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NIOSOMES: A Review of Their Structure, Types, Method of Preparation, Characterization and Application

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Abstract: *Drug targeting is a type of phenomenon in which a drug is distributed in the body in such a way that the drug interacts with the target tissue at the cellular or subcellular level to achieve the desired therapeutic response at the desired site without unwanted interactions at other sites. This can be achieved by modern methods of drug delivery system targeting such as niosomes. Niosomes are a type of non-ionic surfactant vesicles that are biodegradable, non-toxic, more stable and cheaper, which is a new approach to liposomes. Their structure is similar to liposomes and therefore they may represent alternative vesicular systems to liposomes. Niosomes tend to load different types of drugs. This review article presents niosomes structure, advantages, disadvantages, niosomes preparation methods and characterization of pharmaceutical NSVs. The concept of a drug delivery system refers to the process of administering pharmaceutical compounds at a predetermined rate to achieve a therapeutic effect in humans or animals at the site of disease while simultaneously reducing the concentration of the drug in surrounding tissues. The localized action of the drug increases the effectiveness of the drug and reduces systemic toxic effects on tissues.*

Keywords: Niosomes, Structure, Compositions, Method of preparation, Factors affecting, Application

I. INTRODUCTION

Paul Ehrlich proposed the idea of targeted delivery directly to a diseased cell without harming healthy cells in 1909, and this strategy was known as the "magic bullet". Since then, a variety of drug carrier systems have emerged, including immunoglobulins, serum proteins, synthetic polymers, liposomes, microspheres, and niosomes. Among these systems, liposomes and niosomes are well-documented vesicular drug delivery systems. In general, a vesicular system is a drug delivery platform that enables efficient bioavailability of drugs through the controlled release of therapeutic drugs over extended periods of time. Vesicles consist of bilayered amphiphilic molecules that surround an aqueous compartment. Niosomes are vesicles of nonionic surfactant (for example, alkyl ester and alkyl ether) and cholesterol that act as a carrier for amphiphilic and lipophilic drugs. Niosomes improve the therapeutic efficacy of encapsulated drug molecules by protecting the drug from the harsh biological environment, resulting in their delayed clearance.

The concept of a drug delivery system refers to the process of administering pharmaceutical compounds at a predetermined rate to achieve a therapeutic effect in humans or animals at the site of disease while simultaneously reducing the concentration of the drug in surrounding tissues. The localized action of the drug increases the effectiveness of the drug and reduces systemic toxic effects on tissues.

New drug development is both time-consuming and expensive. A new drug costs an estimated $120 million to develop and takes decades to go from discovery, clinical testing and development to regulatory approval. Specific drug delivery systems alleviate the urgency of bringing new drugs to market by increasing drug selectivity and therapeutic index while reducing the effective dose. This narrative review discusses the role of niosomes as a drug delivery system and details their structure, preparation, properties, and mutual applications to form a closed bilayer structure that encapsulates solutes in aqueous solution. As a result, the closed bilayer structure of niosomes has a hydrophilic inner and outer surface sandwiched between them by a lipophilic region. Energy, such as heat or physical mixing, is required

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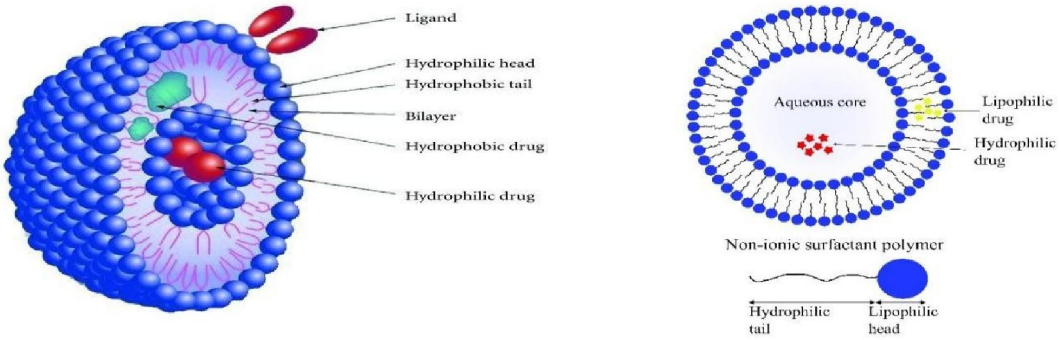
to form a closed bilayer structure. Various forces inside the vesicles have been found to play an important role in maintaining the vesicular structure, such as van der Waals and repulsive forces that exist between surfactant molecules. Changing the vesicle components (including type, composition, and concentration), size, surface charge, or volume is likely to alter the properties of the resulting niosomes. Niosomes can be categorized into 3 groups based on their vesicle size, namely small unilamellar vesicles (0.025–0.05 mm), multilamellar vesicles (>0.05 mm), and large unilamellar vesicles (>0.10 mm).

II. STRUCTURE OF NIOSOMES

The main components of niosomes are nonionic surfactants, a hydration medium, and lipids such as cholesterol. Self-assembly of nonionic surfactants in aqueous media leads to closed bilayer structures (Figure 1). The high interfacial tension between water and the hydrophobic tails of the amphiphile causes their association. The steric and hydrophilic repulsion between the head groups of the nonionic surfactant ensures that the hydrophilic ends face outwards and are in contact with water. Assembly into closed bilayers usually requires some energy input, such as mechanical or thermal. Niosomes can be divided into three groups according to their size and bilayer. Small unilamellar vesicles (SUVs) (10–100 nm), large unilamellar vesicles (LUVs) (100–3000 nm) and multilamellar vesicles (MLVs) where more than one bilayer is present.



The vital components used in the niosomes formulation are:
Non-ionic surfactants
Cholesterol
Charge inducer
Hydration medium

Non-ionic surfactants: The primary component used in the formulation of the noisome is the surface-active agent. They are amphiphilic in nature comprising a polar head and a non-polar tail. These agents are more stable, compatible and less toxic when compared to other surfactants such as anionic, cationic and amphoteric surfactants because they do not carry any charge. These agents cause less haemolysis and irritation to cellular surfaces. They can be used as wetting agents and emulsifiers. The important characteristic of non-ionic surfactant is that they inhibit p-glycoprotein and thus enhance the absorption and targeting of anticancer drugs (example-doxorubucin, daunorubicin, curcumin, morusin), steroids (example- hydrocortisone), HIV-protease inhibitor (example-ritonavir), cardiovascular drugs (example-digoxin, beta-blockers).

Non-ionic surfactant exhibits high interfacial activity and are comprised of both polar and non- polar groups/segments. The bilayer vesicles formation depends on hydrophilic lipophilic balance (HLB) scale, chemical structure of components and critical packing parameter (CPP). The entrapment efficiency of drug is usually altered by chain length and size of hydrophilic head group of non-ionic surfactants. Non-ionic surfactant with larger alkyl chain shows higher entrapment efficiency. The Tween sequence of surfactants possessing an extended alkyl chain and an outsized hydrophilic moiety together with cholesterol during a ratio 1:1 have the very best entrapment efficiency of water-soluble drugs. The HLB value of a surfactant plays avital role in managing drug entrapment of the vesicle it forms . Critical packing parameter (CPP) value of a surfactant can be calculated from the area of the polar head group and

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volume and length of the non-polar group. Using CPP values the type of vesicle going to be formed can be determined (Figure 2) and also by the calculation of CPP using certain formula.

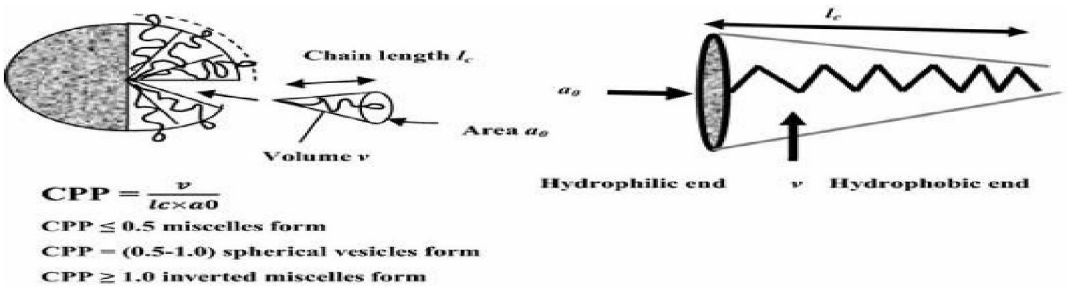

Figure 2: Critical Packing Parameter

Cholesterol: Cholesterol is a waxy steroid derivative found within the cell membrane that is principally employed in the preparation of niosomes. Leakiness of the cell membrane is decreased by stabilizing the membrane by incorporating cholesterol into the bilayer constitution of niosomes; this frequently increases the entrapment efficiency of the niosomes. Cholesterol is usually added to non-ionic surfactants to give hardness and proper direction/adjustment to niosomal bilayer. Cholesterol is renowned to get rid of gel to liquid phase transition of niosomal system leading to niosomes that are less leaky.

Charge inducers: Charge inducers are added in the preparation to increase the stability of niosomes by electrostatic repulsion to avoid coalescence. The negatively charged molecules mostly used are diacetyl phosphate (DCP) and phosphatidic acid. Similarly, positively charged inducers used in niosomal preparations are stearyl amine (STR) and stearyl pyridinium chloride. A concentration of 2-5 mole percentages of charged inducers is bearable because higher concentration can hamper the niosome formation.

Hydration medium: The most commonly used hydration medium in the preparation of niosome is phosphate buffer. These phosphate buffers are used at various pHs. The actual pH of the hydration medium depends on the solubility of the drug being encapsulated.

III. CLASSIFICATION

The three factors of niosomes are classified as a function of the amount of bilayer or as a function of size or as a function of the tactic of preparation. The various types of niosomes are described below:

Multi lamellar vesicles (MLV)

Large unilamellar vesicles (LUV) 3] Small unilamellar vesicles (SUV)

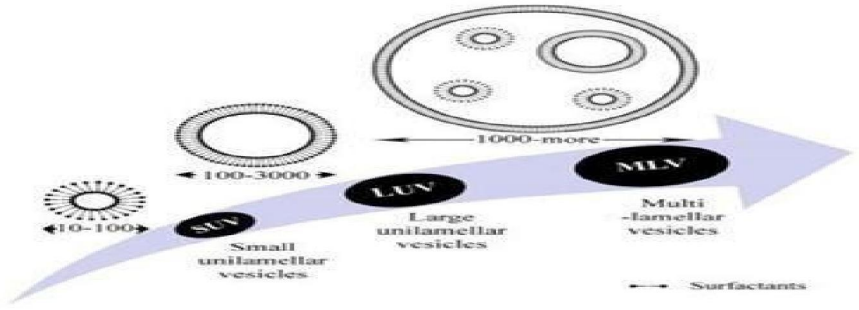

Figure 3: Types of Niosomes

Multilamellar vesicles (MLV): It consists of a number of bilayers surrounding the aqueous lipid compartment separately. The approximate size of those vesicles is 0.5-10 µm diameter.

Multilamellar vesicles are the foremost widely used niosomes. This type of vesicles are highly suitable as drug carrier for lipophilic compounds. The method of preparation of the vesicles is easy and it is mechanically stable upon storage

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for longer periods. It usually consists of number of bilayer surrounding the aqueous lipid component separately. These miltilamellar vesicles are highly suited as drug carrier for lipophilic compounds.

Large unilamellar vesicles (LUV): Niosomes of this sort have a high aqueous/lipid com partment ratio, in order that larger volumes of bio-active materials are often entrapped with a really economical use of membrane lipids. The size of large unilamellar vesicles are in the range of 100-3000 nm length.

Small unilamellar vesicles: (SUV) The approximate size of this vesicle are 10- 100 nm and this types of vesicle is prepared from multilamellar vesicles by sonication method, French press extrusion electrostatic stabilization in that the inclusion of diacetyl phosphate in 5 carboxyfluorescein loaded Span based niosomes.

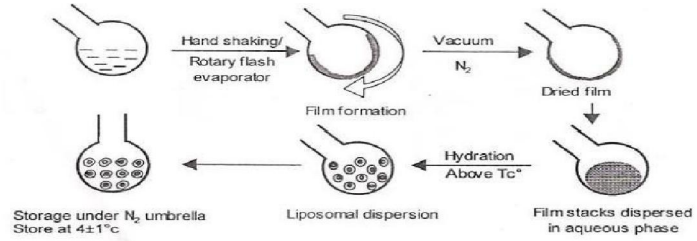
METHOD OF PREPARATION

Niosomes can be prepared by various methods some are as follows:

- Hand shaking method (Thin film hydration technique)
- Micro fluidisation
- Reverse Phase Evaporation (REV)
- Ether Injection Method
- Trans-membrane pH-gradient (inside acidic)
- The Bubble Method
- Sonication
- Multiple extrusion method
- Formation of niosomes from proniosomes

Hand shaking method (Thin film hydration technique)

In hand shaking method, round bottom flask is used in which non-ionic surfactant and cholesterol are dissolved in a volatile organic solvent (such as diethyl ether, chloroform, or methanol). The organic solvent is removed using rotary evaporator at room temperature (20°C) leaving a thin layer of solid mixture which is deposited on the wall of the flask. With gentle agitation the dried surfactant film is hydrated with aqueous phase containing drug at 50-60°C. By this method multilamellar niosomes are formed.



Multilamellar Vesicles (MLVs) Formed by either Hand Shaking Technique or Using Rotary Flash Evaporator

Micro fluidization

Micro-fluidisation is a technique in which unilamellar vesicles of defined size distribution are prepared. It is based on 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 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.

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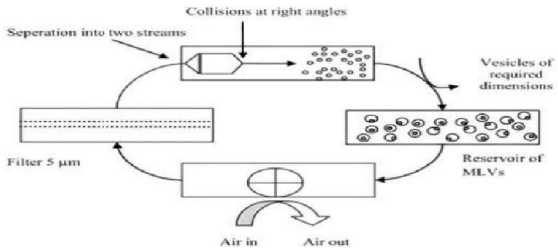
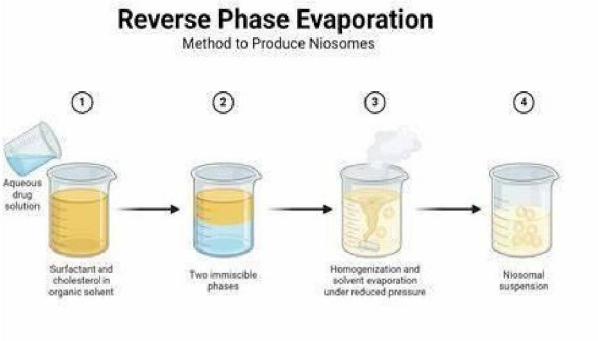


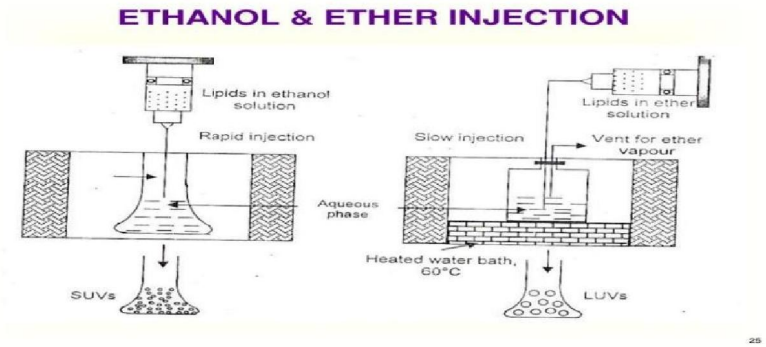
Reverse Phase Evaporation (REV)

In reverse phase evaporation, the cholesterol and surfactant is taken in the ratio 1:1 ratio. The above mixture is dissolved in ether and chloroform mixture. Drug is dissolved in aqueous phase. Both the mixture is sonicated at the temperature 4-6°C. The suspension of niosomes is diluted in the PBS at 60°C using water bath for 10 minutes, which yields the niosomes. PBS is again added to the obtained product and sonicated at low pressure and temperature is maintained at 40-45°C and organic phase is removed at this temperature. The resultant suspension is diluted with PBS and heated on water at 60°C to 10 minutes to yield niosomes.



Ether injection method: In ether injection method

The niosomes are prepared by introducing a solution of surfactant which is dissolved in diethyl ether (volatile organic solvent) into warm water which is maintained at 60°C. The surfactant mixture in ether is injected into an aqueous solution of material with the help of 14-gauge needle. Single layered vesicles are formed by vapourization of ether (volatile organic solvent).



Trans-membrane pH gradient (inside acidic) In this method, the surfactant and cholesterol is mixed/ blended in round bottom flask and dissolved in chloroform. On the wall of the flask, a thin film is formed by evaporating the chloroform under reduced pressure. Hydration of film is done by vortex mixing with 300mM citric acid (pH 4.0). To

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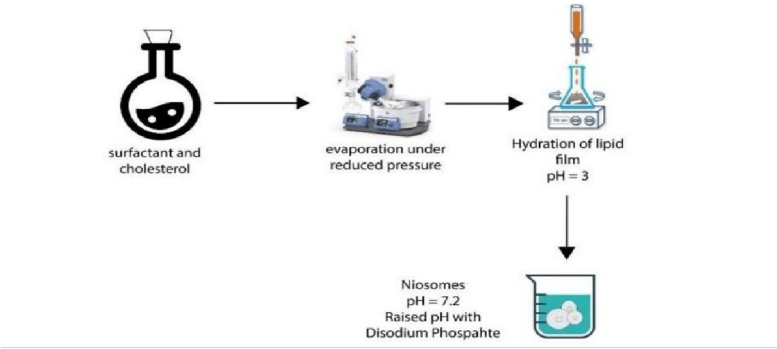
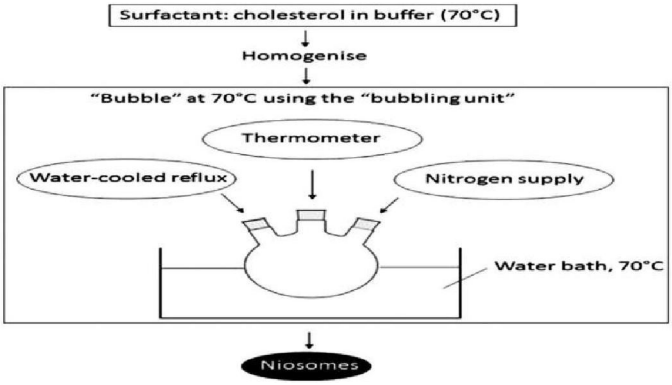
the above niosomal suspension, aqueous solution containing 10mg/ml of drug is added and vortexed. The pH of the sample is adjusted to 7.0-7.2 by adding 1M disodium phosphate and this mixture is heated at 60°C for 10 minutes. Multilamellar vesicles are produced by this method.



The Bubble method

The bubble method is a novel technique in which the niosomes are prepared without using organic solvents. The bubbling unit is used in this method. This unit consist of round bottom flask with 3 necks positioned in water bath by which the temperature is controlled. Water- cooled reflux is placed in first neck, thermometer is placed in second neck and the nitrogen is passed through the third neck. Cholesterol and surfactant are mixed together in buffer solution (pH-7.4) at 70°C. High shear homogenizer is used for mixing the solution for 15 seconds, and then this solution is immediately bubbled at 70°C by the use of nitrogen gas.



Sonication

Sonication is one of the conventional methods for the preparation of niosomes. In this method, the drug solution is prepared by dissolving drug in buffer. Then this buffer drug solution is added the mixture of the non-ionic surfactant at optimized ratio. The desired niosomes are obtained by sonicating the mixture at specific frequency, temperature and time. It is one of the easy way in which the particle size of the niosomes can be controlled. This method can be used to decrease the diameters of niosomes with narrow size distribution. Probe sonicators can also be used but they involve high levels of energy. Due to this it leads to sudden increase in temperature and discharge of titanium.

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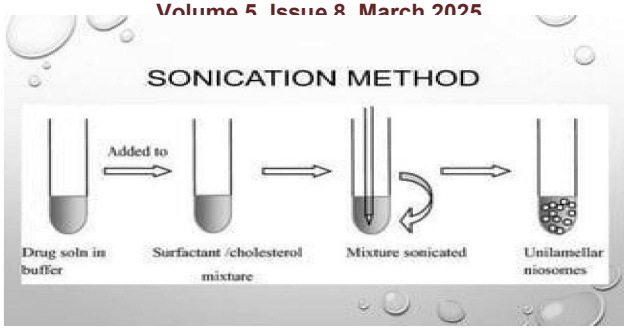

Membrane Extrusion Method

In this method the surfactant, cholesterol and diacetyl phosphate is mixed in chloroform. Then this chloroform mixture is evaporated to obtain thin film. Hydration of thin film is done with aqueous drug polycarbonate membrane. Solution and resultant suspension is extruded through this membrane (which consist of 8 passages). Required size of the niosomes is also obtained by this method.

Formation of niosomes from preniosomes

By addition of aqueous phase with drug to the pre niosomes with short agitation at a temperature greater than mean transition phase temperature of the surfactant results in the formation of the niosomes. T Where, T = Temperature Tm = Mean phase transition temperature Blazek-Walsh A.I et al has described the formulation of niosomes from maltodextrin based pre niosomes. This formulation furnishes rapid reconstitution of niosomes with the minimal left over/ residual carrier. Free flowing powder of formulation was obtained by drying the slurry of maltodextrin and surfactant, which could be rehydrated by addition of warm water.

FACTORS AFFECTING THE NIOSOME FORMATION

DRUG

The physico-chemical properties of encapsulated drug directly affect the charge and rigidity of the niosomal bilayer. Journal of Drug Delivery & Therapeutics. 2021; 11(1):162-170 The vesicle size of the niosomes is improved by entrapping the drug inside the niosomes, also by interaction of solute with head groups of surfactants. Enhancement of charge and mutual repulsion between the bilayers of surfactant increases the vesicle size. Degree of entrapment is also affected by the Hydrophilic-Lipophilic balance of the drug .

Resistance of osmotic stress

The addition of hypertonic salt solution to the niosomal suspension leads the reduction in diameter of niosomes. Again, after the addition of hypotonic salt solution, initially it leads to slow release with slight swelling of the vesicles due the inhibition of elution fluid from vesicles. The release becomes faster due to mechanical loosening of vesicle structure under osmotic stress.

Temperature of hydration medium

Temperature of hydration medium plays a vital role in formation of vesicle. This affects their shape and size. The temperature maintained should be above the gel to liquid phase transition temperature of the system. Changes in the vesicle shape are also observed due to the temperature. It also affects the assembly of surfactants into vesicles. Vesicle structure and yield is affected by the volume of hydration medium and duration of the lipid film.

Cholesterol content

Cholesterol affects the physical properties and structure of the niosomes. The structure is affected due the presence of non-ionic surfactants. Cholesterol is present in biological membranes it also affects the membrane properties like ion permeation, aggregation, fusion processes, size, shape, elasticity and enzymatic activity. Addition of cholesterol leads to change in fluidity of niosomes. Cholesterol plays an important role during preparation of niosomes because it

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provides rigidity to vesicles, which is very important during severe stress conditions. The amount of cholesterol to be added depends on the HLB value of the surfactants. As the HLB value increases above 10, the amount of cholesterol should also be increased in order to remunerate for the larger head groups.

Change in HLB value has impact on noisome formulation (Table 1). Inclusion of cholesterol in niosomes increases the hydrodynamic diameter and entrapment efficiency. At high cholesterol concentration, the gel state is transformed to a liquid ordered phase. An increase in cholesterol content of the bilayers results in a decrease in the release rate of encapsulated material and thereby increases the rigidity of the bilayers obtained

Table 1: HLB value and their impact on niosome formation.

HLB Value	Impact on niosome formation
>6	Need to add cholesterol in formation of bilayer formation.
1.7 – 8.6	Decreases entrapment efficiency of niosomes.
14 – 16	Does not produce niosomes.
8.6	Increases entrapment efficiency of niosomes.
Lower Value	Need to add cholesterol to increase stability

Amount and type of surfactant

The mean size of niosomes increases proportionally with increase in the HLB surfactants like Span 85 (HLB 1.8) to Span 20 (HLB 8.6) because the surface free energy decreases with an increase in hydrophobicity of surfactant. The bilayers of the vesicles are either in the liquid state or in gel state, depending on the temperature, the type of surfactant and the presence of other components like cholesterol. Alkyl chains are present in a well-ordered structure in the gel state, while in the liquid state, the structure of the bilayers is more disordered. The surfactants and lipids are characterized by the gel-liquid phase transition temperature (TC). Phase transition temperature (TC) of surfactant also affects the entrapment efficiency i.e. Span 60 having higher TC.

Membrane Composition

Addition of various additives along with surfactants and drugs leads to the stable formation of niosomes. Niosomes formed have a variety of morphologies and their permeability/porousness and stability properties will be altered by manipulating membrane characteristics by totally different additives. Just in case of polyhedral niosomes formed from C16G2, the shape of these polyhedral niosome remains unaffected due to the addition of low quantity of solution of solulan C24 (cholesterol poly-24-oxyethylene ether), that prevents aggregation due to development of steric.

CHARACTERIZATION OF NIOSOMES

Entrapment Efficiency

The entrapment efficiency (EE) of vesicular systems can be defined as the amount of active substances loaded within the niosomal structure. It can be expressed as: EE = x 100 where, the “total amount” is the total amount of drug in the prepared in the niosomal formulation. The entrapment efficiency is determined spectrophotometrically by using UV-visible spectrophotometer. In case of genetic material, gel electrophoresis is done followed by UV densitometry. In addition, the entrapment efficiency can also be fluorometrically evaluated using a hydrophilic fluorescent.

Vesicle size and shape

The shape of niosomal vesicles is assumed to be spherical, and their mean diameter can be determined by using laser light scattering method. Also, the diameter of these vesicles can be determined by using electron microscopy, molecular sieve chromatography, ultracentrifugation, photon microscopy and optical microscopy and freeze fracture electron microscopy. Freeze thawed niosomes increases the vesicle diameter, which might lead to the fusion of vesicles during the cycle.

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In-vitro release

In in-vitro release study dialysis membrane method is generally used. In this method small amount of niosomes are taken into dialysis bag and are tied at both the ends. Another beaker containing suitable dissolution media is maintained at 37 °C and the dialysis bag is put into the dissolution medium and stirred by a magnetic stirrer. A sample solution is taken from the beaker at specified time intervals and replaced with fresh dissolution media

The samples were analyzed for the concentration of drug at specified wave length reported in the respective monograph of that particular drug.

Number of lamellae

Number of lamellae in niosomes can be determined by using electron microscope, NMR spectroscopy or X-ray scattering method.

Membrane rigidity

Membrane rigidity of the noisome is measured by means of mobility of fluorescence probe as function of temperature.

Bilayer formation

Assembly of non-ionic surfactants to form bilayer vesicle is characterized by the formation of X-cross under light polarization microscopy.

Stability study

The stability of niosomes can be evaluated by determining mean vesicle size, size distribution, and entrapment efficiency over several month storage periods of niosomal suspension at different temperatures. During storage the niosomes are sampled at regular intervals of time and the percentage of drug which is retained into the niosomes is analyzed by UV spectroscopy or HPLC method.

Vesicular surface charge

Niosomes are generally prepared by the inclusion of charged molecules in the bilayer to prevent the aggregation of formed vesicles. When dicetyl phosphate like charged molecule was incorporated in vesicles, a reduction in aggregation of vesicle was observed. The charge on vesicles is expressed in terms of zeta potential and calculated using the Henry's equation:

£=/where,

£ = Zeta potential

μE = Electrophoretic mobility μ = Viscosity of medium Σ = Dielectric constant

ADVANTAGES OF NIOSOMES

- Bioavailability Improvement
- Niosomes increase the invigorative performance of the medication particles by postponed relaxation from the diffusion, shielding the medication from natural condition and limiting efficacy to focus on cells.
- Niosomal dispersion during an aqueous phase are oftene mulsified during an on aqueous phase to manage the delivery.
- Niosomes can increase the rate of drug and adminis tered normal vesicle in external nonaqueous phase.
- They are osmotically active and stable, also as they increase the steadiness of entrapped drug.
- They improve oral bioavailability of poorly absorbed drugs and enhance skin penetration of medicine.

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DISADVANTAGES OF NIOSOMES

- Physical insecurity
- Inadequate drug loading capacity. Aggregation
- Fusion Manufacturing requires specialized equipment.
- It is costly.
- Entrapped medication leakage
- Techniques that take a long time
- The hydrolysis of encapsulated medicines reduces the shelf-life of the dispersion.
- Because opposing charges approach and niosomal vesicles merge, various charges can exist on the surface of niosome vesicles during niosome synthesis.

Applications

1. Niosomes have been used for studying the nature of the immune response provoked by antigens.
2. It is used as Drug Targeting.
3. It is used as Anti-neoplastic Treatment i.e. Cancer Disease.
4. It is used as Leishmaniasis i.e. Dermal and Mucocutaneous infections e.g. Sodium stibogluconate.
5. Niosomes as Carriers for Hemoglobin.
6. It is used act as Delivery of Peptide Drugs.
7. Niosomes can be used as a carrier for hemoglobin.
8. It is used in Studying Immune Response.
9. Transdermal Drug Delivery Systems Utilizing Niosomes.
10. It is used in ophthalmic drug delivery.
11. Niosomal system can be used as diagnostic agents.

1] Immunological application of niosomes: Niosomes have been used for studying the nature of the immune response provoked by antigens. Niosomes can also be utilized for targeting drugs to organs other than the Reticulo- Endothelial System. 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.

2] Sustained Release: Sustained release action of niosomes can be applied to drugs which have low therapeutic index and have low solubility with water since those could be maintained in the circulation via niosomal encapsulation.

3] Localized Drug Action (Navneet et al., 2014) Drug delivery through niosomes is one of the approaches to achieve localized drug action, since their size and low penetrability through epithelium and connective tissue keeps the drug localized at the site of administration

4] 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.

5] Transdermal delivery of drugs by niosomes: Those drugs have slow penetration of medicament 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. From the above discussed studies, and confocal microscopy, it was seen that non-ionic vesicles could be formulated to target pilosebaceous glands. 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.

6] 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.

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7] Delivery of Peptide Drugs: Oral peptide drug delivery has long been faced with a challenge of bypassing the enzymes which would breakdown the peptide. Use of niosomes to successfully protect gastrointestinal the peptides from peptide breakdown is being investigated. In an in vitro study conducted by oral delivery of a vasopressin derivative entrapped in niosomes showed that entrapment of the drug significantly increased the stability of the peptide. Niosome formulation as a brain targeted delivery system for the vasoactive intestinal peptide Radiolabelled (I125) VIP-loaded glucosebearing niosomes were injected intravenously to mice. Encapsulated VIP within glucosebearing niosomes exhibits higher VIP brain uptake as compared to control.

8] Niosomes as carriers for Hemoglobin: Niosomes can be used as a carrier for hemoglobin. Niosomal suspension shows a visible spectrum superimposable which is likely to be or, onto that of free hemoglobin. Vesicles are permeable to oxygen and hemoglobin dissociation curve can be modified similarly to non- encapsulated hemoglobin. 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 are decreased rate of proliferation of tumor and higher plasma levels accompanied by slower elimination.

9] 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 reticulo-endothelial system (RES) preferentially takes. The uptake of niosomes is controlled by circulating serum factors called opsonins. These opsonins mark the niosome for clearance. Such localization of drugs is utilized to treat tumors in animals known to metastasize to the liver and spleen. This localization of drugs can also be used for treating parasitic infections of the liver. Niosomes can also be utilized for targeting drugs to organs other than the RES. 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.

10] Gene delivery: Gene therapy has been utilized as an effective technique in the treatment of hereditary human disorders using non-viral carriers to improve the cellular absorption characteristics of nucleic acids. The properties of the vector significantly impact the effectiveness of gene therapy. Even though niosomes have been present for almost three decades, only a few research have been conducted to investigate their potential as gene delivery vectors. Compared to liposomes, niosomes have higher storage and chemical stability due to the presence of non-ionic surfactants. These non-ionic surfactants also reduce the toxicity of niosomes as well as their fabrication cost. These features encourage research on the use of niosomes in gene delivery applications. In reported studies, niosomes have been employed as oligonucleotide carriers to treat various ailments. A strategy was demonstrated to transfer pCMS-eGFP plasmid to the retina using niosomes. A cationic niosome formulation prepared with 2- di(tetradecoxy)propane-1-amine, squalene and polysorbate 80 was used for compact transport of a 5 kb-long pCMS- eGFP DNA plasmid in the eye. RPE cells were modestly transfected following the sub-retinal injection in rats, while GFP expression in the inner retinal layers was induced by intravitreal injection. While maintaining the transfection efficiency, the inclusion of protamine in the formulation enhanced nucleus targeting and allowed transfection of a small proportion of photoreceptor cells following sub-retinal injection. It was also discovered that encapsulating genes encoding hepatitis B surface antigens (HBsAgs) in niosomes induced an immune response to produce blood antibodies and endogenous cytokines comparable to intramuscularly recombinant HBsAgs or topical liposomes. Qtaish et al. developed a novel niosomal formulation with long-term biophysical stability for non-viral gene delivery to the retina. Niosome as a non-viral vector has shown advantageous features for gene delivery, which include low toxicity, high stability, and easy production.

11] Cancer treatment

Niosomal formulations can deliver various anticancer drugs with low side effects. Conventional chemotherapy cannot selectively target the cancerous cells and is associated with low therapeutic efficacy and a high incidence of side effects and toxicity to normal cells. Colloidal niosomal formulations are promising systems for drug delivery to cancerous tissues, passively and actively. Delivery of anticancer drugs by niosomal formulations can overcome low bioavailability and stability, significant risk of side effects, and inadequate access to the drug because of low permeation of the blood-brain barrier. The niosomal formulations have been reported to decrease the toxicity of Withaferin–A (WA) as an active constituent of Withania somnifera , tamoxifen (TMX)/curcumin , and curcumin

. Niosomes use different release mechanisms in cancer tissues or cells. Various stimuli, including temperature, light,

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pH, enzymatic decomposition, and ultrasound have been employed to activate the decomposition of bilayer vesicles . Sharafshadeh et al. developed a formulation of alginate-coated niosome- based nanocarriers for the co-delivery of doxorubicin (Dox) and cisplatin (Cis) for the treatment of breast and ovarian cancers. Results proved the synergetic cell proliferation inhibitory impacts of Cis and Dox against MCF-7 and A2780 cancer cells.

The efficiency of niosomal formulation for ovarian and breast cancer treatment was explored. Zarepour et al. prepared a new nano-drug delivery platform for the treatment of lung cancer, using niosomal formulation consisting of curcumin coated with a chitosan polymeric shell, alongside Rose Bengal (RB) as a photosensitizer with antibacterial properties. They showed great antibacterial and anticancer effects against Gram-negative bacteria and lung cancer cells. Saharkhiz et al. developed a novel formulation consisting of doxorubicin-loaded pH- responsive stealth niosomes and CdSe/ZnS Quantum dots as an imaging agent. eThis new nanoformulation showed potential for future cancer theranostic applications . Various niosomal formulations allowed a greater reduction in the expression of genes involved in metastasis including COL10A1, MMP2, and MMP9 . Moreover, the niosomal nanoparticles showed high anti-proliferative potential by restraining anti-apoptotic and inducing apoptotic gene expression in A549 lung cancer cells . In the following sections, in-vitro and in-vivo studies of recent works on anticancer drug-loaded niosomes have been examined, and some of the remarkable outcomes achieved in those works have been detailed

COMPARISON OF NIOSOMES VS LIPOSOMES

- Niosomes are now widely studied as an alternative to liposomes, which exhibit certain disadvantages such as – they are expensive, their ingredients like phospholipids are chemically unstable because of their predisposition to oxidative degradation, they require special storage and handling and purity of natural phospholipids is variable.
- Differences in characteristics exist between liposomes and niosomes, especially since niosomes are prepared from uncharged single-chain surfactant and cholesterol whereas liposomes are prepared from double-chain phospholipids (neutral or charged)
- Niosomes behave in-vivo like liposomes, prolonging the circulation of entrapped drug and altering its organ distribution and metabolic stability. Encapsulation of various anti neoplastic agents in these carrier vesicles has been shown to decrease drug induced toxic side effects, while maintaining, or in some instances, increasing the anti-tumor efficacy Such vesicular drug carrier systems alter the plasma clearance kinetics, tissue distribution, metabolism and cellular interaction of the drouthy can be expected to target the drug to its desired site of action and/or to control its release.
- As with liposomes, the properties of niosomes depends both on the composition of the bilayer and on method of their production. It was observed by Baillie et al that the intercalation of cholesterol in the bilayers decreases the entrapment volume during formulation and thus entrapment efficiency. As the concentration of cholesterol increases, entrapment efficiency decreases.
- The entrapment efficiency increases with increase in the concentration and lipophilicity of surfactant Chandraprakash et al made Methotrexate loaded non-ionic surfactant vesicles using lipophilic surfactants like Span 40, Span 60 10 and Span 80 and found that Span 60 (HLB = 4.7) gave highest percent entrapment while Span 85 (HLB = 9.8) gave least entrapment. They also observed that as HLB value of surfactant decreased, the mean size was reduced.

II. CONCLUSION

Niosomes, a nonionic surfactant vesicular system, is a novel and efficient approach to drug delivery. With the incorporation of appropriate nonionic surfactant and cholesterol in the vesicular membrane, a wide range of drugs can be encapsulated into niosomes. In addition, niosomes possess enhanced stability and reduced toxic drug effects, with sustained release of the encapsulated drug. Furthermore, no special conditions are required for handling and storage of niosomes, compared with other drug-delivery systems such as liposomes. Appropriate modifications of niosomes,

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resulting in structures such as proniosomes, enable them to be used in special routes of administration. In summary, niosomes represent a highly effective tool for drug delivery in the therapeutic regime of numerous diseases and have the potential to provide more efficacious treatment than conventional drug-delivery platforms.

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