GSC Biological and Pharmaceutical Sciences
eISSN: 2581-3250 CODEN (USA): GBPSC2
Cross Ref DOI: 10.30574/gscbps
Journal homepage: https://gsconlinepress.com/journals/gscbps/

(REVIEW ARTICLE)

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Niosomes: A promising approach for targeted drug delivery

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GSC Biological and Pharmaceutical Sciences, 2024, 29(01), 179–195

Publication history: Received on 16 August 2024; revised on 12 October 2024; accepted on 15 October 2024

Article DOI: https://doi.org/10.30574/gscbps.2024.29.1.0341

Abstract

Niosomes, also known as nonionic surfactant vesicles, are small lamellar structures that are created by combining nonionic surfactants from the alkyl or dialkyl polyglycerol ether category with cholesterol, and then hydrating them in water-based solutions. These are vesicle systems resembling liposomes that can be utilized as carriers for drugs that are both amphiphilic and lipophilic. The production process of niosomes is derived from liposome technology. The fundamental manufacturing method remains unchanged, wherein the lipid phase is hydrated by the aqueous phase. The lipid phase can consist of either a pure surfactant or a combination of surfactant and cholesterol. Niosomes effectively tackle the challenges associated with medication insolubility, instability, inadequate bioavailability, and fast degradation. The amphiphilic character of niosomes, which combines both hydrophilic and lipophilic properties, enhances their capacity to encapsulate medicines that are either hydrophilic or lipophilic. Cholesterol is frequently utilized as one of the ingredients. Preserving the stiffness of the niosome structure. The present article discusses the essential elements of niosomes, including their structural constituents, methods of manufacturing, and their uses in different disorders.

Keywords: Niosomes; Targeted drug delivery; Cancer Therapy; Sustained Release; Skin permeation enhancer

1. Introduction

Niosomes are vesicles made of synthetic nonionic surfactants that are non-ionic and can include cholesterol or other lipids, depending on the formulation. Handjani-Villa et al. first described this type of vesicles[1,2]. Conventional dosage forms are still in use because of high patient compliance, though they are having side effects[3]. Niosomes are nanosystems consisting of vesicles with lipid bilayers that can be used to encapsulate hydrophilic and hydrophobic drugs[4,5,6]. Niosomes are usually stabilized by the addition of lipids, like cholesterols. The stability, cost efficiency, and bioavailability of the vesicles have made them one of the best nanocarriers in drug and gene delivery systems[7,8,9]. Niosomes are similar, in terms of structure and physical properties to liposomes[10,11]. Microscopically sized lamellar structures called niosomes contain biodegradable, non-immunogenic, and biocompatible surfactants. Their sizes range from 10 to 1000 nm [12]. By combining cholesterol with non-ionic surfactants of the alkyl or dialkyl polyglycerol ether class and then hydrating in water, tiny lamellar structures called niosomes or non-ionic surfactant vesicles are created[13,14]. Since niosomes do not need special preparation or storage, they are less costly and more suitable for industrial manufacture than liposomes[15,16]. Some limitations of niosomes are low drug loading, drug expulsion, instability, and high production cost[17,18]. Zidovudine, an antiretroviral drug release, can be enhanced by niosomal entrapment[19,20]. It acts as a carrier in the release of medicaments, hormones, antigens, and bioactive molecules[21]. Temperature and monomer concentration both play a critical role in the formation of vesicles[22,23]. The examination of these factors in niosome preparation will contribute significantly to the body of knowledge offered by science on these carriers. The quality by design (QbD) methodology involves the design and development of a product that satisfies predetermined product requirements through manufacturing procedures [24,25]. Synthesis of niosomes starts with the

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hydration of a surfactant and lipid combination at higher temperatures, trailed by discretionary niosome size decrease to acquire a colloidal suspension [26].

Niosomes that generate surfactants are biocompatible, nonimmunogenic, and degradable. Drugs with higher bioavailability than free drugs, such as nimesulide, flurbiprofen, piroxicam, ketoconazole, and bleomycin, are more effective when they are incorporated into niosomes[27,28]. The cited reports back up the scope of niosomes in medicine and experimental biology compared to commercial and nano-based technical approaches[29]. Niosomes share structural similarity with liposomes while overcoming limitations associated with stability, sterilization, and large-scale production of liposomes[30]. This pronounced carrier system protects drug molecules against immunological and pharmacological actions that induce degradation and inactivation[31]. Niosomes have been researched much in the past two decades along with the growth of the nanomedicine sector[32]. Niosomes are formed through the self-assembly of nonionic surfactants in an aqueous medium, forming concentric bilayer vesicles with a liposome-like structure [33,34].

1.1. Advantages of Niosomes :[35,36,37,38,39]

- Targeted Drug Delivery
- Reduced side effects and maximal duration of action.
- Improve bioavailability
- In comparison to alternative distribution systems, there is more patient compliance.
- Very little medication is needed to get the desired result.
- The preparation's active component or constituent is shielded from external influences by a bilayer both within and outside the body
- Serve as a depot formulation, allowing for controlled medication release.
- The medication remains protected from gastrointestinal breakdown and first pass metabolism.
- Even as an emulsion, they have a stable structure.
- Niosomes can be obtained orally, topically, or parenterally [40,41]
- They can protect the drug from enzyme metabolism [42]
- Administration routes of niosomes are diverse like (intravenous, oral) [43]

1.2. Disadvantages of Niosomes :[35,36,38,44]

- Time-consuming procedure.
- Specific machinery is needed for processing.
- Short shelf life because of:
    - Fusion
    - Combination
    - Drugs that are entrapped leak
- Drug encapsulation hydrolysis
- Unstable physical states
- Entrapped drug can leak [45,46,47]
- Increase in the polyoxyethylene chain length enhances cytotoxicity.

2. Characterisation of niosomes

The shape of niosomal vesicles is supposed to be spherical and their mean diameter is determined by using laser light scattering method. Diameters can also be measured by using electron microscopy, optical microscopy, ultracentrifugation, molecular sieve chromatography; photon correlation microscopy and freeze fracture electron microscopy. Bilayer formation is measured by an X –cross formation under light polarisation microscopy[48]. Number of lamellae is measured by using nuclear magnetic spectroscopy and electron microscopy. Membrane rigidity can be measured by using fluorescence probe as a function of temperature. Entrapment efficiency is the calculation with a formula [49,50].

$$\text{Entrapment efficieny (EF)} = \left(\frac{\text{Amount entrapped}}{\text{total amount}}\right) \times 100.$$

2.1. Structure of Niosome

A typical niosome vesicle would consist of a vesicle forming amphiphile i.e. a non-ionic surfactant, such as Span860, which is usually stabilized by the addition of cholesterol and a small amount of anionic surfactant, such as dicetyl phosphate, which also helps in stabilizing the vesicle [51,52,53].

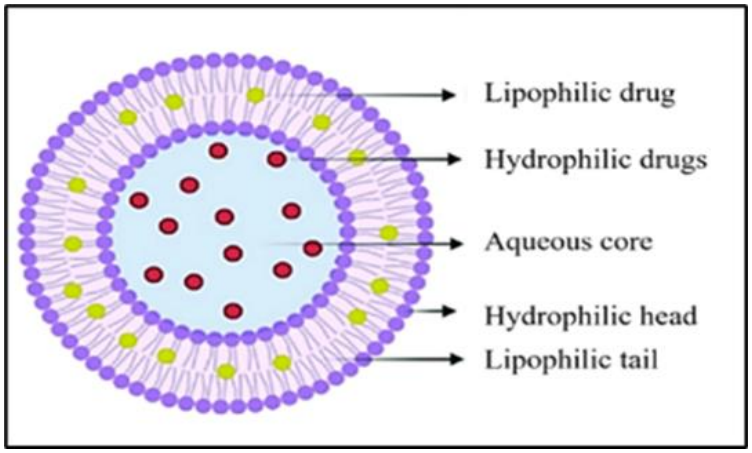


Figure 1 Structure of Niosomes [54]

Niosomes are spherical and consist of microscopic lamellar (unilamellar or multilamellar) structures. Niosomes are made up of a bilayer. Niosomal bilayer made up of nonionic surfactants. Most of surfactants when immersed in water there is formation of micellar structures, however some surfactants are form bilayers which converts into niosomes[54]. The formation of bilayer is done by non-ionic surfactants, with or without cholesterol and a charge inducer. Various types of surfactants at variable combinations and molar ratios are used to form niosomes. Instance of surfactants include alkyl ethers, alkyl glyceryl ethers, sorbitan fatty acid esters, and polyoxyethylene fatty acid esters. The addition of cholesterol maintains the rigidity of the double layer and makes niosomes less leaky. At the same time, the loading sensor assists the loading of the vesicles, which increases the size of the vesicles and improves the efficiency of drug absorption. Negative charge inducers, including dicetyl phosphate, dihexadecyl phosphate, and lipoamino acid, and positive charge inducers, including stearylamine and cetylpyridinium chloride help to stabilize the vesicles [55]. Non-ionic surfactants in niosomes tend to orient themselves in such a way that hydrophilic end faces outward (toward the aqueous phase), and the hydrophobic ends point inward to each other, forming a closed two-layer structure, containing dissolved substances in the aqueous solution. Therefore, the closed bilayer structure of niosomes has hydrophilic inner and outer surfaces, with a sandwiched lipophilic area in between. The formation of a closed two-layer structure necessitates the input of energy, typically in the form of heat or physical stirring. Within vesicles, various forces play a crucial role in maintaining their structural integrity. Notably, van der Waals and repulsive forces among surfactant molecules are vital to preserving the vesicular structure.

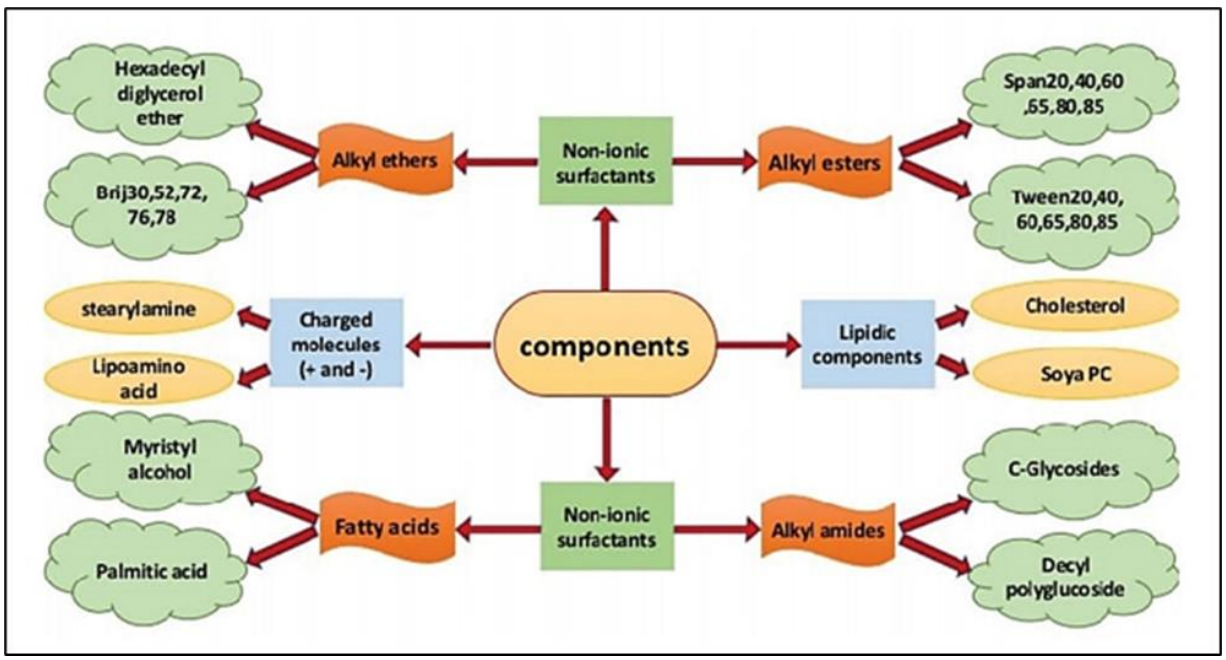


Figure 2 Components of Niosomes [58]

These vesicles are derived from multilamellar vesicles (MLVs), large unilamellar vesicles (LUVs), and small unilamellar vesicles (SUVs), with their specific formation dependent on the preparation methods employed. The niosomal bilayer has the hydrophobic chains are face each other within the bilayers and hydrophobic ends exposed on the outer side and inside of the vesicles [56,57].

2.2. Mechanism of action of niosomes as permeation enhancer

Niosomes ability to increase drug transfer through the skin has been attributed to a number of different mechanisms, including the alteration of the stratum corneum's barrier function as a result of reversible perturbation of lipid organisation, reduction of transepidermal water loss, which increases the stratum corneum's hydration and loosens its tightly packed cellular structure, and adsorption and/or fusion of niosomes. Three routes—intercellular, transcellular (paracellular), and transappendageal—can be used for drug transport across the stratum corneum, which is primarily a passive process. After it has travelled through the epidermis, a substance could be eliminated by the deeper tissues that may go through the dermal circulation. The effectiveness of various tactics has been evaluated to enhance the stratum corneum's barrier function of drug penetration of the skin. Penetration improvement in particular one or more of the following three mechanisms could be used by ers to act. Niosomes can lengthen the period that a medication stays in the SC and epidermis when given topically they are believed to enhance the smoothness and characteristics of the horny layer by restoring lost skin lipid and minimising transepidermal water loss [59,60,61,62].

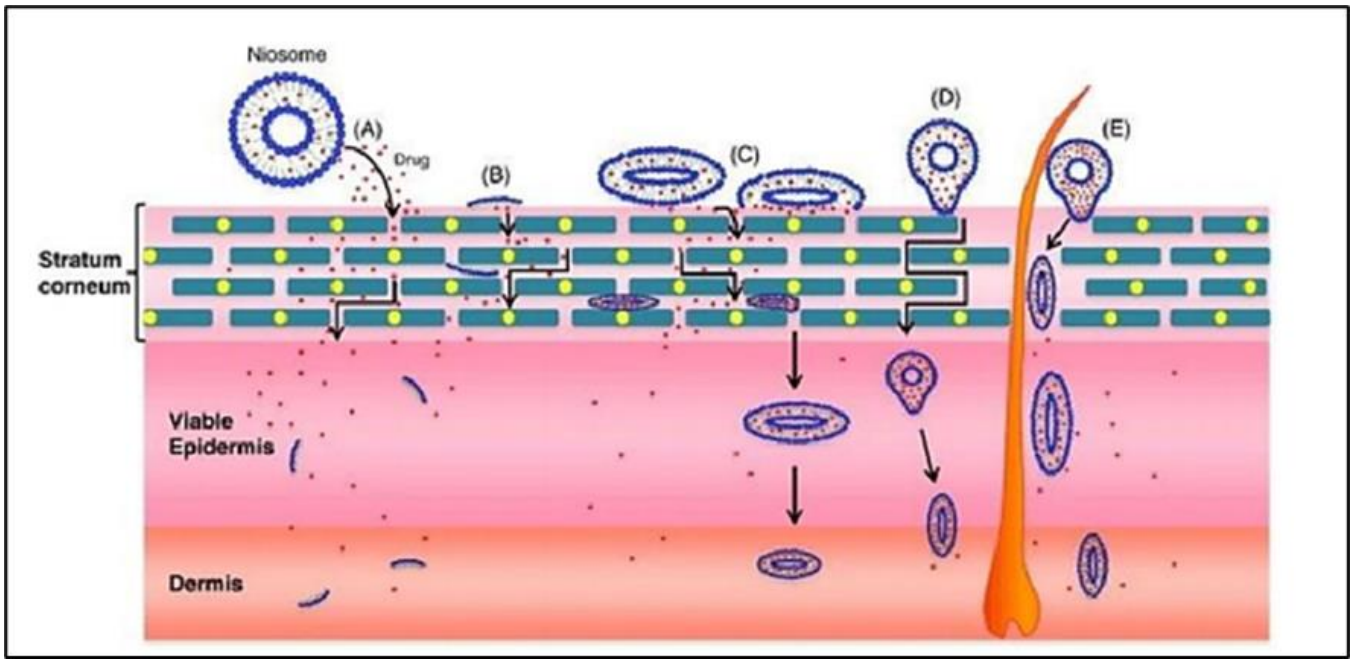


Figure 3 Possible mechanisms of action of niosome act as skin permeation enhancer: (A) drug molecules are released by niosomes; (B) niosome constituents act as penetration enhancer; (C) niosome adsorption and/or fusion with stratum corneum; (D) intact niosome penetration through the intact skin; (E) niosome penetration through hair follicles and/or pilosebaceous units[59].

2.3. Types of Niosomes: [63,64,65,66,67]

Niosomes are classified by the number of bilayers, by the size, or by the manufacturing method. The different types of niosomes are described below.

- Multilamellar vesicles (MLV)
- Large unilamellar vesicles (LUV)
- Small unilamellar vesicles (SUV)

2.3.1. Multilamellar vesicles (MLV):

The aqueous lipid compartment is surrounded by multiple bilayers. The diameter of these vesicles is approximately 0.5 to 10 μm. The most commonly used niosomes are multilaminar vesicles. It is easy to manufacture and mechanically stable when maintained for a long period of time. Lipophilic compounds are ideal as drug carriers for these vesicles.

2.3.2. Large unilamellar vesicles (LUVs):

Niosomes of this type have a high ratio of water to lipid compartments, allowing larger amounts of bioactive materials to be captured with very moderate use of membrane lipids.

2.3.3. Small unilamellar vesicles (SUVs):

Small unilamellar vesicles are mainly prepared from multilamellar vesicles by ultrasonic method.

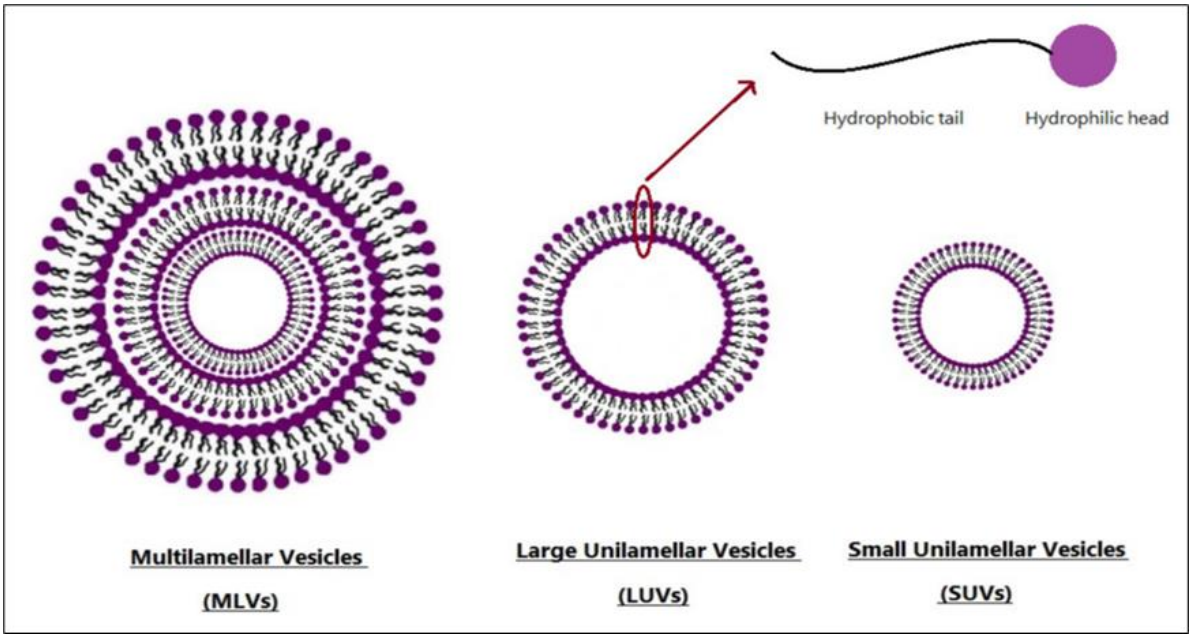


Figure 4 Types of Niosomes[65]

2.4. Composition of Niosomes

The three main ingredients used to make niosome are:

- Cholesterol
- Non-ionic Surfactant
- Charged Molecules

2.4.1. Cholesterol

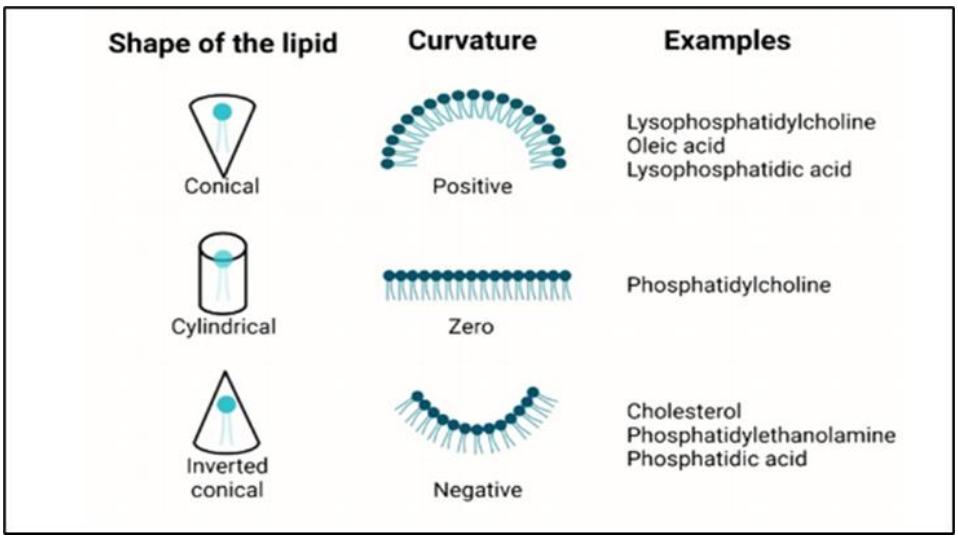


Figure 5 Lipids with different intrinsic curvature[72]

Cholesterol is a steroid derivative [69] that provides strength to nonionic surfactants; typically cholesterol, a waxy steroid metabolite, is added. Cholesterol is also known to prevent leakage by preventing the transition from the gel phase to the liquid phase[70]. The hydrophilicity–lipophilicity balance value of the surfactant determines how much cholesterol should be used[71]. This molecule is a waxy, fat-like compound with binding effects on the structure of niosomes. This curvature is important for fusion with other membranes. This creates hemifusion, a temporary, high-energy state before full fusion is achieved. Interestingly, removal of cholesterol from vesicles, including niosomes, inhibits hemifusion, which concomitantly leads to a reduction in vesicle fusion with other platforms, such as. B. lipid bilayers microorganisms, etc. Thus, the negative curvature of the membrane stimulates hemifusion, the first transitional step to the fusion of the two bilayers (niosome + cell membrane), modulated by cholesterol[72].

2.4.2. Non-ionic surfactant

Non-ionic surfactants play an important role in the preparation of Niosomes. They are the basic component. They consists of a polar head and a hydrophobic tail. They arrange themselves in a bilayer with their hydrophilic head towards aqueous media and hydrophobic or on the polar tail facing inside[73,74,75]. High HLB value surfactants are not suitable for preparation of Niosomes. Highest entrapment efficiency is found with an HLB value of 8.

Examples

- Spans like span 60, 40, 20, 85, and 80
- Tweens tween 20, 40, 60, 80[74,76]

2.4.3. Charged molecules:

Some charged molecules to increase the stability of some Niosomes through electrostatic repulsion to prevent the fusion will add a little Di-cetyl phosphate (DCP) and phospho lactideacid is used as negatively charged molecules. Similarly, stearylamine (STR) and stearyl pyridinium chloride is a well-known positively charged molecule used in the preparation Niosomes[77].

3. Formation of Niosomes from Proniosomes:

The niosomes can be prepared from the proniosomes by adding the waterless phase with the medicine to the proniosomes with brief agitation at a temperature lesser than the mean transition phase temperature of the surfactant.

$$T > Tm$$

Where,
T = Temperature
Tm = mean phase transition temperature [78,79]

Another method of producing niosomes is to coat a water-soluble carrier such as sorbitol with surfactant.The result of the coating process is a dry formulation.In which each watersoluble particle is covered with a thin film of dry surfactant[80-82].

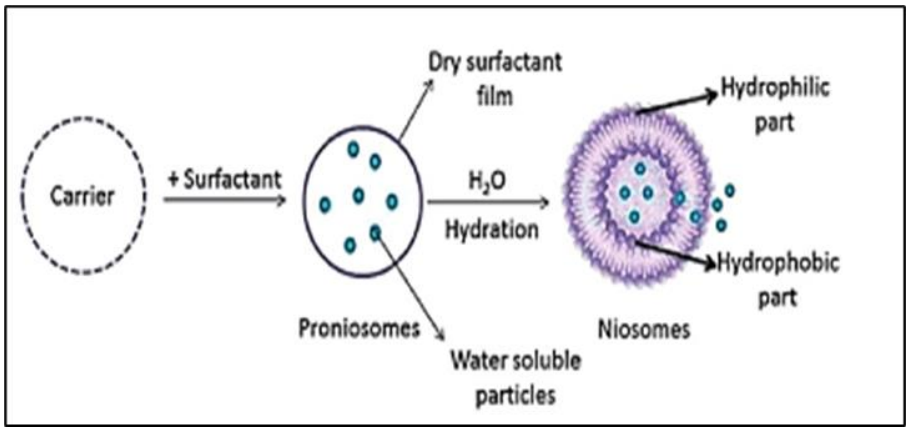


Figure 6 Formation of Niosomes from proniosomes [83]

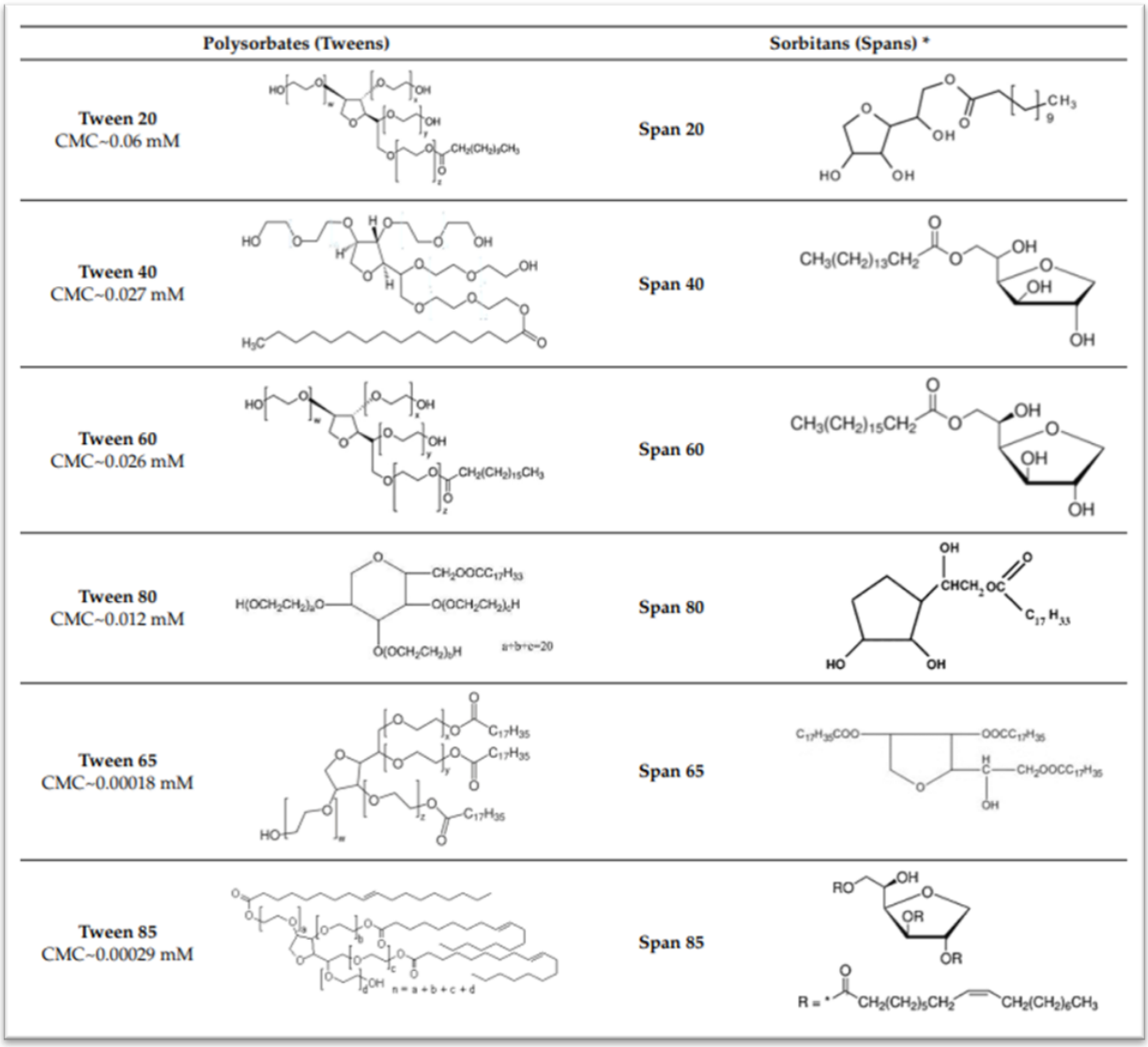


Figure 7 Surfactants commonly used for niosomes preparation [84]

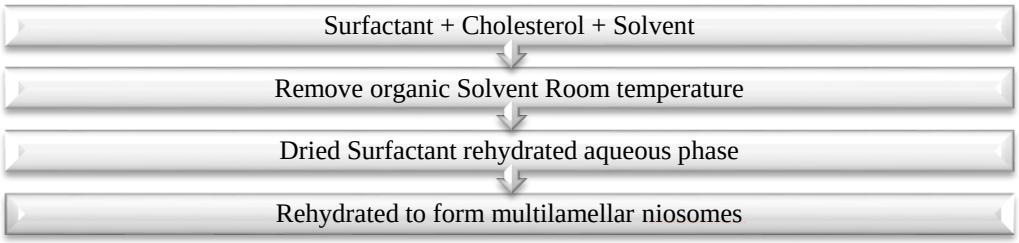
Due to ethoxylation, the Tweens are water soluble opposite to the oil soluble spans. Therefore, Critical Micelle concentration (CMC)is not an applicable parameter for spans

3.1. Method of preparation

3.1.1. Thin film hydration or Hand shaking method :[85]

The mixture of vesicles forming ingredients i.e. surfactant, cholesterol dissolved in volatile organic solvent in a round bottom flask solvent removed at room temperature 20°C then the dried surfactants rehydrated with aqueous phase at 0-60°C with gentle agitation & forms typical multilamellar niosomes.

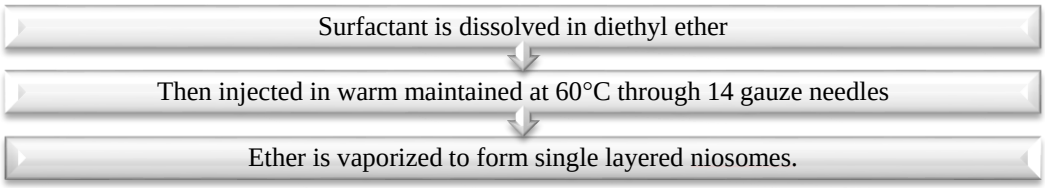
Preparation Steps



3.1.2. Ether Injection method:[85]

This method involves forming niosomes by slowly introducing a surfactant solution dissolved in diethyl ether into warm water at 60°C. The mixture is then injected through a gauze needle into an aqueous solution of the encapsulating material, resulting in vesicles with diameters ranging from 50 to 100 nm

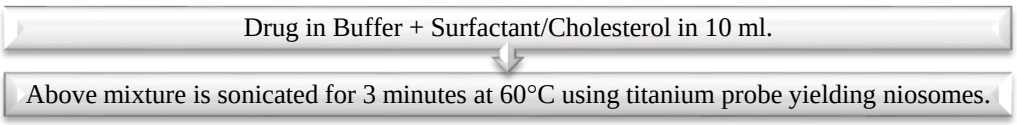
Preparation Steps



3.1.3. Sonication method

Niosomes can be fabricated by sonicating an amalgamation of surfactant, cholesterol, and an aqueous phase containing the drug maintained at 60°C. The vesicles thus formed have less particle size and exhibit size uniformity [86-88].

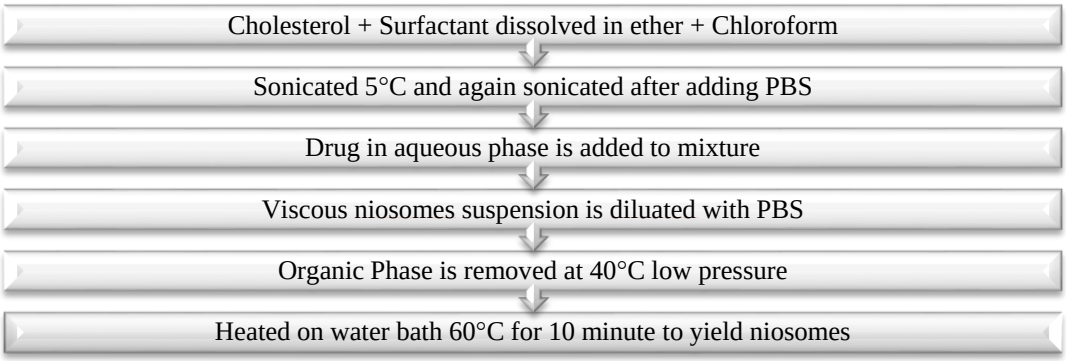
Preparation Steps:[89,90]



3.1.4. Reverse phase evaporation (RPE)method :[85]

Cholesterol & Surfactant (1:1) are dissolved in ether & chloroform. An aqueous phase containing drug added to this & resulting two phases are sonicated at 4-5°C. Clear gel formed is further sonicated added Phosphate buffered in a small amount. Organic phase removed at 40°C under low pressure vesicles noisome suspension diluated PBS heated water bath 60°C for 10 min to yield niosomes.

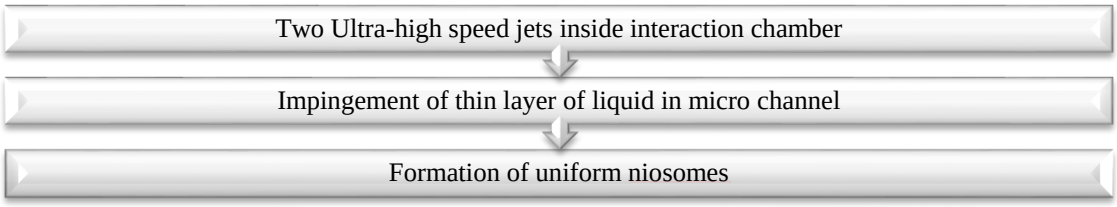
Preparation Steps



3.1.5. Micro Fluidization method :[85]

This method is used for preparing unilamellar vesicles. It is based on submerged jet principle in which two fluidized streams intract at ultra-high velocities.

Preparation Steps



3.1.6. Supercritical Carbon Dioxide Fluid:[91]

A novel method for niosome synthesis utilizing supercritical reverse-phase evaporation is described. The process involves introducing Tween 61, cholesterol, glucose, phosphate-buffered saline (PBS), and ethanol into a view cell, followed by the addition of carbon dioxide (CO2). Magnetic stirring is employed until equilibrium is achieved, after which the pressure is released, resulting in the spontaneous formation of niosomal dispersions. This technique offers the advantages of simple scale-up and single-step production.

3.1.7. Heating Method:(91)

Surfactants and cholesterol are hydrated separately in a separate buffer, then heated to 120°C with stirring to dissolve cholesterol. While stirring continues, the temperature is lowered, and surfactants and other chemicals are introduced to the buffer in which the cholesterol is dissolved. This procedure produces niosomes, which are then allowed to cool to room temperature before being kept in a nitrogen atmosphere at 4-5°C until required.

3.1.8. The bubble method:

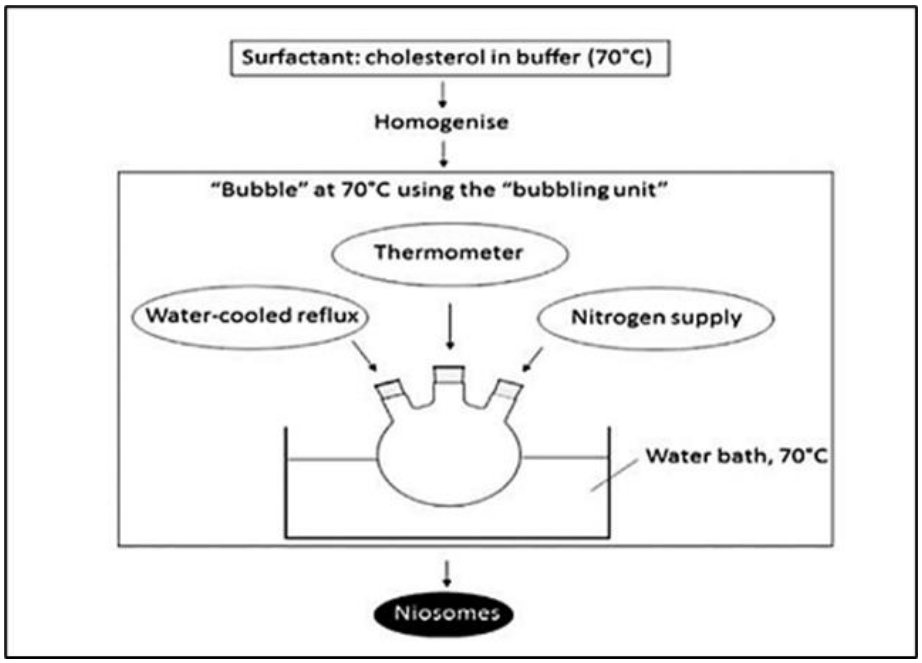


Figure 8 The Bubble Method [86]

Niosomes can also be fabricated in the absence of organic solvents through the bubble method, wherein a bubbling unit containing a roundbottomed flask with three necks is placed in a water bath; a water-cooled reflux condenser and thermometer are placed in the first and second necks, respectively, whereas nitrogen gas is introduced through the third neck. Surfactant and cholesterol amalgamated at 70°C in a buffer are blended and bubbled at 70°C by introducing nitrogen gas into the apparatus[86,92,93].

Proniosome

Proniosomes are surfactant-coated water-soluble carriers. Dry formulations are produced through coating. Before using "Proniosomes," they must be hydrated. Niosomes are formed in the aqueous phase. In comparison to typical niosomes, this method eliminates the problems of aggregation, leakage, and fusion while also enhancing dose, distribution, transportation, and storage [94,95]. Cholesterol, surfactants, and ethanol are transferred to a vial and heated in a water bath. Then, while the above solution is in a hot water bath, an aqueous phase is added to produce a clear solution. In the following, the niosomes are formed by the hydration of the proniosomal gels. Niosome preparation is achieved by adding a buffer to the vials containing proniosomes and stirring with a homogenization shear in a water bath at 70°C [96,97,98].

4. Factors affecting physico-chemical properties of niosomes

4.1. Nature of surfactant

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 esterlinked surfactant degraded by esterase's to triglycerides and fatty acid in vivo. Surfactants with alkyl chain length from C12-C18 are suitable for preparation of niosomes [99,100].

4.2. Resistance to osmotic stress

When a hypertonic saline solution (e.g.KCl or glycerol) is added to a niosome suspension, the size of the niosome decreases [101,102]. Studies have been conducted to understand the influence of osmotic upward shift on niosome development. The vesicle is relatively permeable to the osmolyte (e.g. However, if the osmolyte is relatively impermeable (e.g.KCl), the vesicle remains in the contraction state for hours[103,104,105].

4.3. Hydration temperature:[103]

Hydration temperature affects the structural properties of niosomes, their shape and size. Changes in the temperature can also affect the formation of vesicles. Ideally, the hydration temperature for niosome formation should be above the gel to liquid phase transition temperature, once temperature affects the assembly of surfactants into vesicles [101,104,106,107].

Vesicles composed of C16:C24-solulan (91:9) undergo a thermally induced morphological transformation. At 25°C, polyhydric vesicles form, whereas spherical vesicles emerge at temperatures between 45–48°C. Upon cooling from 55 to 49°C, these vesicles break down into smaller, spherical niosomes, ultimately adopting a polyhedral structure at 35°C. In stark contrast, vesicles formed from C16:cholesterol:C24-solulane (49:49:2) exhibit thermal stability, retaining their shape regardless of heating or cooling conditions[101,108,109,110].

4.4. Nature of Encapsulated Drug

The charge and the rigidity of the niosomal bilayer are greatly influenced by the physical chemical properties of the encapsulated drug. Entrapment of drug occurs by interacting with the surfactant[111].

4.5. Membrane Additives

The stability of niosomes can be increased by the amount of additives in the niosome formulation as well as surfactants and drugs. Membrane stability, morphology and permeability of vesicles are influenced by the amount of additives. For example, the addition of cholesterol to the niosomal system increases rigidity and decreases the permeability of drugs across the membrane[112]. Niosomes prepared with C16G2/cholesterol/M-polyethylene glycol (PEG)-chol show spherical vesicles with diameters ranging from 20 to 200 nm[101,113,114].

5. Application of Niosomes

5.1. Delivery of anticancer drugs/ cancer Therapy

Cancer is a group of conditions that lead to abnormal cell growth that has a high eventuality to foraying into other corridor of the body[115,116]. Niosomes can be used to achieve targeted delivery of cancer drugs. This administration could be passive (deposition of niosomes within the tumor due to special properties of tumor cells not found in normal

cells), physical (administration based on specific environmental conditions such as pH or magnetic fields), or active (active uptake of niosomes by the tumor cell). Active targeting can be achieved by modifying the structural features of the surface or by binding the ligand to niosomes. For ligand binding, either cholesterol-PEG ligand conjugate can be incorporated into niosomes or attached to cholesterol or the end of the polyethylene glycol chain[117]. Target infectious cells to improve therapeutic effect compared to normal cells[118].

5.2. Delivery of proteins and peptides

It has always been difficult to administer protein and peptide drugs orally because they are destroyed by the acidic media and enzymes of the gastrointestinal tract. But niosomes protect these drugs from proteolytic enzymes[117].

5.3. Useful in studying the immune response

Niosomes are used for testing the immune response produced by antigens. Stable and immulogical selectivity with very low toxic effects makes niosomes a good candidate for studying immune response[53,119].

5.4. Hemoglobin carrier

Niosomes beingvesicles can easily permeate to oxygen and the haemoglobin dissociation curve is modified similarly to non-encapsulated haemoglobin. So, they are used as the carrier for haemoglobin[120,121].

5.5. Transdermal delivery of drugs by niosomes

In transdermal drug delivery, the drug penetrates into the skin at a slow rate which is a major limitation of the transdermal route. Transdermal drug delivery is particularly suitable for diseases requiring long-term, frequent dosing[122,123]. Penetration can be enhanced through the skin using niosomes as drug carriers in transdermal drug delivery [119,124]. The transdermal route stands out as a practical and secure option for drug delivery[27,125].

5.6. Sustained Release

Drugs having low solubility and a short therapeutic index can be used in sustained release drug delivery using niosomes as a drug carrier[119].

5.7. Ophthalmic drug delivery

Achieving the required bioavailability of the drug in ophthalmic preparation is an easy task. Niosomes can act by lowering the intraocular pressure resulting in enhanced drug bioavailability[119,126].

6. Conclusion

Niosomes, non-ionic surfactant-based vesicles, offer a promising drug delivery system with advantages including enhanced bioavailability, reduced toxicity, and improved therapeutic efficacy. They can encapsulate hydrophilic and lipophilic drugs, and their stability, cost-efficiency, and biocompatibility make them suitable for various applications. Niosomes have been explored for cancer therapy, protein and peptide delivery, immune response studies, hemoglobin carrier systems, transdermal delivery, sustained release, and ophthalmic drug delivery. Despite limitations such as low drug loading and instability, ongoing research aims to optimize niosome formulation and manufacturing processes. With their versatility and potential, niosomes hold significant promise for advancing targeted drug delivery and nanomedicine.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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