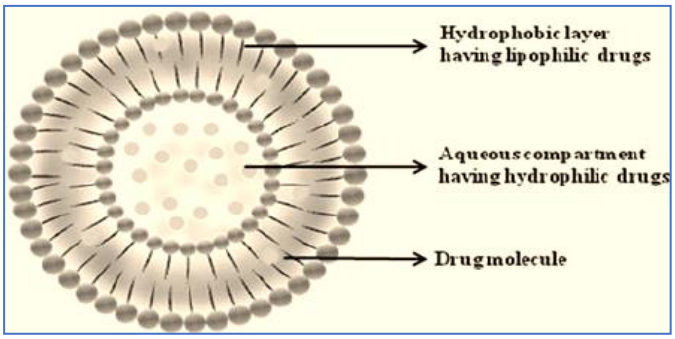

Figure 1: Structure of Niosome

Types of Niosomes

Based on the vesicle size, niosomes can be divided into three groups [9]:

1. **Small Unilamellar Vesicles** (SUV)- Size=0.025-0.05 μm)
2. **Multilamellar Vesicles** (MLV)- Size=>0.05 μm)
3. **Large Unilamellar Vesicles** (LUV)- Size=>0.10 μm).

COMPOSITIONS OF NIOSOMES

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

I. Non-ionic surfactants:

Selection of surfactant is done on the basis of HLB value. As Hydrophilic Lipophilic Balance (HLB) is a good indicator of the vesicle forming ability of any surfactant, HLB number in between 4 and 8 was found to be compatible with vesicle formation [10].

a) Alkyl ethers:

Some surfactants for the preparation of niosomes containing drugs/chemicals [11].

1) Surfactant-I (Mol.Wt.473) is C16 monoalkyl glycerol ether with average of three glycerol units.
2) Surfactant-II (Mol.Wt.972) is diglycerol ether with average of the seven glycerol units.
3) Surfactant III (Mol.Wt.393) is ester linked surfactant.

b) Alkyl esters:

Sorbitan esters are most preferred surfactant used for the preparation of niosomes amongst this category of surfactants. Vesicles prepared by the polyoxyethylene sorbitan monolaurate are relatively soluble than other surfactant vesicles]. For example, polyoxyethylene (polysorbate 60) has been utilized for encapsulation of diclofenac sodium [12].

c) Alkyl amides: Alkyl amide (e.g. galactosides and glucosides) have been utilized to produce niosomal vesicles.

d) Fatty acid and amino acid compounds: Long chain fatty acids and amino acid moieties have also been used in some niosomes preparation.

II. Cholesterol:

Steroids are important components of the cell membrane and their presence in membrane affect the bilayer fluidity and permeability. Cholesterol is a steroid derivative, which is mainly used for the formulation of niosomes.

Although it may not show any role in the formation of bilayer, its importance in formation of niosomes and manipulation of layer characteristics cannot be discarded.

In general, incorporation of cholesterol affects properties of niosomes like membrane permeability, rigidity, encapsulation efficiency, ease of rehydration of freeze dried niosomes and their toxicity [13].

III. Charged molecule:

Some charged molecules are added to niosomes to increase stability of niosomes by electrostatic repulsion which prevents coalescence.

The negatively charged molecules used are diacetyl phosphate (DCP) and phosphotidic acid. These charged molecule sare used mainly to prevent aggregation of niosomes [14].

METHODS OF PREPARATION

(A) Preparation of small unilamellar vesicles

1. Sonication

A typical method of production of the vesicles is by sonication of solution as described by Cable.

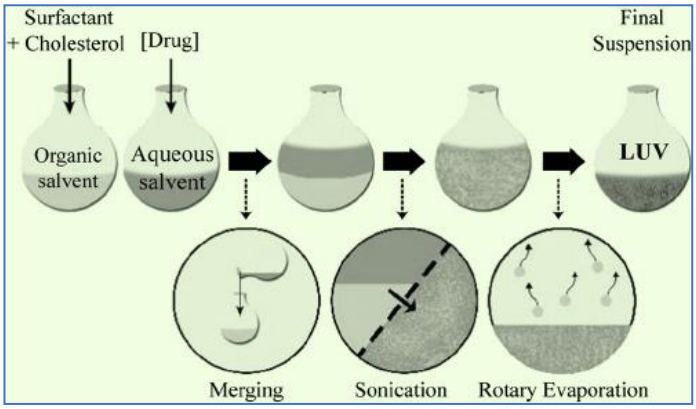

Figure 2: Sonication method

In this method an aliquot of drug solution in buffer is added to the surfactant/cholesterol mixture in a 10 ml glass vial. The mixture is probe sonicated at 60°C for 3 minutes using a sonicator with a titanium probe to yield niosomes [15].

2. Microfluidization

In this method two fluidized streams move forward through precisely defined micro channel and interact at ultra-high velocities within the interaction chamber. A common gateway is arranged such that the energy supplied to the system remains within the area of niosomes formation. The result is a greater uniformity, smaller size and better reproducibility [16].

(B) Preparation of multilamellar vesicles

1. Hand shaking method (Thin film hydration technique)

In this method, mixture of vesicles forming ingredients like surfactant and cholesterol are dissolved in a volatile organic solvent (diethyl ether, chloroform or methanol) in a round bottom flask. The organic solvent is removed at room temperature (20°C) using rotary evaporator leaving a thin layer of solid mixture deposited on the wall of the flask. The dried surfactant film can be rehydrated with aqueous phase at 0-60°C with gentle agitation. This process leads to formation of typical multilamellar niosomes film of lipid on the wall of rotary flash evaporator. The aqueous phase containing drug was added slowly with intermittent shaking of flask at room temperature followed by sonication [17].

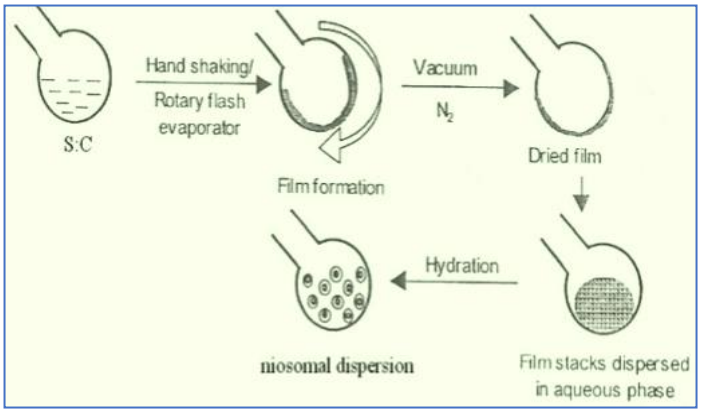

Figure 3: Hand shaking method

2. Trans-membrane pH gradient (inside acidic) drug uptake process (remote loading):

In this method surfactant and cholesterol are dissolved in chloroform. The solvent is then evaporated under reduced pressure to obtain a thin film on the wall of the round-bottom flask. The film is hydrated with 300 mm citric acid (Ph 4.0) by vortex mixing. The multilamellar vesicles are frozen and thawed three times and later sonicated. To this niosomal suspension, aqueous solution containing 10 mg/ml of drug is added and vortexed. This mixture is later heated at 60°C for 10 minutes to produce the desired multilamellar vesicles [18].

(C) Preparation of Large Unilamellar Vesicles

1. Reverse Phase Evaporation Technique (REV)

In this method Cholesterol and surfactant (1:1) are dissolved in a mixture of ether and chloroform. An aqueous phase containing drug is added to this and the resulting two phases are sonicated at 4-5°C. The clear gel formed is further sonicated after the addition of a small amount of phosphate buffered saline (PBS).

The organic phase is removed at 40°C under low pressure. The resulting viscous niosome suspension is diluted with PBS and heated on a water bath at 60°C for 10 min to yield niosomes [19].

2. Ether injection method

This method is based on slow injection of niosomal ingredients in ether through a 14-gauge needle at the rate of approximately 0.25 ml/min into a preheated aqueous phase maintained at 60 °C.

Formation of larger unilamellar vesicles is due to slow vaporization of solvent results in an ether gradient extending towards the interface of aqueous-nonaqueous interface. The disadvantages of this method are that a small amount of ether is frequently present in the vesicles suspension and is difficult to remove [20].

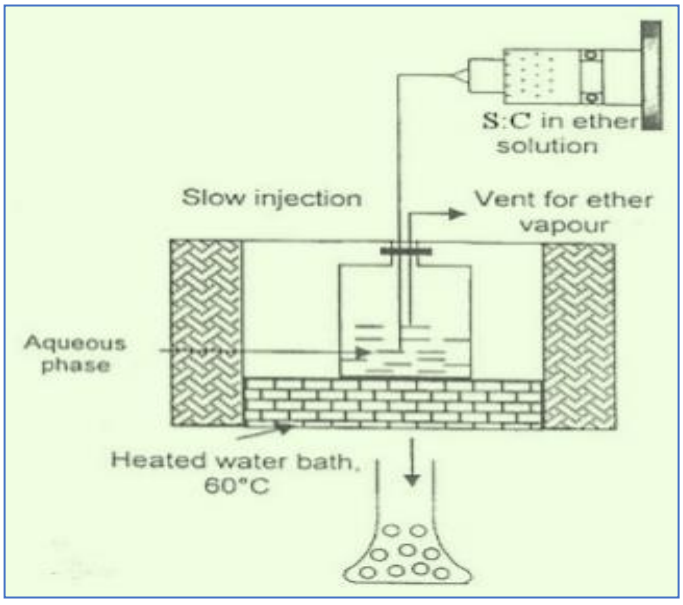

Figure 4: Ether injection method

(D) Miscellaneous

1. Multiple membrane extrusion method

Mixture of surfactant, cholesterol and dicetyl phosphate in chloroform is made into thin film by evaporation. The film is hydrated with aqueous drug solution and the resultant suspension extruded through polycarbonate membranes, which are placed in series for upto 8 passages. It is a good method for controlling niosome size [21].

2. The bubble method

It is a one-step preparation of niosomes without the organic solvent. The bubbling unit consist of round bottom flak with three necks position in water bath to control the temperature

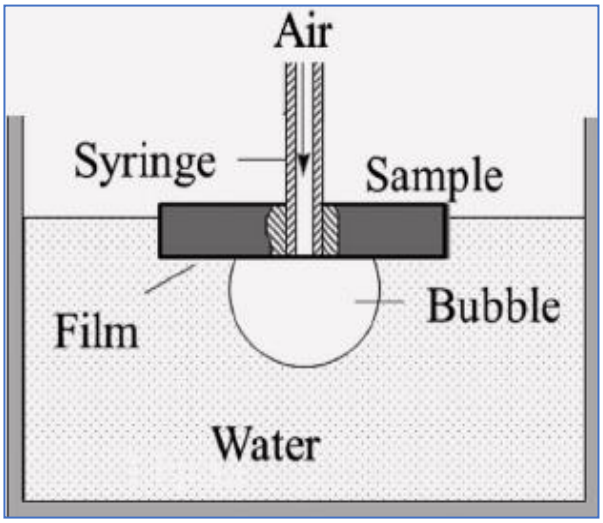

Figure 5: Bubble method

Water cooled reflex and thermometer is positioned in the first and second neck and nitrogen supply through the third neck

Cholesterol and surfactant are dispersed in this buffer (pH 7.4) at 70ºC the dispersion mixed for 15 seconds with high shear homogenizer and immediately afterward bubble at 70ºC using nitrogen gas [22].

3. Formation of niosomes from proniosomes

In this method water-soluble carrier such as sorbitol are coated with surfactant. The result of the coating process is a dry formulation. In which each water-soluble particle is covered with a thin film of dry surfactant [23]. This preparation is termed "Proniosomes". The niosomes are recognized by the addition of aqueous phase at T > Tm and brief agitation (T = Temperature. Tm = mean phase transition temperature)

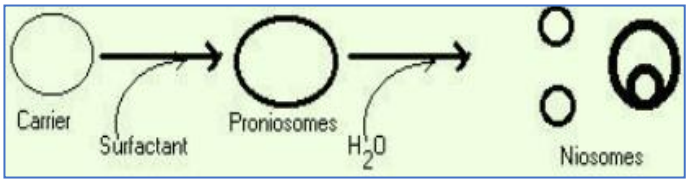

Figure 6: Formation of niosomes from proniosomes

Separation of unentrapped drug

The removal of unentrapped solute from the vesicles can be accomplished by various techniques, which include:

(i) Dialysis

The aqueous niosomal dispersion is dialyzed in dialysis tubing against phosphate buffer or normal saline or glucose solution [24].

(ii) Gel Filtration

The unentrapped drug is removed by gel filtration of niosomal dispersion through a Sephadex-G-50 column and elution with phosphate buffered saline or normal saline [25].

FACTORS AFFECTING PHYSICO-CHEMICAL PROPERTIES OF NIOSOMES

(i) Nature of Surfactants

A surfactant has a hydrophilic head and hydrophobic tail. The hydrophobic tail may consist of one or two alkyl or perfluoro alkyl groups or in some cases a single steroidal group. The ester type surfactants are chemically less stable than ether type surfactants and the former is less toxic than the latter due to ester-linked surfactant degraded by esterase's to triglycerides and fatty acid *in vivo*. The surfactants with alkyl chain length from C12-C18 are suitable for preparation of niosomes [26].

(iii) Osmotic stress

Addition of a hypertonic salt solution to a suspension of niosomes brings about reduction in diameter. In hypotonic salt solution, there is initial slow release with slight swelling of vesicles probably due to inhibition of eluting fluid from vesicles, followed by faster release, which may be due to mechanical loosening of vesicles structure under osmotic stress [27].

(iv) Temperature of Hydration

Hydration temperature influences the shape and size of the niosome. For ideal condition it should be above the gel to liquid phase transition temperature of system. Temperature change of niosomal system affects assembly of surfactants into vesicles and also induces vesicle shape transformation [28].

(v) Nature of Encapsulated Drug

The drug interacts with surfactant head groups and develops the charge that creates mutual repulsion between surfactant bilayers and hence increases vesicle size. The aggregation of vesicles is prevented due to the charge development on bilayer [29].

(vi) Membrane Composition

Niosomes can be prepared with addition of different additives along with surfactants and drugs. Addition of cholesterol molecule to niosomal system provides rigidity to the membrane and reduces the leakage of drug from niosome. Inclusion of cholesterol in niosomes increases its hydrodynamic diameter and entrapment efficiency.

In general, the action of cholesterol is two folds; on one hand, cholesterol increases the chain order of liquid-state bilayers and on the other, cholesterol decreases the chain order of gel state bilayers. An increase in cholesterol content of the bilayers leads to decrease in the release rate of encapsulated material and therefore an increase of the rigidity of the bilayers obtained.

Presence of charge tends to increase the interlamellar distance between successive bilayers in multilamellar vesicle structure and is responsible for increase in entrapped volume [30].

(vii) Method of Preparation

Hand shaking method forms vesicles with greater diameter (0.35-13 nm) compared to the ether injection method (50-1000 nm). Small sized niosomes can be produced by Reverse Phase Evaporation method.

Micro fluidization method gives greater uniformity and small size vesicles. Niosomes obtained by Trans membrane pH gradient (inside acidic) drug uptake process showed greater entrapment efficiency and better retention of drug [31].

(viii) Amount and type of surfactant

The mean size of niosomes increases proportionally with increase in the HLB of surfactants because the surface free energy decreases with an increase in hydrophobicity of surfactant. In the gel state, alkyl chains are present in a well-ordered structure, and in the liquid state, the structure of the bilayers is more disordered [32].

EVALUATION PARAMETERS OF NIOSOMES

1. Size

Shape of niosomal vesicles is assumed to be spherical, and their mean diameter can be determined by using laser light scattering method. Also, diameter of these vesicles can be determined by using electron microscopy, molecular sieve chromatography, ultracentrifugation, photon correlation microscopy, optical microscopy and freeze fracture electron microscopy [33].

2. Bilayer formation

Assembly of non-ionic surfactants to form a bilayer vesicle is characterized by an X-cross formation under light polarization microscopy [34].

3. Membrane rigidity

Membrane rigidity can be measured by means of mobility of fluorescence probe as a function of temperature.

4. Entrapment efficiency

After preparing niosomal dispersion, unentrapped drug is separated by dialysis, centrifugation, or gel filtration as described above and the drug remained entrapped in niosomes is determined by complete vesicle disruption using 50% n-propanol or 0.1% Triton X-100 and analyzing the resultant solution by appropriate assay method for the drug [35].

5. Number of lamellae

This is determined by using nuclear magnetic resonance (NMR) spectroscopy, small angle X-ray scattering and electron microscopy [36].

6. *In vitro* release study

In vitro release rate study has been performed by many researchers with the help of dialysis tubing. A dialysis sac is washed and soaked in distilled water. The vesicle suspension is pipetted into a bag made up of the tubing and sealed. The bag containing the vesicles is then placed in 200 ml buffer solution in a 250 ml beaker with constant shaking at 25°C or 37°C. At various time intervals, the buffer is analyzed for the drug content by an appropriate assay method [37].

APPLICATIONS

The application of niosomal technology is widely varied and can be used to treat several diseases.

1. Niosomes as drug carriers

Niosomes have also been used as carriers for iobitridol, a diagnostic agent used for X-ray imaging. Topical niosomes may serve as solubilization matrix, as a local depot for sustained release of dermally active compounds, as penetration enhancers, or as rate-limiting membrane barrier for the modulation of systemic absorption of drugs [38].

2. Drug targeting

One of the most useful aspects of niosomes is their ability to target drugs. Niosomes can be used to target drugs to the reticuloendothelial system. The reticuloendothelial system (RES) preferentially takes up niosome vesicles. A carrier system (such as antibodies) can be attached to niosomes (as immunoglobulin's bind readily to the lipid surface of the niosome) to target them to specific organs [39].

3. Anti-neoplastic Treatment

Most antineoplastic drugs cause severe side effects. Niosomes can alter the metabolism; prolong circulation and half-life of the drug, thus decreasing the side effects of the drugs. Niosomes, is decreased rate of proliferation of tumor and higher plasma levels accompanied by slower elimination [40].

4. Leishmaniasis

Leishmaniasis is a disease in which a parasite of the genus Leishmania invades the cells of the liver and spleen. Use of niosomes in tests conducted showed that it was possible to administer higher levels of the drug without the triggering of the side effects, and thus allowed greater efficacy in treatment [41].

5. Niosomes as carriers for Hemoglobin

Niosomes can be used as a carrier for hemoglobin. Niosomal suspension shows a visible spectrum superimposable onto that of free hemoglobin. Vesicles are permeable to oxygen and hemoglobin dissociation curve can be modified similarly to non-encapsulated hemoglobin [42].

6. Transdermal delivery of drugs by niosomes

Slow penetration of drug through skin is the major drawback of transdermal route of delivery. An increase in the penetration rate has been achieved by transdermal delivery of drug incorporated in niosomes [39].

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8. Ophthalmic drug delivery

From ocular dosage form like ophthalmic solution, suspension and ointment it is difficult to achieve excellent bioavailability of drug due to the tear production, impermeability of corneal epithelium, non-productive absorption and transient residence time. But niosomal and liposomal delivery systems can be used to achieve good bioavailability of drug [42].

CONCLUSION

Niosomes appeared to be a well preferred drug delivery system stable and economic. Niosomes can lead to better bioavailability and targeting properties, reduction in the toxicity and side effects of the drugs.

Drug delivery potential of niosome can enhance by using novel concepts like proniosomes. The concept of incorporating the drug into niosomes for a better targeting of the drug at appropriate tissue destination is widely accepted by researchers.

There is lot of scope to encapsulate many varieties of drugs including toxic anti-cancer drugs, anti-infective drugs, anti-AIDS drugs, anti-inflammatory drugs, anti-viral drugs, etc.

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