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"An Worthwhile Review of Niosmes"

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ABSTRACT

Niosomes are vesicular nanocarriers, biodegradable, relatively non-toxic, stable, and inexpensive, that provide an alternative for lipid-solid carriers (e.g., liposomes). Niosomes may resolve issues related to the instability, fast degradation, bioavailability, and insolubility of different drugs or natural compounds. Niosomes can be very efficient potential systems for the specific delivery of anticancer, antioxidant, anti-inflammatory, antimicrobial, and antibacterial molecules. This review aims to present an overview of their composition, the most common formulation techniques, as well as of recent utilizations as delivery systems in cancer therapy. As drug carriers, nano-sized niosomes expand the horizons of pharmacokinetics, decreasing toxicity, enhancing drug solvability and bioavailability. In this review, we review the components and fabrication methods of niosomes, as well as their functionalization, characterization, administration routes, and applications in cancer gene delivery, and natural product delivery. We also discuss the limitations and challenges in the development of niosomes, and provide the future perspective of niosomes.

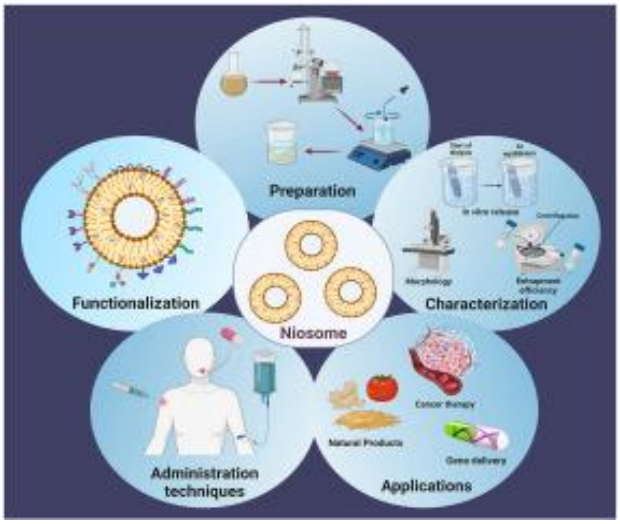

Fig 1 : Graphical Abstract of noisome

Keywords: Surfactant, Drug entrapment,lamellar noisome, bilayer, Targeted drug delivery.

INTRODUCTION

Nanotechnology is one of the most promising technologies of the 21st century Currently, the aim is to integrate biotechnology and nanotechnology, thus offering a technology based on green chemistry, recent applications of niosomes as delivery systems in cancer therapy. currently, the aim is to integrate biotechnology and nanotechnology, thus offering a technology based on green chemistry, being ecological for the production, characterization, and application of nanomaterials [5]. Typical examples include gold and silver nanoparticles, nano-vesicle systems, solid lipid nanoparticles, nanostructured lipid carriers, nano-micelles, dendrimers, polymeric nanoparticles, mesoporous silica nanoparticles, etc. [6,7,8]. In addition, using interdisciplinary

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approaches, the results of biotechnology, nanomaterials, pharmaceutical science, artificial intelligence, and genetic engineering can be applied in the field of healthcare systems, known as nanomedicine [4,9,10].

Composition of Niosomes

Niosomes get thermodynamically stable, with a bilayered structure made up of non-ionic surface-active substances that can only be created when surfactants and cholesterol are combined in the appropriate ratio at temperatures above the gel liquid transition point. Its - has a hollow region in the center where hydrophilic and hydrophobic medicines are enclosed. Conventional niosomal vesicles can be made up of vesicles that create an amphiphilic, i.e., nonionic, surfactant like Span60, which is normally maintained by a combination of cholesterol and a tiny quantity of anions such dicetyl phosphate for use in vesicle stability surfactant.The following three components are used in the production of niosomes:

- Cholesterol
- Non-ionic surfactants
- Charged molecule

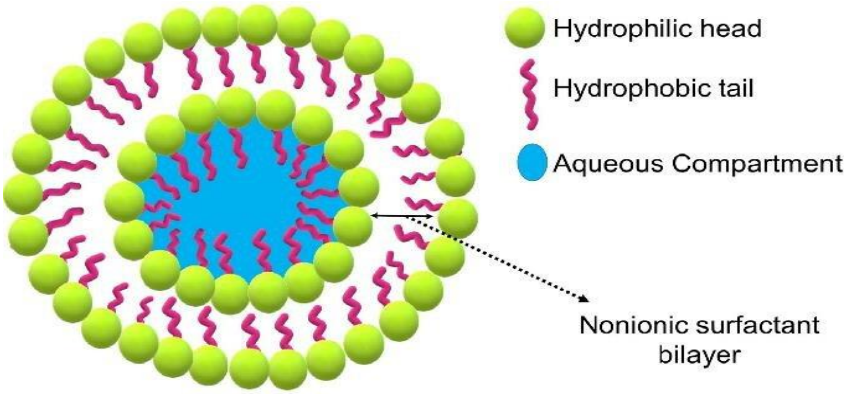

Fig 2: Niosome structure

Cholesterol is a steroids precursor utilized for imparting stiffness and appropriate shape to niosomes, as well as to strengthen and produce niosome preparations. Steroids influence the fluidity and permeability of the bilayer .Cholesterol has additionally been shown to inhibit leaks by preventing the gel to liquid form conversion.

Non-ionic Surfactants are commonly employed in the synthesis for niosomes. Nonionic surfactants comprise surfactants that lack charged groups within their hydrophilic heads. When contrasted with anionic, amphoteric, or cationic equivalents, they are more stable, biocompatible, and less poisonous. The hydrophilic-lipophilic balance (HLB) and critical packing parameter (CPP) values are important in determining which surfactant molecules to use over niosome synthesis.

Charged molecule: The insertion of charged groups to the vesicle bilayer increases the stability for the vesicles. They reduce vesicle aggregation through increased its surface charge density. They inhibit vesicle fusion due to repulsive forces of the same charge resulting in larger zeta values for potential.

Types Of Niosomes

Multilamellar Vesicles(MLV)

It is made up of many bilayers that enclose the aqueous lipid compartment individually. The diameter of such a vesicle is around 0.5 to 10 m. MLV are the most often utilized niosomes. These generally quick to build and mechanically stable over lengthy periods of storage. These kinds of vesicles have the greatest potential for medication delivery of lipophilic substances. The hand shaking technique is used to prepare niosomes.

Large Unilamellar Vesicles (LUV)

These Niosomes have a higher aqueous for lipid compartment ratio, allowing a significant amount of bioactive compounds to be captured while using little membrane lipids. Large unilamellar vesicles have a diameter larger than 0.10m.[7,14,15,18]

Small UnilamellarVesicles(SUV)

The most common methods used to create these kinds of niosomes include solvent dilution, homogenization, French press extrusion, and sonication of multilamellar vesicles. Small unilamellar vesicles, with a diameter of 0.025-0.05 μm, are prone to aggregation and fusion due to their thermodynamic instability. Their proportion of an aqueous solute entrapped is modest, and their entrapped volume is minimal

Classification of Niosomes

Niosomes are non-ionic surfactant vesicles with a bilayer structure,

1. a hydrophilic part opposite to aqueous solutions, and
2. a hydrophobic part opposite to organic solutions. Depending on which method is used for the formulation of niosomes, the structure can be classified based on the number of bilayers and based on the size.

Niosome Preparation Methods

There are several techniques for creating lipid-based vesicles, known as niosomes, which are employed as medication delivery systems. It contains therapeutically active ingredients, non-ionic surfactants with a hydrophilic head and a hydrophobic tail [e.g. - Spans (Span 20, 40, 60, 80, 85), Tweens (tween 20, 40, 60, 80)], cholesterol, which acts as a derived steroids employed for its flexibility, stiffness, alongside shape, phospholipids (e.g., phosphatidylcholine), and organic solvent.[8,10]

Several techniques for preparing niosomes have been documented, including:

Ether injection method: In this method, the lipidic component (cholesterol) and non-ionic surfactant are dissolved in ether and slowly injected through a needle into the aqueous phase containing a drug or natural molecule under stirring at a temperature above 60 °C in a heated water bath. The disadvantages include the extremely slow process and the presence of a limited amount of ether in the vesicle suspension**.**

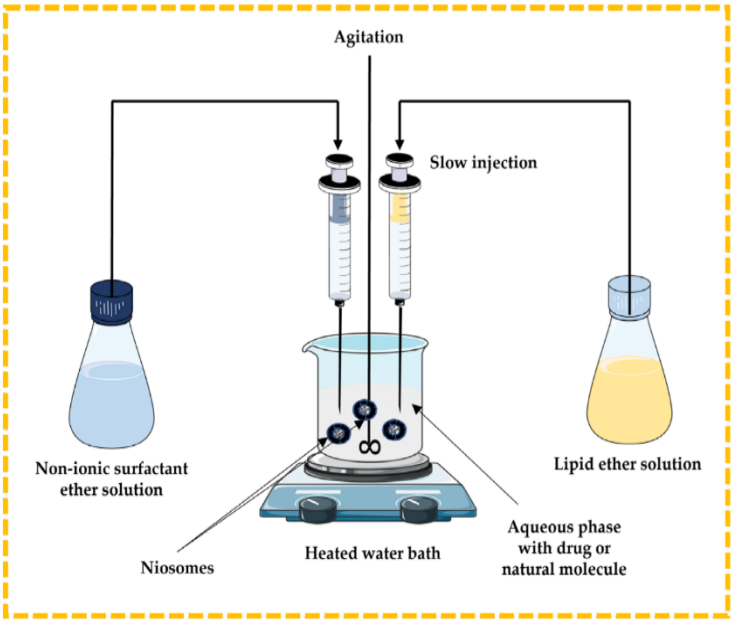

Fig :3 Ether injection method

Lipid injection technique: There are no organic solvents involved in this technique. Molten surfactant and cholesterol are quickly injected into a heated aqueous phase containing the dissolved drug or natural molecules, resulting in the formation of niosomes

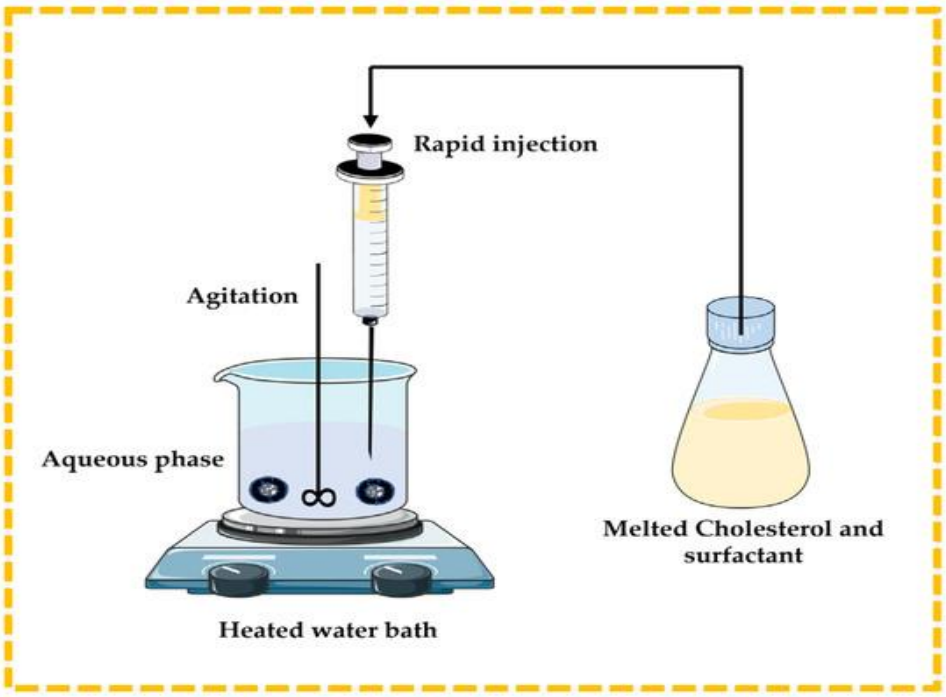

Fig 4 : Lipid injection technique

Sonication Technique: In this technique, cholesterol and a non-ionic surfactant are dispersed in a buffer solution containing the dissolved drug or natural compound. This mixture is further subjected to a bath sonicator to yield niosomes. Rapid size reduction and accurate temperature regulation are both advantages, but heat generation could be the main disadvantage.

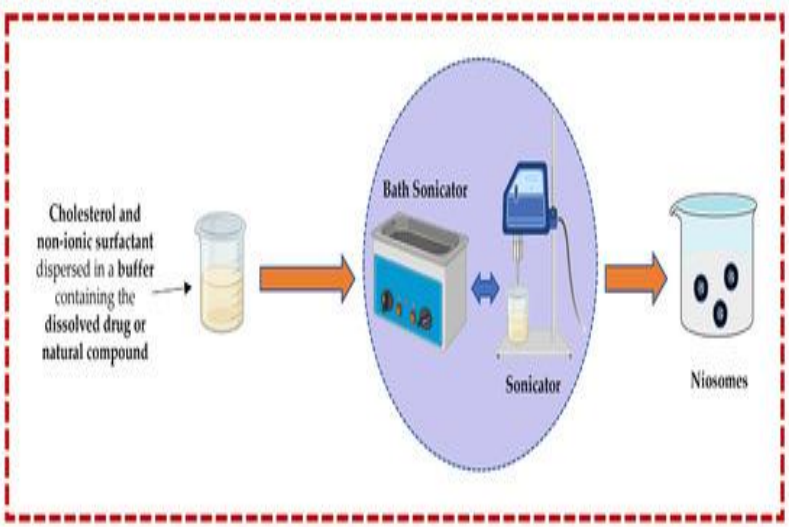

Fig 5: Sonication technique

Hand shaking method (Thin film hydration technique): This technique is widespread in the formulation of niosomes. The surfactant and cholesterol are dissolved in a suitable organic solvent (e.g,ethanol, chloroform). A dried thin-film layer forms inside the flask after the organic solvent is removed by vacuum/rotary evaporation. The drug is dissolved in an aqueous solution and then applied to the obtained film to hydrate it.

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To produce niosomes, the hydrated film must be incubated in a water bath above the transition temperature of the surfactants.

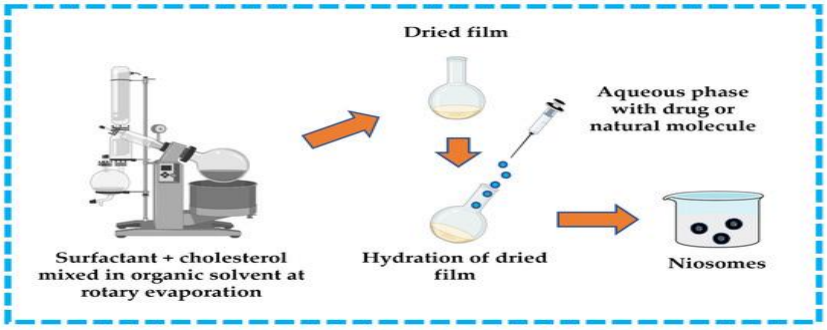

Fig 6: Thin film hydration technique

Bubble Technique: This is a unique single-step process used to prepare niosomes, especially to develop large unilamellar vesicles, without using any organic solvent. Cholesterol, buffer solution, and non-ionic surfactant are mixed and placed in a three-neck round bottom flask. The temperature is controlled using a thermometer and water-cooled reflux, while nitrogen is supplied from the third neck . The dispersion is introduced into a water bath at 70 °C to yield niosomes.

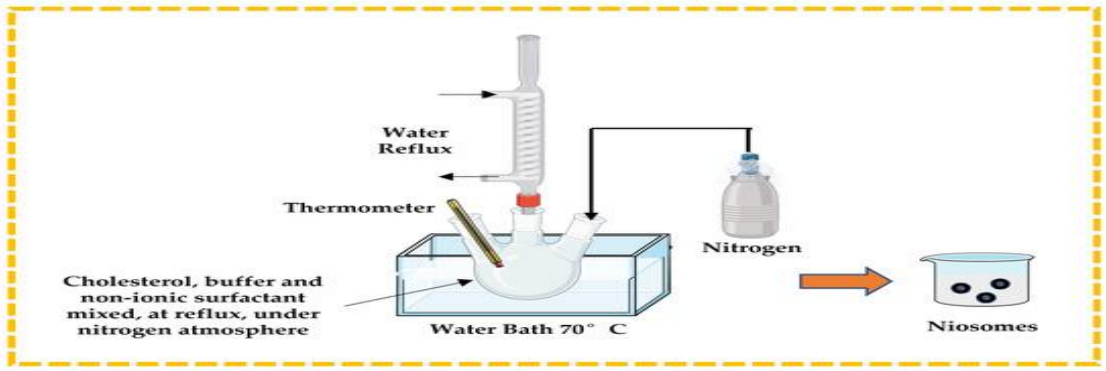

Fig 7: Bubble Technique

Reverse phase evaporation technique (REV):

Surfactant and cholesterol are dissolved in suitable organic solvent (e.g., chloroform, ethyl ether). An aqueous phase that contains the drug or natural molecule is added, and then the two immiscible phases are homogenized and sonicated. The organic solvent is removed from the formed emulsion by rotary evaporation to obtain niosomes.

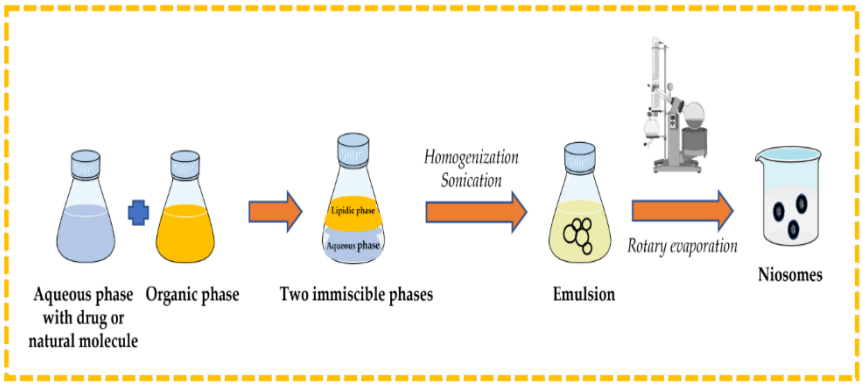

Fig 8: Reverse phase evaporation technique

Trans-Membrane pH Gradient Technique:This approach is suitable for ionizable hydrophobic compounds. The hydrophobic compound, surfactant, and cholesterol are dissolved in an appropriate solvent (e.g., chloroform). The solvent is then removed by rotary evaporation to produce a thin film on the wall of a round bottom flask and the residue is hydrated with citric acid at pH 3.0 or 4.0 in a beaker. The obtained suspension is subsequently frozen and thawed, followed by sonication. An aqueous solution containing the drug or natural molecule is then added to the suspension and mixed using a vortex mixer. The pH is raised to pH 7.0 with disodium phosphate solution, and then the mixture is heated at 60 °C to yield niosomes .

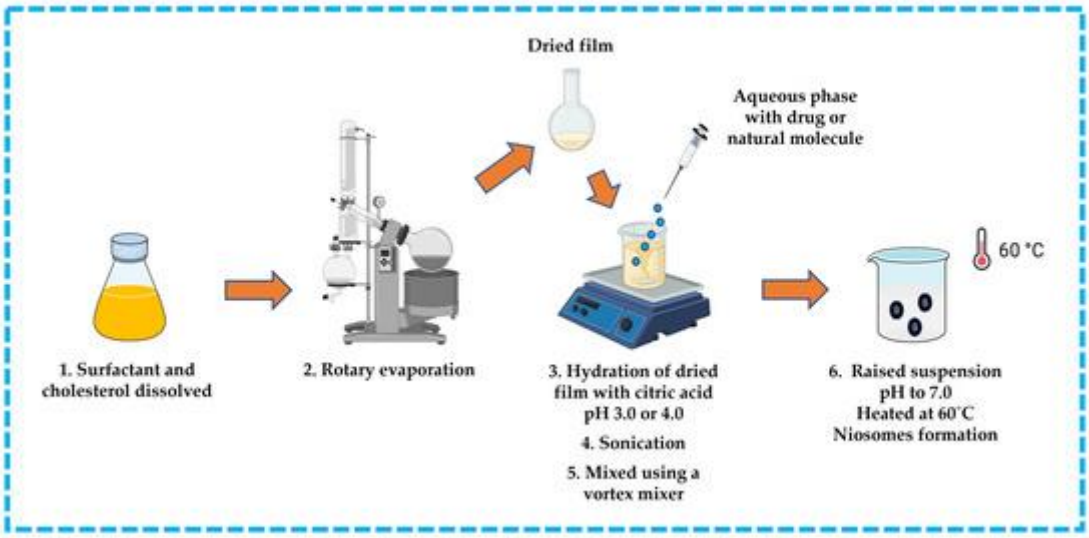

Fig 9: Trans membrane pH gradient technique

Multiple membrane extrusion method: This technique allows for the size of niosomes to be controlled. Surfactant, cholesterol, and diacetyl phosphate are dissolved in an organic solvent (e.g., chloroform), and then the solvent is removed by rotary evaporation to form a thin-film which is subsequently hydrated by using an aqueous solution containing the drug or natural molecule. The suspension is extruded through polycarbonate membranes to obtain the niosomes. Improved control of the niosomes size and the resulting reduction in the polydispersity are important advantages. However, there are also disadvantages, such as increased product loss and extended formulation time.

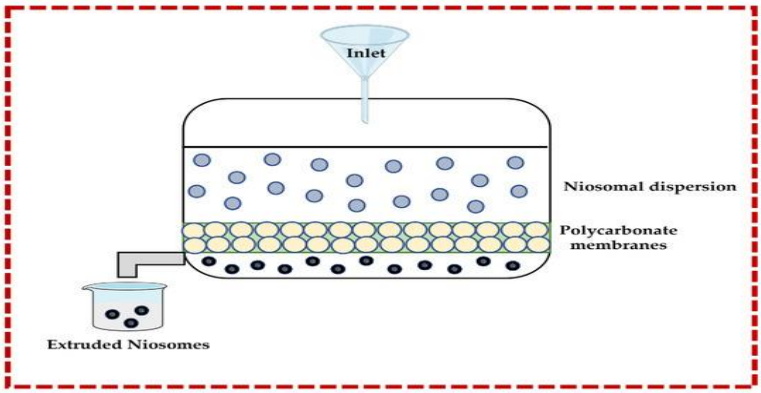

Fig 10: Multiple membrane extrution method

Application Of Niosomes

1. Niosomal drug delivery holds potential for the effective administration of various pharmacological agents targeting diverse diseases. Several therapeutic applications are discussed below.
2. **Niosomesas Drug Carriers**: Utilizing niosomes as carriers has been explored, including their application in transporting iobitridol, a diagnostic agent employed in X-ray imaging. Topical niosomes can function as a solubilization matrix, provide a local depot for sustained release of dermally active compounds, enhance penetration, or act as a membrane barrier influencing the systemic absorption of

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drugs. Additionally, niosomes have been employed for the transportation of iobitridol, a diagnostic substance used in X-ray imaging.[23,24]

3. **Drug Targeting**: One of the key advantages of niosomes is their capacity for targeted drug delivery. Niosomes can be employed to direct drugs specifically to the reticuloendothelial system (RES), which exhibits a preference for the uptake of niosome vesicles. The uptake of niosomes is regulated by circulating serum factors known as opsonins, which label the niosomes for clearance. This targeted drug localization has been utilized in the treatment of tumors prone to metastasize to the liver and spleen in animals. It is also applicable in addressing parasitic infections affecting the liver. Beyond the RES, niosomes can be employed to target drugs to other organs. Attaching a carrier system, such as antibodies, to niosomes is one approach, given that immunoglobulins readily bind to the lipid surface of niosomes, facilitating specific organ targeting.[23,24]
4. **Anti-neoplastic Treatment:** The majority of antineoplastic drugs are associated with severe side effects. Niosomes offer a potential solution by modifying drug metabolism, extending drug circulation and half-life, thereby reducing the adverse effects associated with these drugs. Niosomes contribute to a decrease in the rate of tumor proliferation, leading to higher plasma levels of the drug accompanied by a slower elimination process.[24]
5. **Delivery of Peptide Drugs:** The challenge of oral peptide drug delivery lies in overcoming enzymatic breakdown in the gastrointestinal tract. Current research is exploring the use of niosomes to protect peptides effectively from gastrointestinal degradation. In an in-vitro study focusing on the oral delivery of a vasopressin derivative encapsulated in niosomes, it was observed that the entrapment of the drug significantly enhanced the stability of the peptide. Overcoming the issue of enzymatic breakdown of peptides in oral medication administration is a longstanding challenge, and investigations are underway to determine if niosomes can serve as an effective shield against gastrointestinal peptide degradation.[23,24]
6. **Study of Immune Response:** Niosomes are currently employed in the investigation of immune responses due to their immunological selectivity, low toxicity, and enhanced stability. These non-ionic surfactant vesicles have proven their ability to serve as adjuvants when administered parenterally with various antigens and peptides, contributing to a better understanding of the nature of immune responses.[24]
7. **Diagnostic Imaging with Niosomes:** Niosomes function as carriers for radiopharmaceuticals, exhibiting site specificity for the spleen and liver in imaging studies through the use of 99mTc-labeled DTPA-containing niosomes. Enhanced tumor targeting of a paramagnetic agent has been achieved through the formulation of gadobenate with conjugated niosomes, incorporating (N-palmitoyl glucosamine, NPG), PEG 4400, and a combination of both PEG and NPG.[7]
8. **Niosomes as Hemoglobin Carriers:** Niosomes can be utilized as carriers for hemoglobin within the bloodstream, providing a permeable vesicle for oxygen transport. This property makes niosomes suitable as carriers for hemoglobin in patients suffering from anemia[24]
9. **Magnetic Targeting in Drug Delivery:** Niosomes demonstrate effective magnetic targeting in drug delivery, particularly in cancer therapy applications. The encapsulation of both a model anti-tumor and EMG 707 magnetic ferrofluids within the water core of niosomes has led to the development of doxorubicin-loaded atom-loaded formulations without additional toxicity.[23,24]
10. **Ophthalmic Applications:** In experimental studies with eye drops, gentamicin sulfate, a water-soluble antibiotic, exhibited a notable variation in release rates. The niosomal formulation, unlike conventional drug samples, demonstrated delayed release. Additionally, timolol maleate niosomes (0.25%), prepared with chitosan coating, have demonstrated a more significant impact on intraocular pressure with fewer side effects compared to commercially available products.[23,24]
11. **Anticancer Drug Delivery:** Niosomes, composed of non-ionic surfactants, cholesterol, and diketyl phosphate, have encapsulated anticancer drugs like methotrexate, vincristine, bleomycin, and paclitaxel. This encapsulation has led to increased absorption from the gastrointestinal tract upon oral administration, reduced toxicity, and improved antitumor activity.[23,24]
12. **Transdermal Drug Delivery:** Niosomes have been employed to address the slow penetration of drugs through the skin in transdermal drug delivery. Incorporating drugs into niosomes has enhanced the penetration rate, overcoming a major drawback of the transdermal route.[24]

13. **Cosmetic Applications:** L'Oreal pioneered the use of non-ionic surfactant vesicles (niosomes) for cosmetic applications, leading to the introduction of the first product, 'Niosome,' in 1987 by Lancôme. Niosomes in cosmetics offer advantages such as increased stability of entrapped drugs, improved bioavailability of poorly absorbed ingredients, and enhanced skin penetration.[23,24]
14. **Hormone Delivery**: Niosomes composed of non-ionic n-alkyl polyoxyethylene ether surfactants have been studied for the in-vitro permeation of estradiol through human stratum corneum. The mechanisms involved include the penetration-enhancing effect of surfactant molecules and the impact of vesicular structures at the stratum corneum suspension interface.[23,24]
15. **Neoplasia Treatment**: Niosomal delivery of anthracyclic antibiotic doxorubicin to mice bearing S-180 tumors increased their lifespan and decreased sarcoma proliferation. Niosomal entrapment enhanced the half-life of the drug, prolonged circulation, and altered its metabolism. Intravenous administration of methotrexate entrapped in niosomes to S-180 tumor-bearing mice resulted in total regression of the tumor, higher plasma levels, and slower elimination.[23,24]
16. **Vaccine Delivery**: Niosomes, weakly immunogenic on their own, are being explored as carriers for vaccines, particularly for oral and topical immunization.Topical niosomes demonstrated comparable immune-stimulating activity to intramuscular recombinant HBsAg and topical liposomes.[23,24]
17. **Diagnostic Imaging with Niosomes**: Niosomes are considered effective carriers for iobitridol, a diagnostic agent for X-ray imaging. The preparation of niosomes using the film hydration method followed by sonication allows increased encapsulation and stability of vesicles in diagnostic imaging studies.[7]
18. **Prolonged Release Capability of Niosomes**:The sustained release property of niosomes finds practical application for drugs characterized by a low therapeutic index and poor water solubility. This is because niosomal encapsulation enables the maintenance of such drugs in the circulation. [30,31,33,34]
19. **Targeted Drug Action at Specific Sites**: Utilizing niosomes for drug delivery presents an avenue to achieve localized drug action. The inherent characteristics of niosomes, including their size and limited penetrability through epithelium and connective tissue, contribute to keeping the drug localized at the specific site of administration

Marketed Formulations of Niosomes:

Sr. no.	Brand	Name of Products
1.	Britney Spears – Curious	Curious Coffret: Edp Spray 100ml +Dual ended Parfume& Pink Lipgloss + Body soufflé 100 ml
2.	Orlane – Lipcolor and Lipstick	Lip Gloss
3.	Loris Azzaro – Chrome	Chrome Eau De Toilette Spray 200 ml

Advantages Of Niosome:

1. When compared to oily dose forms, a vesicle suspension's based on water carrier provides good patient compliance.
2. Controlled and precise medication administration.
3. Drug compounds with a wide variety of solubilities may be supported in the infrastructure supplied via hydrophilic, lipophilic, and amphiphilic in moieties in niosomes.
4. Changes within vesicle composition, size lamellarity, surface charge, tapped volume, and concentration may all be used to influence vesicle properties.
5. They have the ability to release the medicine in a regulated and continuous manner.
6. Niosomes are immune-inhibiting, safe, environmentally friendly, and disposable.
7. Surfactants require no particular conditions enable storing or transportation, such as low temperature or an inert environment, and can act as a depot formulation, allowing for regulated drug release.
8. They improve the oral bioavailability of medicines that are poorly soluble.

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9. Even though they are in emulsion form, they have a stable structure.
10. Oral, parenteral, and topical methods can all be used to aggressively achieve the location of action.
11. They are cost effective for large-scale manufacture.
12. They have the ability to shield the medication through enzyme metabolism.
13. They can improve drug penetration through the skin.
14. Niosomes appear in a variety of medications, including pharmaceuticals as well as cosmetics.
15. Late elimination into bloodstream can increase the beneficial effects of medicinal compounds.
16. They have the ability to shield the active component from physiological circulation.
17. Niosomes can be delivered to the site that acts by oral, topical, or parenteral methods

Limitations Of Niosome:

- Aggregation and Fusion:
  Niosomes can aggregate or fuse due to physical instability or the presence of opposing charges on their surfaces during synthesis.
- Drug Leakage:
  The trapped drug can leak out of the niosomal vesicles, leading to loss of medication.
- Hydrolysis:
  Encapsulated drugs can undergo hydrolysis, which degrades the drug and limits the overall shelf-life of the niosome dispersion.
- Low Drug Loading:
  Niosomes may have an inadequate capacity to load drugs, which can limit their effectiveness as a delivery system.
- Time-Consuming & Complex Preparation:
  The methods used to prepare niosomes can be time-consuming and complex, requiring multiple steps.
- Specialized Equipment:
  Manufacturing niosomes often requires specialized equipment and sophisticated techniques, increasing costs and complexity.
- Scalability Challenges:
  Scaling up the production of niosomes to industrial levels can be challenging and may require further process optimization.

CONCLUSION

Niosomes, a recent technological advancement, exhibit potential in the realms of cancer and infectious disease treatments. Serving as an alternative to liposomes, they offer advantages such as increased chemical stability, enhanced purity, and reduced cost. Niosomes, which are non-ionic surfactant vesicles, influence drug plasma clearance, tissue distribution, metabolism, and cellular interaction. Already employed in cosmetic products, they hold promise for diverse drug delivery applications, such as targeting, ophthalmic, topical, and parenteral. Advanced targeted niosomal systems utilizing active, passive, and magnetic mechanisms have been devised for precise macromolecular drug delivery. Niosomes are deemed safer and more practical than ionic drug carriers, without requiring special handling or storage conditions. The potential of efficiently delivering drugs to tumor sites is highlighted, particularly with the assistance of activated macrophages. While currentl findings are limited to animal experiments, further clinical investigations are imperative to fully leverage niosomes as effective drug carriers for cancer, infections, and other ailments. There exists considerable potential for encapsulating various drugs, including toxic anti-cancer, anti-infective, anti-inflammatory, and anti-viral agents, within niosomes.

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