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RECENT DEVELOPMENTS IN NIOSOMES: A SMARTER VESICULAR DRUG DELIVERY SYSTEM

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ABSTRACT

In the field of nanotechnology, researchers have shown an optimistic progress in the development of novel dosage forms. Niosomes are one of the novel dosage forms which overcome limitations associated with other vesicular drug delivery systems. They are the non-ionic surfactant-based vesicle formed by self-association in an aqueous phase. It is mainly designed to delivery of drug to the targeted site, release of drug by controlled manner, in skin disorders, viral infection, microbial illnesses, in diagnostic imaging, as a vaccine adjuvant, etc. There are several factors which affect the niosomal vesicle formation like the type of surfactant, method of preparation, temperature. This review focuses on the basic details of niosomes, additives for formulation of niosomes, types of niosomes, factors affecting on niosomes, methods of preparation, characterization of niosome, applications, recent researches in niosomes and published patents on niosomes.

Keywords *– Niosomes; Non-ionic surfactants; Vesicles; Controlled delivery.*

1. INTRODUCTION

Niosomes (**Fig. 1**) are the novel vesicular carrier made up of non- ionic surfactant. These are non-toxic due to non- ionic surfactant used in formulation [1]. It also contains cholesterol and charged molecules. Cholesterol provides rigidity to the vesicles and the charged molecule makes the preparation stable [2-4]. Both the hydrophilic and lipophilic molecules can be delivering due to unique structures of niosomes.

Niosomes are distinguished from liposomes are made from phospholipids and it shows several disadvantages like toxicity, fusion of vesicles and stability issues at different pH [5-8]. The physicochemical characteristic of niosome like their size, charge, lamellarity, elasticity and thermodynamic phase are depending upon the composition of niosomes. A feasible and the latest approach to formulate stable niosome is the provesicular carrier system i.e. proniosomes [9-16]. They are more benificial as it delivers drug by simultaneous fashion, for example, doxorubicin and curcumin (anticancer drugs). It also important as it deliver drug at ocular site (example-tacrolimus, naltrexone HCl) [17], transdermal (example-gallidermin, clomipramine) [18], pulmonary

(example-glucocorticoid) [19], oral (example-cefdinir, Lornoxicam) [20] as well as they can be used to deliver drug across blood-brain barrier (example-temozolomide) [21-24].

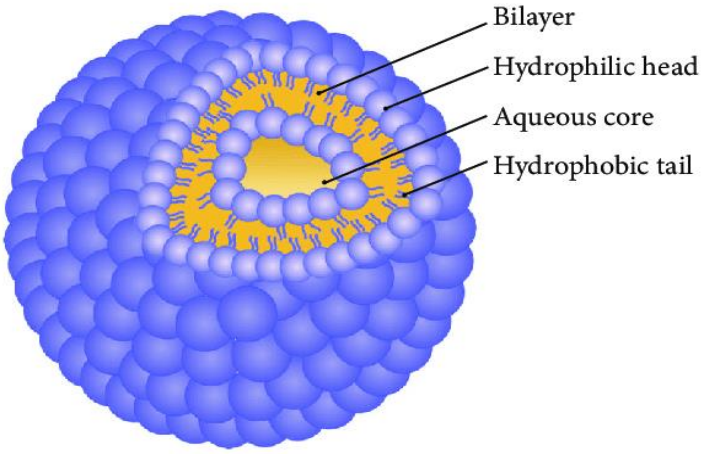

Fig. 1: Structure of Niosomes

2. TYPES OF NIOSOMES

Niosomes are classifying in three classes according to their sizes and vesicles present in the structure **(Fig. 2)** [25-28].

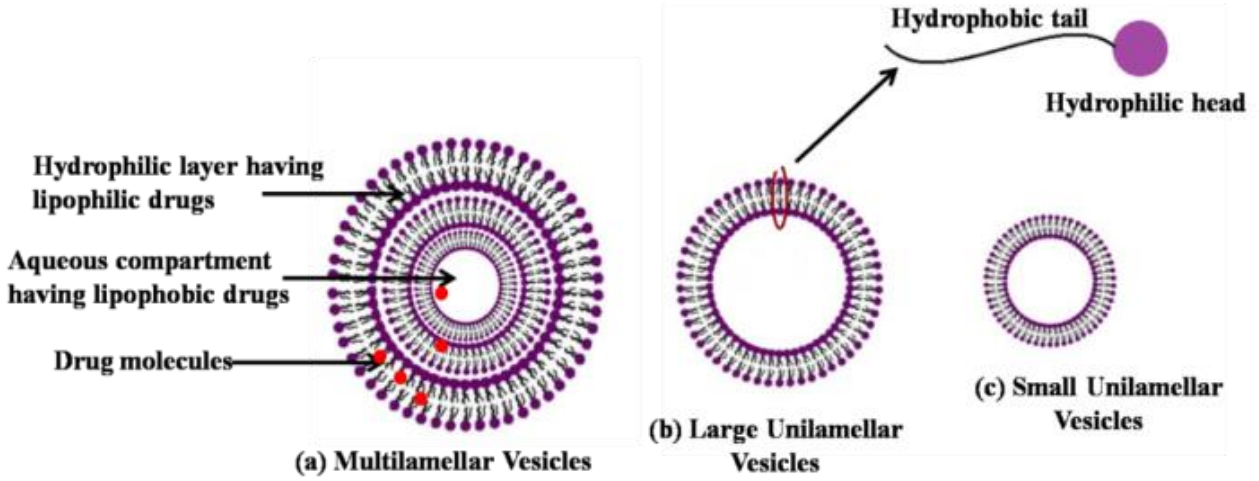

Fig. 2: Types of niosomes

2.1. Multilamellar vesicles (MLV)

More than one layer is present in the structure and having size range greater than 1000 nm.

2.2. Large Unilamellar vesicles (LUV)

Having Size ranges from 100–3000 nm contains single lamella but larger in size.

2.3. Small Unilamellar vesicles (SUV)

Having size ranges from 10–100 nm and composed of only one lamella.

3. ADVANTAGES OF NIOSOMES

Niosomes possesses following advantages [29-34].

- Niosomes are osmotically active and stable as compare to liposomes.
- Niosomes are made up of non-ionic surfactant result in reduced toxicity and enhanced compatible of the formulation.
- Niosomes helps to release the drug in controlled manner.
- They improve the therapeutic performance of the drug molecules by delayed clearance from the circulation, protecting the drug from biological environment and restricting effects to target cells.
- Due to the unique structure of niosomes, they can be used to encapsulate both hydrophilic as well as hydrophobic drugs as a result can accommodate drug molecules with a wide range of solubilities.

4. DISADVANTAGES OF NIOSOMES

There are several advantages of niosomal delivery system but leakage from entrapment site and stability of niosomes could be an issue with the niosomes because the drug may get hydrolyzed [35].

5. FORMULATION COMPONENTS OF NIOSOMES

The Important components used for formulation of niosomes are: Non-ionic surfactants, Cholesterol, Charged molecule.

5.1. Non-ionic Surfactants

The nonionic surface-active agents are used for preparation of niosomes. These are amphiphilic in nature having hydrophilic head and a Hydrophobic tail. These surfactants are more stable, compatible, and less toxic in comparison to anionic, cationic and amphoteric surfactants as they do not carry any charge to react with other molecule. They act as permeability and solubility enhancer, wetting and emulsifying agents **(Table 1)** [36-40].

5.2. Cholesterol

Cholesterol is a steroid derivative, which is mainly used for the formulation of niosomes. Incorporation of cholesterol affects properties of niosomes like membrane permeability, rigidity, encapsulation efficiency, ease of rehydration of freeze dried niosomes and their toxicity. If cholesterol is used with low HLB surfactants, it can increase the stability of the vesicle and if the HLB value is more than 6, it helps in the formation of bilayer vesicles. The addition of cholesterol increases the viscosity and hence rigidity of the preparation [41-44].

5.3. 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. Stearylamine (STR) and stearyl pyridinium chloride are the well-known positively charged molecules used in niosomal preparations [45-46].

Table 1: Non-ionic surfactants used in the niosomes

Surfactant	Properties
Alkyl Ethers and Alkyl, lyceryl Ethers, Polyoxyethylene 4 Lauryl Ether (brij 30)	HLB value is 9.7 and Phase transition temperature < 10. It forms LUV when combined with specific concentration of cholesterol ie; 30mmol/L. It causes oxidation when used with benzocaine, tretinoin, and oxidizable medications, leading to discoloration
Polyoxyethylene Cetyl Ether (Brij 58)	It has the capacity of forming inverse vesicles. HLB value is 15.7
Polyoxyethylene Stearyl Ethers (Brij 72 and Brij 76)	Brij 72 HLB value is 4.9 and Brij 76 is 12.4. so, the entrapment efficiency of Brij 72 is higher than Brij 76.
Sorbitan Fatty Acid Esters (Span)	Generally used in water-based cosmetic preparations to solubilize oils. Gel transition temperature of span 60 is higher than span 20 and span 40. Vesicles prepared from a higher span are more stable and less leaky.
Polyoxyethylene fatty acid esters	This fatty acid ester is used for preparation of niosomes usually, Tween 20, 40, 60 and 80.
Pluronic L64 and Pluronic p105	Pluronic L64 and p105 are copolymers made up of polyethylene oxide (EO) and polypropylene oxide (PO). Arranged one by one as EO-PO-EO. Pluronics interact themselves with multidrug-resistant cancer tumors.

6. METHODS OF PREPARATION

6.1. Ether injection

In this method, mix of cholesterol and surfactant together in an organic solvent like diethyl ether through a 14-gauze needle in preheated 4ml aqueous phase maintained at >60°C. The ether solution was evaporated using rotary evaporator, after evaporation of the organic solvent forms unilamellar vesicles of the surfactant-containing drug. The diameter of niosomes prepared by this method may vary from 50 to 1000µm [47].

6.2. Sonication

In this method, surfactant: cholesterol mixture was dispersed in 2ml aqueous phase in vial. The dispersion is subjected to probe sonication for 3 min at 60°C. This method involved the formation of MLV which are subjected to ultrasonic vibration. Probe sonicator is use when sample volume is small and Bath sonicator is use when sample volume is large [48].

6.3. Hand shaking method

In this method, surfactant: cholesterol mixture was dissolved in 10ml diethyl ether in RBF. The ether is evaporated under vacuum at room temperature in rotary evaporated. Upon hydration the surfactant swells and is peeled off the support in to a film. Swollen amphiphiles eventually fold to form vesicles. The liquid volume entrapped in vesicles appears to be small that is 5-10% [49].

6.4. Multiple membrane extrusion method

A blend of surfactant, cholesterol and diacetyl phosphate is prepared and after that solvent is evaporated utilizing rotary vacuum evaporator to leave a thin film. The film is then hydrated with aqueous drug solution and the suspension subsequently acquired is extruded through the polycarbonate layer (mean pore size 0.1mm) and then placed in series up to eight passages to get uniform size niosomes [50].

6.5. Reverse phase evaporation technique

In this method, surfactant is dissolved in chloroform and added into the 0.25 volume phosphate saline buffer solution is emulsified to get w/o emulsion. The mixture is then solicited and subsequently chloroform is evaporated under reduce pressure. The lipid or surfactant forms a gel first and subsequently hydrates to form vesicles [51].

6.6. Bubble method

It is novel technique for the one step preparation of niosomes without the use of organic solvents. It consists of round bottomed flask with three necks placed in water bath to control the temperature. Water-cooled reflux and thermometer is positioned in the first and second neck and nitrogen supply through the third neck. Cholesterol and surfactant are dispersed together in pH 7.4 buffers at 70°C. A continuous stream of nitrogen gas bubbles is generated and introduced through the dispersion and produce a niosomes [52].

6.7. Micro fluidization method

Micro fluidization is a current strategy to plan unilamellar vesicles of characterized estimate circulation. Based on submerged jet principle, in this strategy two fluidized streams connect at ultrahigh speeds, in correctly characterized smaller scale channels inside the interaction chamber. The impingement of thin liquid sheet along a common front is arranged such that the energy supplied to the system remains within the area of niosomes formation. The outcome is a more prominent consistency, smaller size and better reproducibility of niosomes shaped [53-54].

6.8. Supercritical carbon dioxide fluid

In this method solvents used are non-inflammable, non-toxic and volatile. Niosomes prepared by this method have the size in the range of 100–440 nm [55].

6.9. Single pass technique

In this method, a suspension of a lipid-containing drug is passed from a porous device and then through a nozzle. It produces uniform size niosomes, usually in the range of 50–500 nm [56].

6.10. Trans-membranes pH gradient (inside acidic) drug uptake process

A solution of surfactant and cholesterol are dissolved in chloroform. The solvent is then evaporated under reduced pressure to get a thin film on the wall of the round bottom flask. This film is hydrated with 300mm citric acid pH 4 by vertex mixing. The resulting multilamellar vesicles are frozen and shared three times and later sonicated.

To this niosomal suspension, aqueous solution containing 10 mg/ml of drug is added and vortexes. The PH of the sample is then raised to 7.0-7.2 with 1M disodium phosphate. This mixture is later heated at 60°c for 10 minutes to give niosomes [57].

6.11. Lipid layer hydration method

Span 60 and cholesterol (1:1) are dissolved in chloroform and the solvent was evaporated utilizing rotary flash evaporator. Phosphate buffer saline PH 7.4 containing drug is added to the dried thin film with gentle agitation. The blend is irregularly mixed on a vortex mixer. Sonic dispersion of the blend is completed at 25°C utilizing probe sonicator set at 200 watts for 1min [58].

7. CHARACTERIZATION OF NIOSOMES

7.1. Measurement of angle of repose

The angle of repose of dry niosomes powder was measured by a funnel method. The niosomes powder was poured into a funnel which was fixed at a position so that the 13mm outlet orifice of the funnel is 5cm above a level black surface. The powder flows down from the funnel to form a cone on the surface and the angle of repose was then calculated by measuring the height of the cone and the diameter of its base [59-60].

7.2. Scanning electron microscopy

Particle size of niosomes is very important characteristic. The surface morphology (roundness, smoothness, and formation aggregates) and the size distribution of niosomes were studied by Scanning Electron Microscopy (SEM). Niosomes were sprinkled on to the double- sided tape that was affixed on aluminum stubs.

The aluminum stub was placed in the vacuum chamber of a scanning electron microscope. The samples were observed for morphological characterization using a gaseous secondary electron detector [61].

7.3. Optical microscopy

The niosomes were mounted on glass slides and viewed under a microscope with a magnification of 1200X for morphological observation after suitable dilution. The photomicrograph of the preparation also obtained from the microscope by using a digital SLR camera [62-63].

7.4. Measurement of vesicle size

The vesicle dispersions were diluted about 100 times in the same medium used for their preparation. Vesicle size was measured on a particle size analyzer. The apparatus consists of a He-Ne laser beam of 632.8 nm focused with a minimum power of 5 mW using a Fourier lens [R-5] to a point at the center of multi-element detector and a small volume sample holding cell (Su cell). The sample was stirred using a stirrer before determining the vesicle size. Average particle size of niosomes is approximately 6µm while that of conventional niosomes is about 14µm [64].

7.5. Membrane rigidity

Membrane rigidity can be measured by means of mobility of fluorescence probe as a function of temperature [65].

7.6. Entrapment efficiency

Entrapment efficiency of the niosomal dispersion in can be done by separating the unentrapped drug 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 [66].

7.7. Osmotic shock

The change in the vesicle size can be determined by osmotic studies. Niosomes formulations are incubated with hypotonic, isotonic, hypertonic solutions for 3 hours. Then the changes in the size of vesicles in the formulations are viewed under optical microscopy [67].

7.8. Stability studies

To determine the stability of niosomes, the optimized batch was stored in airtight sealed vials at different temperatures. Surface characteristics and percentage drug retained in niosomes and niosomes derived from proniosomes were selected as parameters for evaluation of the stability, since instability of the formulation would reflect in drug leakage and a decrease.

In the percentage drug retained. The niosomes were sample at regular intervals of time (0,1,2,and 3months), observed for color change, surface characteristics and tested for the percentage drug retained after being hydrated to form niosomes and analyzed by suitable analytical methods [68].

7.9. Zeta potential analysis

Zeta potential analysis is done for determining the colloidal properties of the prepared formulations. The suitably diluted niosomes derived from proniosomes dispersion was determined using zeta potential analyzer based on electrophoretic light

scattering and laser Doppler velocimetry method. The temperature was set at 25°C. Charge on vesicles and their mean zeta potential values with standard deviation of measurements were obtained directly from the measurement [69].

8. APPLICATIONS OF NIOSOMAL SYSTEMS [70-88]

8.1. Anticancer drug delivery

The therapeutic efficacy of many anticancer drugs is limited by their poor penetration into tumor tissue and by their severe side effects on healthy cells. Various attempts have been made to overcome these drawbacks, including the use of niosomes as a novel drug delivery system.

8.2. Ophthalmic drug delivery

Niosomal formulations are used in ophthalmic drug delivery to achieve good bioavailability of drug.

8.3. Delivery of peptide drugs

For oral delivery of 9-desglycinamide, 8-arginine vasopressin entrapped in niosomes in an in-vitro intestinal loop model and reported that the stability of peptide increased by niosomes.

8.4. Niosome as a carrier for hemoglobin

Niosomal suspension shows a visible spectrum super imposable onto that of free hemoglobin so can be used as a carrier for hemoglobin. Vesicles are also permeable to oxygen and hemoglobin dissociation curve can be modified similarly to non-encapsulated hemoglobin.

8.5. Niosomes in gene delivery

Novel niosome detailing in light of the 2,3-di (tetradecyloxy) propan-1-amine cationic lipid, joining with squalene and polysorbate 80 to assess the transfection productivity in rodent retinas. Lipoplexes at 15/1 proportion were 200 nm in measure, 25mV in zeta potential and displayed circular morphology. At this proportion, it was seen that niosomes consolidated and secured the DNA from enzymatic processing.

8.6. Oral mucosal delivery

The oral route is the preferred route for the administration of many drugs, this is also possible route for administration of drug by niosomes. A problem in the oral delivery of the drug is the acidic environment and digestive enzymes in stomach which may destroy the drug. However, niosomes are reported to deliver the drug successfully to gastric mucosa Niosomes of tenofovir disoproxil fumarate, cefdinir, paclitaxel and ginkgo biloba extract are prepared to enhance the oral bioavailability.

8.7. The vaginal route of drug delivery

It is usually employed for the treatment of microbial infections, such as vulvovaginal candidiasis and bacterial vaginosis. This route is extensively used for the delivery of various molecules, such as antimicrobials, antimycotics, sexual hormones, and peptides as it

is highly vascularized and has high permeability. Moreover, it bypasses the hepatic first-pass metabolism and overcome the gastrointestinal absorption that is why it is an outstanding route for mucosal drug delivery for both local and systemic purposes.

8.8. Intranasal delivery

Intranasal delivery is a promising noninvasive technique to deliver the drugs directly to the CNS by avoiding the blood brain barrier (BBB). Intranasal route is superior to other conventional drug delivery methods. But nasal delivery has some demerits such as rapid removal of drugs due to mucociliary clearance system, mucosal damage on repeated use of this route, nasal irritation, nasal congestion, and partial degradation by nasal peptidase enzyme system.

8.9. Management of psoriasis

Psoriasis is a chronic skin disorder which affects joint. It is recurrent in nature. Topical therapy is used for mild to moderate psoriasis. Systemic therapy is used for more than 20% of the patient's body area is involved. Niosomes play an important role in treatment of psoriasis. Topical treatment in psoriasis includes emollients, Keratolytic agents, coal tar, anthralin, calcipotriene, and corticosteroids. Methotrexate, cyclosporine, corticosteroids, and etretinate are commonly used for systemic therapy in psoriasis.

8.10. Delivery of vaccine and antigen (Bilosomes)

Bilosomes for the oral delivery of vaccines. These bilosomes protects the antigens from degradation by enzymes present in the GIT.

8.11. 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.

8.12. Targeted delivery

The efficiency and particularly the specificity of cellular targeting of niosomal drug delivery systems can be further improved by active targeting for tumor therapy, by using a ligand coupled to the surface of niosomes, which could be actively taken up.

8.13. Antibiotics

Niosomal carriers are also suitable for the delivery of antibiotics and anti-inflammatory agents. These carriers have been used extensively to improve poor skin penetration and as well as enhance skin retention of the drugs.

8.14. Anti-inflammatory drugs

Nonsteroidal anti-inflammatory drugs (NSAIDs) loaded niosomes have been prepared by several groups. These drugs may cause adverse effects such as mucosal irritation. Topically applied NSAIDs loaded niosomes can substantially improve drug permeation.

8.15. Diagnostic imaging

Niosomes can also be used as a carrier for radiopharmaceuticals and hence they could be useful in diagnostic imaging of organs like liver and spleen. 99mTc labeled DTPA is used for imaging Niosomes are used iobitridol as a diagnostic agent for x-ray imaging.

8.16. Antiviral drugs

Niosomes have also demonstrated the capability to deliver various antiviral agents. Drug like zidovudine enhances drug release for a longer time by this formulation.

8.17. Delivery of natural products

Now a day's researchers show an interest towards novel delivery systems to deliver natural products **(Table 2)**.

9. PATENTS

Because niosomes are becoming increasingly popular for clinical use, the numbers of patents for niosomal formulations are increasing enormously **(Table 3)**.

10. ANALYSIS OF NIOSOMES

There are various methods of analytical methods commonly used for analysis of various pharmaceutical formulations including niosomes. These methods include UV-spectroscopy, HPTLC, HPLC, gas chromatography, etc. [95-124].

Table 2: Niosomes for *natural products*.

Product	Botanical name	Use	Action
Curcumin	*C. longa*	As anti-inflammatory, antioxidant, anti-tumor agent.	Increases bioavailability, Enhances synergistic antitumor activity
Morusin	*M. alba*	Antibacterial, anti-oxidant anti-inflammatory, anti-tumor activity.	Enhances solubility and stability
Ginkgo extract	*G. biloba*	Enhances functioning of brain.	Enhancement of oral bioavailability
Papain	*C. Papaya*	Used in the treatment of scar.	Enhances the transdermal permeation

Table 3: Patents on Niosomes [89-94]

Patent number	Title	Patent description in brief
US2010/0226932 A1	Adjuvant and vaccine composition	Addition of aluminium salts; encapsulation in niosomes improve the stability of antigens in vaccine for a specific immunological response
US2010/0068264 A1	Niosome hydro gel drug delivery	Drug encapsulated in niosomes made of a biodegradable polymer with a temperature and pH-sensitive hydro gel network (cross linked chitosan) providing controlled release of drug.
US2005/0239747 A1	Compositions and methods of enhanced transdermal delivery of steroidal compounds and preparation methods	Niosomes are a delivery system that increases permeation of steroidal drugs across dermal tissue
US2006/0292211 A1	Ultrasound enhancement of drug release across nonionic surfactant membranes	Ultrasound enhances the delivery of drug encapsulated in niosomes when given noninvasively by altering the niosome membrane structure
US2008/0050445 A1	Niosome hydro gel drug delivery	Drug encapsulated in niosomes made of a biodegradable polymer hydro gel network providing a twofold increase in controlled release rate

11. CONCLUSION

Thus, niosomes can be used to encapsulate drugs of natural origin, enzymes, peptides, genes, vaccines, anti-cancer and almost all varieties of drugs. It also offers flexibility in the route of administration and its advantages over liposomes for being non-toxic makes niosomes more suitable for drug delivery.

12. DISCLOSURE OF CONFLICT OF INTEREST

The author declares no conflict of interest.

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