INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA):IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Review Article

Niosomes As A Potential Approach For Enhancing Topical Application

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ARTICLE INFO

Received: 21 Feb 2024
Accepted: 25 Feb 2024
Published: 03 March 2024

Keywords:
Niosomes, liposomes, pharmaceutical, topical application.

DOI:
10.5281/zenodo.10775271

ABSTRACT

The investigators have worked to increase the effectiveness of medication use for a range of illnesses over the years. Niosomes and other current drug delivery system can be achieved by the various techniques. An innovative drug delivery technique called niosomes encapsulates the medication in a vesicle. Niosomes are formed by self-assembling vesicles of non-ionic surfactants. Due to their stability and affordability, niosomes are typically chosen over liposomes. As niosomes shield pharmaceuticals from biological environments, delay drug clearance from circulation, limit the drug's effects to specific target cells, and enhance the pharmacological action of pharmaceutical compounds. The desired range for niosome particle size is between 10 nm and 100 nm. Niosome preparation involves a variety of techniques, some of which are as follows, the thin film hydration technique, the bubble method, etc. With several commercially accessible niosome products, niosome has numerous uses in both pharmaceutical and non-pharmaceutical fields. Compared to liposomes, niosomes have a larger storage capacity, making them advanced. Niosome is currently marketed in a wide variety of therapeutic formulations. It can be valued with various evaluation parameters and discussed in detail. The developments in the field of niosomal research, together with literature reviews related to studies conducted during the last decade made niosomes a novel delivery system for enhanced topical application.

INTRODUCTION

Paul Ehrlich initiated the process of developing targeted drug delivery in 1909. The desired or targeted site is where the targeted drug delivery directly manifests its action. A therapeutic agent is said to exhibit targeted drug delivery if it can act directly on a desired location while interacting with non-targeting sites in minimal or no way1. Niosomes are a new type of vesicular drug delivery system that can be applied to deliver medications in a targeted, controlled, and sustained manner2. The niosome is made up of cholesterol-containing non-ionic surfactants and a trace amount of ionic surfactants for stability, like diacetyl phosphate3. Niosomes were created as an alternate delivery mechanism to liposomes

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

because they can address the issues with large-scale manufacture, sterilization, and physical stability. They share structural similarities with liposomes4. The development of cosmetics was the initial use for non-ionic surfactant vesicles, or Niosomes. These vesicles are created with non-ionic amphiphiles in specific aqueous solutions by the use of self-assemble technology. Niosomes are vesicles with a structure like that of multilamellar or unilamellar vesicles. They have hydrophilic holes on the inside and hydrophobic shells on the outside that house the active chemicals. The niosomes have a tiny, microscopic size. Niosomes range in size from 20 to 100 nm on the nanometric scale. Since they are so tiny-measured in nanometers—they can be administered transdermally by any transdermal route with ease. Because of their nanometric size, niosomes have reduced reticular endothelium system metabolism and elimination5. Due to the stratum corneum barrier, transdermal administration of many medications is typically problematic, particularly for hydrophilic compounds8. Many physical and chemical technological advancements have been made in recent decades to improve percutaneous drug penetration. These include the use of penetration enhancers, which are substances that help molecules absorb through the skin by temporarily reducing its impermeability, lowering mucus viscosity, allowing proteins to pass through membranes, and opening tight junctions . Niosomes are also adaptable carrier systems that can be applied transdermally among other ways. Since topical application of niosomes has been reported to increase the residence time of drugs in the stratum corneum and epidermis, while reducing their systemic absorption and improving the horny layer properties, particular efforts have been made to use niosomes as an effective dermal and transdermal drug vehicle in the treatment of dermatological disorders6. Topical application of niosomal preparation enhances medication retention in the stratum corneum, the epidermis' viable layers, and, to a lesser degree, the dermis' upper layer (the most superficial layers of the skin). If, however, a transdermal effect is required, then encapsulated medications in niosomal preparation should have an easier time penetrating the skin, crossing the dermis and epidermis, and getting to the blood vessels and systemic circulation above the hypodermic tissue7.

STRUCTURE OF NIOSOME:

The bi-layered structure of non-ionic surface-active substances is known as a niosome. Only when cholesterol and surfactants are combined in the right amounts and the temperature is higher than the gel liquid transition point can these thermodynamically stable bilayered structures develop. In the middle of this two-layered structure lies a hollow area as shown in fig 1. Niosomes have a unique geometry that allows them to encapsulate both hydrophilic and hydrophobic drugs within their structures. Hydrophobic medications enter the bilayer structure via partitioning into it, while hydrophilic drugs are entrapped in niosomes either on the bilayer surface or in the core aqueous domain2.

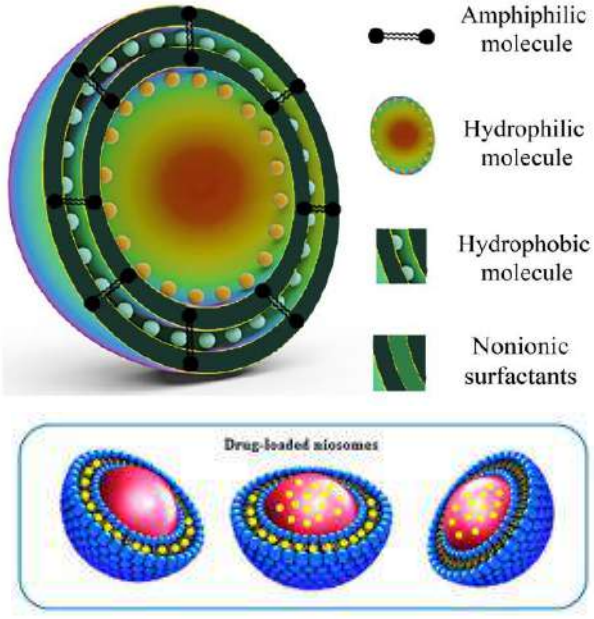

Fig1: Structure of Niosome

Salient features of Niosomes:

- Osmotically stable, niosomes have the ability to entangle a solution and strengthen the medication that is entangled.
- The structural flexibility of niosomes allows for variation in the specific scenario that needs to be addressed.
- Niosomes are biocompatible, non-immunogenic, and biodegradable non-ionic surfactants.
- Niosomes are an easy way to distribute medication that is sensitive and labile.
- Just by protecting the drug from the biological environment, the drug's availability at that specific location is enhanced8.
- Niosomes are another tool for achieving targeted drug delivery; they carry the medication to the precise location in the body where it is required to have a therapeutic impact. As a result, less control over measurement will be required to get the desired result.
- When administered topically, they enhance the permeability of pharmaceuticals via the skin. They also improve the solubility and oral bioavailability of treatments with poorly soluble substances9.

COMPONENTS OF NIOSOMES:

The two main components required to produce niosomes are

- Cholesterol
- Nonionic surfactants

1. **Cholesterol:-**

Cholesterol is indeed a steroid product that is used to give niosome preparations rigidity or proper shape and conformation.

2. **Nonionic surfactants**:-

Non-ionic surfactants such as the ones listed below are commonly utilized during the process of making niosomes.

A. Spans (span 60, 40, 20, 85, 80)

B. Tweens (tween 20, 40, 60, 80)

C. Brijs (Brij 30, 35, 52, 58, 72, 76). The hydrophilic head and hydrophobic tail of nonionic surfactants10.

ADVANTAGES:

- Niosome formulation is more cost-effective than other formulations. All of the components needed to make niosome are readily available and reasonably priced.
- Due to their nanoscale size, niosome formulations have very few harmful effects and can be administered via a variety of routes, including topical, oral, parenteral, and ophthalmic. They also facilitate drug penetration into the skin1.
- Niosomes have the highest duration of activity with fewer adverse effects.
- The preparation's active ingredient or constituent is shielded from external and internal forces by a bilayer of defence8.
- It can enhance the skin's ability to absorb drugs10.

METHOD OF PREPARARTION:

a. Reverse Phase Evaporation (REV)
b. Multiple membrane extrusion method
c. Trans-membrane pH-gradient (inside acidic)
d. The Bubble Method
e. Ether Injection Method
f. Micro fluidization
g. Sonication
h. Handshaking method (Thin film hydration technique)

1. **Reverse phase evaporation method:**

Using this technique, an aqueous drug solution is added after surfactants are dissolved in an organic ether and chloroform solution. Subsequently, a niosome suspension is formed by homogenizing the two immiscible phases and removing organic solvents at low pressure. Because of its high EE and large, slightly variable particle size, this approach is thought to be perfect for creating hydroxychloroquine niosomes. Large hydrophilic

macromolecules have been reported to be encapsulated with a comparatively greater EE using the reverse phase approach compared to other methods1.

2. Multiple membrane extrusion method:

The optimal technique for regulating niosome size is this one. The organic solvent is evaporated in this procedure by adding a mixture of surfactant, cholesterol, and diacetyl phosphate in chloroform to a rotary flash evaporator, which creates a thin layer out of it.90 Drug-polycarbonate membrane solution is added to the aqueous phase. Up to eight passages can be arranged in sequence through the resulting suspension that is extruded1.

3. Trans Membrane pH Gradient (inside acidic):

This technique uses the same amounts for cholesterol and surfactant. These are subsequently dissolved in an organic solvent, such as chloroform. Less pressure is used to extract the organic solvent. The round-bottom flask's inner surface develops a thin coating of lipids as a result. Usually, a solution of citric acid or any other comparable acidic solution is vortexed to hydrate the thin lipid layer. An aqueous medication solution is added to the resulting mixture and blended by vortexing after it has undergone the freeze-thaw cycle. With the disodium hydrogen phosphate solution, the ultimate pH can be changed. This approach allows for the medication to be remotely loaded2.

4. The "Bubble" method:

Niosomes are prepared without the need for an organic solvent in this approach. Here, all the ingredients—cholesterol, surfactant, and phosphate buffer-are combined in a flask with three necks. A water bath is used to keep the flask at the desired temperature. The system is set up so that the thermometer is placed in one neck, the nitrogen is passed through a second neck, and the water-cooled reflux is connected to a final neck. After distributing these ingredients at 70°C and homogenizing them for 15 seconds, nitrogen gas is added to the mixture right away. This produces huge, unilamellar vesicles. It has to undergo additional size reduction to produce tiny unilamellar vesicles2.

5. Ether Injection Method:

This process entails combining surfactant with cholesterol in an organic solvent, such as diethyl ether. The medicine is added gradually to this mixture in an aqueous solution that has been heated. This solution is maintained at a temperature of over 60°C. The drug's unilamellar vesicles containing surfactant are created as the solvent evaporates. The stavudine-prepared niosomes produced with this approach can range in diameter from 50 to 1000 μm8.

6. The micro fluidization method:

In the micro-fluidization technique, unilamellar vesicles with a specific size distribution can be created. It is based on the submerged jet principle, in which two fluidized streams interact in the interaction chamber's tightly defined microchannels at incredibly high speeds (100 ml/min). The single front of the thin liquid sheet impingement arranges the energy supplied to the system to remain in the region where niosomes are formed. This process produces smaller, more uniform, and repeatable niosomes9.

7. Sonication:

Using this procedure, the medication is combined with cholesterol and a surfactant in an aqueous phase inside a scintillation vial. A sonic probe is used to homogenize the mixture at 60°C for three minutes. The vesicles were uniformly small in size10.

8. Hand Shaking Method (Thin Film Hydration Technique):

This procedure involves filling a round-bottom flask with a mixture of vesicle-forming chemicals, such as cholesterol and surfactant that have been dissolved in an organic volatile solvent, such as chloroform or diethyl ether. The organic solvent is

removed at room temperature using a rotary evaporator, leaving the mixture coated in a thin layer on the flask walls. Multilamellar niosomes are created by slowly rehydrating this dehydrated surfactant film with an aqueous phase. The resultant multilamellar vesicles can then be subjected to membrane extrusion, microfluidization, or sonication processes to create unilamellar niosomes and smaller niosomes10.

CHARACTERIZATION OF NIOSOMES

a. Entrapment efficiency
b. Vesicle size and shape
c. In-vitro release
d. Number of lamellae
e. Bilayer formation
f. Membrane rigidity
g. Vesicular Surface charge
h. Stability studies

a. Entrapment efficiency:

The number of active compounds loaded into the niosomal structure is known as the vesicular systems' entrapment efficiency (EE). It can be expressed as:

% EE=(Amount Entrapped) / (Total Amount)×100

Where "total amount" refers to the entire amount of medication prepared in the niosomal formulation. A UV-visible spectrophotometer is used to perform spectrophotometric analysis to assess the entrapment efficiency. When dealing with genetic material, UV densitometry is carried out after gel electrophoresis. Furthermore, the entrapment efficiency can be assessed fluorometrically with a hydrophilic fluorescent8.

b. Vesicle size and shape:

Niosomal vesicles are thought to have a spherical form, and the laser light scattering technique can be used to measure their mean diameter. The diameter of these vesicles can also be ascertained by other methods such as freeze-fracture electron microscopy, photon microscopy, optical microscopy, ultracentrifugation, electron microscopy, and molecular sieve chromatography. Frozen thawed niosomes exhibit an increase in vesicle diameter, potentially resulting in vesicle fusion during the cycle3.

c. In-vitro release:

In vitro release studies frequently employ the dialysis membrane technique. Using this technique, a dialysis bag is filled with a modest amount of niosomes, which are knotted at both ends. The dialysis bag is inserted in another beaker that has an appropriate dissolving medium in it and is maintained at 37°C. The beaker is then agitated using a magnetic stirrer. A sample solution is taken out of the beaker and replaced with a new dissolving medium at prearranged intervals. According to the guidelines provided in the drug's corresponding monograph, the drug concentration in the samples was measured at the designated wavelength3.

d. Number of lamellae:

The number of lamellae can be determined using a variety of methods, including electron microscopy, AFM, NMR, and small-angle X-ray spectroscopy. In situ, energy-dispersive X-ray diffraction combined with small-angle X-ray scattering can be utilized to quantify the thickness of bilayers2.

e. Bilayer formation:

When non-ionic surfactants are assembled to form bilayer vesicles, light polarisation microscopy shows the development of an X-cross8.

f. Membrane rigidity:

The fluorescent probe's mobility is used to calculate the niosome's membrane stiffness as a function of temperature3.

g. Vesicular Surface charge:

Niosome stability is largely dependent on their surface charge; charged niosomes are often more stable than uncharged vesicles. A zeta sizer or the electrophoresis method is used to calculate it3.

h. Stability studies:

To test the niosome stability, the optimized batch was stored in hermetically sealed vials at different

temperatures. Since instability of the formulation would reflect in drug leakage and degradation, surface features, the percentage of drug preserved in niosomes, and niosomes generated from prionosomes were selected as metrics for assessing the stability. Concerning the rate of medicine retention. At predefined intervals (0, 1, 2, and 3 months), the niosomes were collected, their medicine content was measured, their color and surface properties were investigated, and they were then properly evaluated using UV spectroscopy and HPLC procedures, among other techniques9.

Topical application of Niosomes:

The application of topical drug delivery has significant advantages, particularly in transdermal/ topical drug delivery. This method allows for the localized release of medication at the target site, reducing systemic side effects by minimizing overall absorption into the body. Transdermal delivery offers higher bioavailability by avoiding first-pass hepatic metabolism, non-invasive administration without needles, and elimination of potential drug-food interactions. It is especially beneficial for drugs with the ideal characteristics for transdermal delivery, such as low molecular weight, lipophilicity, and effectiveness at low dosages. Niosomes play a vital role in enhancing cutaneous drug delivery, providing mechanisms for penetration, and altering the skin's properties to increase permeability. Additionally, the use of gelling agents creates niosomal gels, which promote the sustained release and enhanced penetration of drugs across the skin. Moreover, the latest development in vesicle design for transdermal delivery involves elastic vesicles, which have shown the potential to enhance permeation through the skin. This advancement is essential for various applications, including wound healing, preventing burn infections, and delivering antigens for topical vaccines4.

1. **Niosomes on Cosmetics:**

L'Oreal's cosmetic uses were the source of the initial report on non-ionic surfactant vesicles. In the 1970s and 1980s, L'Oréal created and patented niosomes. In 1987, Lancôme released "Niosome," their debut product. Niosomes provide benefits for cosmetic and skin care applications because they can improve skin penetration, enhance the stability of entrapped medications, and raise the bioavailability of poorly absorbable substances8.

The application of niosomes in skin interactions and drug delivery is evident from the study's findings. Niosomes were observed to interact with the stratum corneum, potentially fusing with native SC lipids. The concentration of vesicular components diminishes towards the inner SC region, indicating the potential permeability of the vesicles with active substances into the skin. Specifically, the study demonstrated that niosomes were significantly more successful in delivering enoxacin compared to liposomes or simple active component solutions. This suggests that niosomes have the potential to deliver even larger molecules to the skin, particularly when the skin barrier function is significantly lower11.

2. **Niosomes on skin cancer:**

The application of niosomes as a delivery system for 5-Fluorouracil (5-FU), an anticancer drug used in the treatment of various forms of skin cancers. Studies demonstrated that niosomes significantly improved percutaneous permeation of 5-FU, leading to enhanced anticancer activity. The niosomal system, particularly bola-niosomes, resulted in a substantial increase in drug penetration through the human stratum corneum and epidermal layers12. Furthermore, compared to non-vesiculized dosage forms, the vesiculization of 5-FU not only improved topical delivery but also increased its cytotoxic effect for the treatment of actinic keratosis and non-melanoma skin carcinoma. This highlights the potential of niosomes as an effective delivery system for

enhancing the efficacy of anticancer drugs in dermatological applications13.

3. Niosomes on local anesthesia:

The application of nonionic surfactant vesicles in delivering lidocaine and lidocaine hydrochloride for topical anesthetics in dermatological procedures. Development of these vesicles using Tween 20 and cholesterol to improve the efficiency of local anesthetics and minimize side effects. The study compared the diffusion of lidocaine through both nonionic surfactant vesicles and classical liposomes, revealing that the vesicle encapsulation facilitated the flux of charged lidocaine through membranes. Furthermore, positively and negatively charged vesicles showed varying drug entrapment efficiency, emphasizing the importance of charged nonionic surfactant vesicles in dermal drug delivery for effective pain relief in dermatological procedures14.

4. Niosomes on the acne:

Niosomes offer significant potential in the treatment of acne by enhancing the dermal delivery of antiacne agents and minimizing their adverse effects. For example, benzoyl peroxide, commonly used for acne management, can cause skin irritation and discomfort when administered dermally. However, niosomal benzoyl peroxide incorporated into HPMC gel demonstrated increased skin retention, extended drug release, and improved permeation across the skin, thereby reducing drug toxicity and enhancing therapeutic efficacy15. Similarly, niosomal gallidermin, known for its activity against acne-causing bacteria, showed lower antibacterial activity against tested microorganisms due to the niosomes protective role and sustained release of the drug16. Additionally, the application of tretinoin, a widely used topical treatment for skin diseases, was shown to benefit from niosomes, as they improved the stability of tretinoin and demonstrated enhanced cutaneous drug retention compared to commercial and liposomal formulations17. This suggests that niosomes have the potential to optimize the delivery of various antiacne agents while minimizing their adverse effects, making them a valuable tool in acne treatment18.

5. Niosomes on psoriasis:

Niosomes offer a promising carrier system for topical drug delivery, thereby enhancing the efficacy and safety of topical products used in psoriasis treatment. The encapsulation of medications like dithranol and methotrexate in niosomal systems has demonstrated improved drug permeation and reduced adverse effects19. Additionally, niosomal urea gel, prepared using Span 60, showed increased drug diffusion through the skin and led to a significant decrease in the severity of psoriatic lesions when compared with plain urea gel. These findings suggest that niosomes, particularly in combination with chitosan gel, hold potential as a valuable adjuvant in the treatment of psoriasis, offering improved clinical effectiveness and patient compliance20.

6. Niosomes on the Antioxidants:

The application of antioxidant compounds derived from rice bran, such as g-Oryzanol, phytic acid, and ferulic acid, in anti-aging skincare products. It discusses a study that investigated the use of these bioactive compounds encapsulated in niosomes, a type of nano-scale vesicles, for dermal delivery. The study evaluated the antioxidant activity of these compounds through various assays and found that the niosomal gel and cream formulations containing rice bran extracts exhibited greater antioxidant activity and higher lipid peroxidation inhibition, indicating the potential for preventing UV-induced peroxide formation21. Furthermore, the formulations, when topically applied to human volunteers, resulted in improvements in skin hydration, lightening, thickness, roughness, and elasticity, without causing any signs of skin irritation22. Additionally, niosomal formulations loaded with

semipurified fractions containing gallic acid were formulated and evaluated, showing improvements in skin elasticity and roughness without causing skin irritation in both rabbit skin and human volunteers23.

7. Niosomes on the whitening effect:

The application of N-acetyl glucosamine (NAG) and ellagic acid in pigment-lightening cosmeceuticals. NAG, known for its role in inhibiting melanin production, was encapsulated into niosomes to enhance its penetration into the skin. The study demonstrated that niosomal formulations significantly improved the localization of NAG in the skin, showing potential for treating hyperpigmentation disorder24. Similarly, ellagic acid, known for its ability to inhibit tyrosinase and melanin synthesis, was formulated into niosomes for dermal delivery. Skin distribution studies revealed that the niosomal formulation of ellagic acid showed more efficient delivery through the epidermis and dermis compared to the ellagic acid solution, suggesting that niosomes could be a promising carrier for dermal delivery of ellagic acid in skin-lightening products25.

8. Niosomes on the Anti-scarring ingredients:

The evaluation of elastic niosome particles as carriers for skin treatment compounds. Firstly, it highlights the effectiveness of elastic niosome particles packed with papain in improving transdermal absorption, increasing papain penetration, and reducing scarring. These particles have shown potential in improving the chemical stability and dermal penetration of gallic acid, indicating their suitability as carriers for anti-aging compounds26. Additionally, the successful encapsulation of black tea extract in niosomes has shown effective dermal penetration of gallic acid and caffeine, demonstrating the potential of niosomes as carriers for skin antioxidants27. Furthermore, in an in vivo comparative experiment on rabbits, elastic niosomes containing papain demonstrated superior chemical stability and higher accumulation and flux compared to non-elastic niosomes and nanospheres, resulting in a significant reduction of collagen fibers and height of treated scars. Overall, the findings suggest that elastic niosomes have the potential to be effective carriers for skin treatment compounds, offering improved transdermal absorption and therapeutic benefits28.

9. Niosomes on the vitiligo:

The potential application of elastic cationic niosomes in the treatment of vitiligo through gene therapy. Vitiligo, a dermatological disorder causing depigmented skin, can have a significant negative impact on the quality of life. The use of novel dermal drug delivery systems, such as elastic cationic niosomes, shows promise in vitiligo treatment, as conventional topical dosage forms often have poor efficacy and side effects affecting patient compliance29. Research has demonstrated the effectiveness of elastic cationic niosomes in delivering genes responsible for melanogenesis30. These niosomes showed superior efficacy in delivering tyrosinase-encoding plasmid and luciferase plasmid when compared to nonelastic niosomes and liposomes, potentially serving as an efficient topical delivery system for gene therapy in vitiligo treatment. The findings suggest that elastic cationic niosomes have the potential to be an effective and promising approach for gene therapy in vitiligo treatment without requiring additional equipment31.

10. Niosomes on the Alopecia:

The potential applications of niosomes for targeted drug delivery to the pilosebaceous unit, with a focus on diseases of follicular origin such as androgenic alopecia32. Research has shown that cationic niosomes efficiently deliver unsaturated fatty acids and extracts of Thai Lanna medicinal plants to the pilosebaceous unit, demonstrating anti-hair loss activity and increased hair density, thereby offering a promising approach for the

treatment of nonhereditary alopecia 33. Additionally, studies have highlighted the successful delivery of finasteride and minoxidil via niosomes and liposomes, indicating their potential as effective carriers for dermal drug targeting and the treatment of skin diseases such as hair loss. These findings suggest that niosomes could be a viable and practical therapeutic approach for treating conditions related to the pilosebaceous unit, providing enhanced efficacy and reduced systemic effects, thus, addressing the needs of patients with diseases of follicular origin, including androgenic alopecia34.

GENERAL APPLICATION:

Niosomal formulations represent an innovative approach to medication administration with a wide range of uses, such as:

a. Gene transfer
b. Drug pinpointing
c. Antineoplastic therapy
d. Leishmaniasis treatment
e. Peptide drug delivery
f. Research immune response
g. Carriers for haemoglobin
h. Transdermal drug administration systems
i. Cosmetics and cosmeceuticals10

CONCLUSION:

Niosomes are an innovative and promising drug delivery technology, functioning as carriers for the creation of effective drug delivery systems. They present a notable option for combining hydrophilic, lipophilic, or both types of drugs. Numerous studies have illustrated that niosomes enhance the stability of encapsulated drugs, reduce the required dosage, and enable targeted delivery to specific sites. Niosomes appear to be a preferred drug delivery system over liposomes due to their stability and cost-effectiveness, bringing in extensive acceptance among researchers and academics. Niosomal formulations can be administered through various routes, such as oral, topical/transdermal, parenteral, and ocular, to achieve both systemic and local effects. Niosomes increase the bioavailability of drugs and aid in decreasing their toxicity. Their smaller size allows them to bypass or be less metabolized by the reticular-endothelial system (RES). Moreover, niosomes do not require special handling or storage conditions.

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HOW TO CITE: Priyadarshini K. , E. Gopinath, Ganesh N. S. , Vineeth Chandy, Niosomes As A Potential Approach For Enhancing Topical Application, Int. J. of Pharm. Sci., 2024, Vol 2, Issue 3, 35-45. https://doi.org/10.5281/zenodo.10775271