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Niosome: A Comprehensive Review of Novel Drug Delivery System

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ABSTRACT

Non-ionic surfactant vesicles, which make up niosomes, are made by hydrating a mixture of non-ionic surfactant and cholesterol. They can be employed as both lipophilic and amphiphilic drug carriers. Niosomes are a kind of delivery mechanism where drugs are contained within vesicles. Niosomes have a variety of characteristics, including being non-immunogenic, biodegradable, and structurally flexible. The reason for writing this review is to shed light on the several ways that niosomes are utilized to treat a variety of illnesses. We will examine several facets of niosomes in this review paper. These include their manufacture method, mechanism of action, how neosomes aid in drug penetration, how they are used as a permeation enhancer, how they are applied, how they can be used to treat various diseases and their toxicity, and how surfactants can be used to mitigate their toxicity.

KEYWORDS: Niosome, Non- Ionic surfactants, Liposomes, Nanocarrires, Charge Inducers.

INTRODUCTION

A drug delivery system involves administrating pharmaceutical substances at targeted rates to produce a therapeutic impact in humans or animals at affected areas while decreases the medication levels in the adjacent tissues. (S, 2021). Niosomes are novel drug delivery systems that encapsulate medication within vesicles. (RM., 2015) They are also known to be as vesicular drug delivery systems. The initial vesicular drug delivery was liposomes: however, liposomes have several drawbacks, such as stability issues, high cost, and toxicity. (Muzzalupo R, 2015) To address these problems, researchers have turned to niosomes. Niosomes consist of non- ionic surfactant, which contribute to their non- toxic nature due to the surfactant content. (Abdelkader H, 2014) Besides non – ionic surfactants, niosomes may also contain cholesterol, a hydration medium, and some charged molecules. Niosomes are unilamellar and multilamellar bilayer vesicles formed by hydration of non- ionic surfactants, with or without added cholesterol. Niosomes possess qualities such as biodegradability, biocompatiability, non-immunogenicity, and flexicity in their structural features. Niosomes are less toxic and demonstrate activity at the targeted site. (Bansal S, 2021). In 1909, Paul Ehrlich introduced the concept of targeting treatment to the specific to the affected cells, while leaving healthy cell untouched. This approach has since been referred to as the "MAGIC BULLET". Since then, a various drug carrier system has been developed such as immunoglobulins, serum

protein, liposomes, synthetic polymers and microspheres. Among these, Liposomes and Niosomes are two of the most well – documented researched vesicular drug delivery systems. (S, 2021) Niosomes have recently garnered significant interest as promising carriers for drug delivery through multiple administration routes. These vesicular systems have become prominent options among all types of vesicles. Niosomes possess many advantages over the other drug delivery system, enhancing their valuable across an extensive range of applications. A notable key advantage of Niosomes is their ability to encapsulate a variety of genes, drugs, proteins, and vaccines. (Pourmadadi M, 2022)

Structure of Niosomes:

Structurally, Niosomes share a similar structure with liposomes, with both consisting of Bilayers which is composed of non – ionic surfactants for niosomes and phospholipids in case of liposomes. Both hydrophilic and hydrophobic drugs can be incorporated into niosomes. The noisome are amphillic in nature, which enable the encapsulation of hydrophilic drugs within the core cavity and hydrophobic drugs in the non – polar regions with in the bilayer. Niosomal gels contain nanometric systems which are embedded in a gel matrix. These nanomatric systems possess a larger surface area, making them highly satisfactory for drug application uniform drug release. Such structures have been explored as alternatives to traditional formulations based on chemical skin permeation enhancers. Additionally, the nano – sized nature of these systems allows for easy application to the skin in dermatological products (Khan A, 2011) (Hu C, 1999).

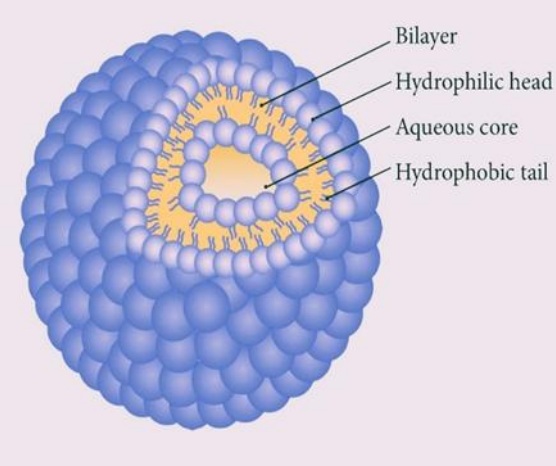


Figure no. 1: Structure of Niosomes:

COMPOSITION OF NIOSOMES:

The composition of niosomes significantly affects their formulation, pharmacokinetic behaviour, and application. Typically, a noisome consists of lipids such as cholesterol, substances that induce a charge, and non – ionic surfactants. These components are generally harmless and compatible with biological systems (Yao Y, 2020).

1. Non – Ionic Surfactants:

The fundamental components required for the preparation of niosomes are non- ionic surfactants. The molecules possess a non-polar tail and a polar head, giving them amphiphilic properties. Compared to anionic, cationic and amphoteric surfactants, these uncharged surfactants are less toxic and exhibit more stability. These non- ionic surfactants perform various functions, such as minimizing homolysis and inflammatory response at cell surfaces, enhancing transcellular transport, and boosting solubility. Furthermore, they have the ability to inhibit p-glycoprotein. Researchers have shown that non- ionic surfactants can be utilized in cardiovascular treatment, HIV protease inhibitors,

anticancer agents, and steroid drug to enhance absorption and targeting. These non- ionic surfactants possess the potential to be utilized in drug delivery systems, offering a method to achieve sustained release in terms of rate, duration, and site of action. Key factors that affect entrapment efficiency (EE) include the critical packing parameter (CPP), gel- liquid transition and the hydrophilic-lipophilic balance (HLB). Researches indicate that higher HLB levels result to longer alkyl chains and larger vesicles. It has been demonstrated that HLB value ranging from 14 to 17 are deemed suboptimal, while an HLlB value of 8 resulted the highest encapsulation efficiency (EE). For instance, utilizing a surfactant with a lower HLB value has the potential to improve the encapsulation efficiency of a lipophilic medication. Another important component in EE is the phase transition temperature. Span-60, a biodegradable surfactant, offer excellent EE due to its elevated transition temperature (Moghtaderi M, 2022) (S M. , 2020) (Masjedi M, 61) (P:, 2020) (Yaghoobian M, 2020) (Wu KW, 2021).

2. Cholesterol:

Cholesterol is commonly recognized for its interaction with non- ionic surfactants, influencing the morphology and physical characteristic of niosomes. Several surfactants, at concentration of up to 30-50 mol%, are capable of forming vesicles when CHOL is introduced. The HLB value of the surfactants indicates the how much CHOL is necessary. To counteract the impact of the larger head group on the critical packing parameter (CPP), the concentration of CHOL must be increased as the HLB value rinse over 10.

Niosomes are often formulated by combining with a non- ionic surfactant in a 1:1M ratio. Cholesterol can impact the efficacy of drug absorption, membrane permeability, and stiffness, stability, storage condition, toxicity, and the capacity to dehydrate niosome to be rehydrated. It not only prevents the degradation of drugs but also mitigates undesirable pharmacological and immunological consequences. Nevertheless, the impact of CHOL is contingent upon the specific non – ionic surfactant used (Chen S, 2019). (Akbarzadeh I, 2021)

Cholesterol can enhance the hydrophobicity of bilayers, resulting to a reduction in a surface free energy. There are two primary impacts of cholesterol: in liquid – state bilayers, cholesterol enhances chain order, while in gel – state bilayers, it reduces chain order. Because cholesterol inhibits the release of the encapsulated material and slows down the release process, it makes bilayers stiffer. The charge present in multilamellar vesicle increase the distance between adjacent bilayers, which subsequently increase the volume of the encapsulated material. Additionally, cholesterol can influence the structure of niosome vesicles. By forming hydrogen bonds between its hydroxyl groups and the alkyl chains of surfactant molecules.

Cholesterol boosts the stability of bilayers. These interactions restrict the movement of bilayer acyl – chain and strengthen membrane cohesion. By modifying the flexibility of chains within bilayers, it increases vesicle stability by raising their transition temperature.

3. Hydration Medium:

A hydration medium is necessary for the production of niosomes in addition the previously mentioned ingredients. Niosome synthesis requires hydration, with phosphate buffer often utilized due to ability to assist in both drug loading and noisome synthesis. Factors such as the composition and hydration condition of the medium, including pH, temperature, and the duration of entrapment for niosome nanoparticles- affect the size, distribution, and entrapment efficiency of niosome nanoparticles.

The pH of the medium plays a crucial role in both the drug encapsulation and formulation processes. The solubility of the drugs being encapsulated determines the applied pH of the buffer; researches indicated that phosphate buffer at Ph 7.4 yields stable vesicles composed with tiny

particles. Researchers have shown that both the volume of media used and the duration of hydration can affect the resulting characteristics of drug – loaded niosomes, such as drug leakage and entrapment efficiency. It is evidence that more acidic condition generally lead to increased drug release, while extended hydration periods reduce niosome size, enhanced entrapment efficiency, contribute to increase stability (Moghtaderi M, Niosomes: a novel targeted drug delivery system for cancer., 2022.) (Asaithambi K, 2020) (Sahrayi H, 2021).

4. Charge Inducers:

The induction charge by this molecule increases the stability of niosomes through electrostatic repulsion. There are two categories of charged inducers: those that carry a positive charge and those that carry a negative charge. Examples of positive charge inducers include sterylamine and cetyl pyridinium chloride, while negative charge inducers consist of dicetyl phosphate (DCP), dihexaadecyl phosphate, and lipoamine acid (Geeta M. Khillari, 2022).

TYPES OF NIOSOMES

Niosomes are categorized into Small unilamellar vesicles (SUV), large unilamellar vesicles (LUV), or Multilamellar vesicles (MUV) according to their size and the quantity of layers (Moammeri A, 2023).

1. **Small unilamellar vesicles (SUV):**

These small unilamellar vesicles are primarily prepared from multilamellar vesicles using methods such sonication, French pressing, and extrusion. Electrostatic stabilization involves incorporating dicetyl phosphate into Span-60 based niosomes loaded with 5(6) – carboxyfluorescein (CF) (Gadhiya P, 2012).

2. **Multi lamellar vesicles (MUV):**

It comprises several bilayers surrounding the aqueous lipid compartment individually. These vesicles approximate range in size from 0.5- 10 um in diameter. Multilamellar vesicles represent the most widely utilized noisome. They are simple to produce and maintain stability over extended storage durations. These vesicles are particularly highly- suited for transporting lipophilic drugs (Gadhiya P, 2012).

3. **Large unilamellar vesicles (LUV):**

LUV, which varies in size from 100 to 1000nm, possesses a considerable amount of water in relation to surfactants. These niosomes can be formed through various techniques such as the transmembrane pH gradient method (also referred to as remote loading), reserve phase evaporating, heating, solvent injection, and both dehydration and rehydration processes. Due to the minimal use of non- ionic surfactants, LUVs are an excellent choice for large – scale production (Sharma R, 2022).

SILENT FEATURES OF NIOSOMES: (Gadhiya P, A Review- Niosomes in Targeted Drug Delivery, International Journal for , 2012)

- Niosomes have the ability to encapsulate solutes in a similar manner to liposomes.
- Niosomes exhibit osmotically active and maintain stability.
- Niosomes possess a structure that combines both hydrophobic and hydrophilic mostly together, allowing them to accommodate drug molecules with varied solubility.
- Niosomes exhibits adaptability in their structural properties such as composition, fluidity, and size) and can designed to meet specific requirements.
- Niosomes can improve the effectiveness of drug molecules.
- They provide improved particular site by shielding the drug from the biological environment.
- The surfactants used in Niosomes are biodegradable, biocompatible, and non-immunogenic.

ADVANTAGES OF NIOSOMES: (Jain C.P., 2006) (Chandraprakasha K. S., 1993) (Raja Naresh R.A., 1993)

1. Niosomes can serve as a reservoir, releasing the drugs in a controlled manner.

2. It enhances the oral bioavailability of Pharmaceutical Products.
3. It facilitates targeted drug delivery boost cellular uptake, and protection to drugs integrity.
4. It improves the permeability of drugs through the skin.
5. It can be delivered through parenteral route.
6. It promotes better patient compliance over oil-based systems.
7. It can accommodate drug compounds with a wide range of solubility.
8. They are somatically active and stable, thus increases stability of the encapsulated drug.
9. They enhance the therapeutic efficacy of drug molecules by delayed their clearance from circulation.
10. An aqueous phase niosomal formulation can be emulsified within a non – aqueous phase to regulate the drug delivery rate.
11. Niosomes are biodegradable, biocompatible, and non- immunogenic.

DISADVANTAGES OF NIOSOMES:

(Priyanka B., 2013)

1. Niosomes may experience fusion, leakage, aggregation, of encapsulated drugs, and hydrolysis of the entrapped substances.
2. They have a limited shelf – life.
3. The preparation methods for multilamellar vesicles, such as sonication and extraction, are time-intensive.
4. They necessitate specialized equipment for processing.

METHODS OF PREPARATION:

Reversed Phase Evaporation Method (REV): A mixture of cholesterol and surfactant is combined in a 1:1 ratio and dissolved within the mixture of chloroform and ether. The drug is then introduced within the aqueous phase, resulting in the formation of two distinct phases, which are sonicated at a temperature of 4-5^{o}C. Following this process, a transparent gel is formed, and after adding phosphate buffered saline, further sonication is performed. The organic phase is subsequently eliminated at a temperature of 40^{o}C under low pressure. The resulting niosome solution is now present in a viscous state, which is then diluted with the help of buffer of phosphate, and the diluted solution is heated in a water bath for 10 minutes at 60^{o}c to achieve maximum niosome yield (Ijeoma F., 1998).

Ether Injection Method: The ether injection technique was first described in 1976 by Deamer and Bangham. Niosomes are prepared using non- ionic surfactants and cholesterol in varying concentration. Surfactants and cholesterol are dissolved in diethyl ether and combined with a drug in methanol. The resulting organic solution is gradually injected with a micro syringe into an aqueous solution (Phosphate Buffer) while stirring continuously and maintaining a temperature of 60-650C. As the organic solution is added to the aqueous phase, the temperature difference between the two phases cause rapid vaporization of ether, resulting in the formation of single – layered vesicles (Ravalika V, 2017) (Gadhiya P, A Review- Niosomes in Targeted Drug Delivery,, 2012) (Srinivas S, 2010).

Sonication Method: The glass- vial containing a combination of surfactants and cholesterol is firstly filled with a drug – containing buffer solution. Following this, the mixture is then to probe- sonication with a titanium probe sonicator for three minutes at 60oC. This process can yield both unilamellar vesicles and mutlilamellar vesicles (MLVs). (Moammeri A C. M., 202).

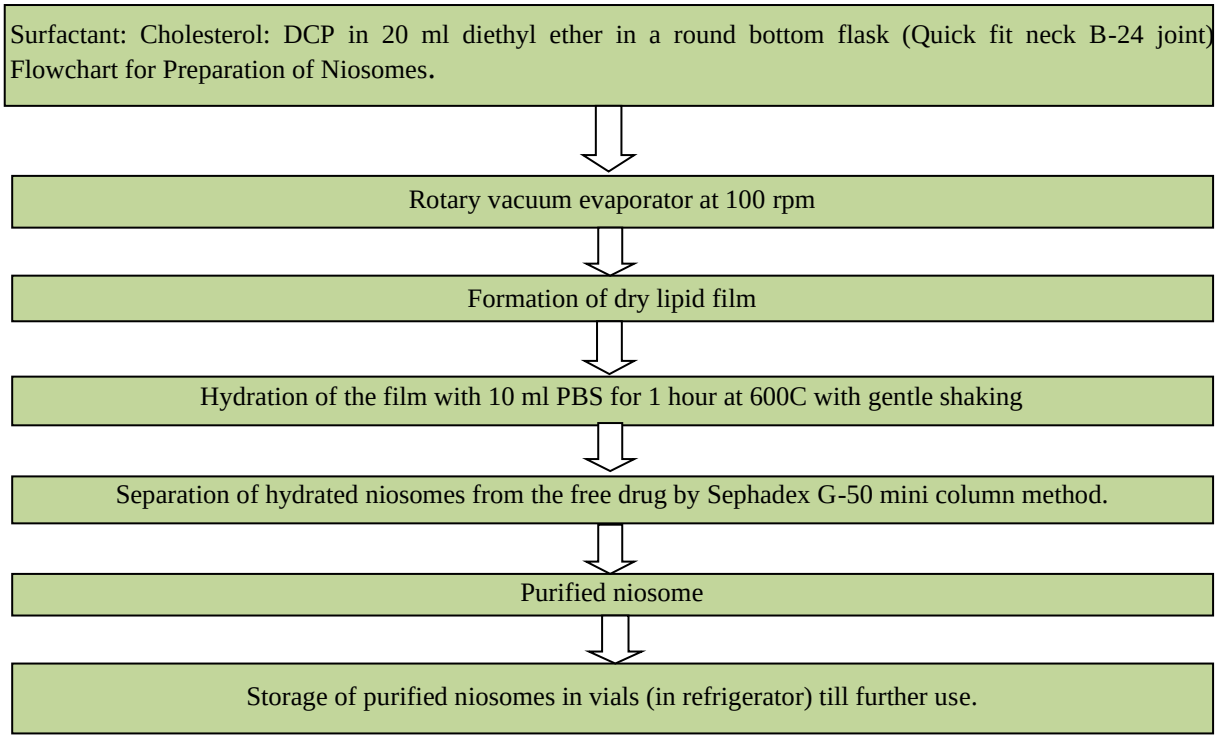
Bubble Method: The foaming unit consists of the round- lined flagon with three necks, which will be placed in very hot water bath to manage the temperature. The thermometer and water – cooled reflux are installed in the primary and secondary opening, while the tertiary opening is connected to a nitrogen supply. Cholesterol and surfactant are combined within the buffer solution with a pH of 7.4 at a temperature of 70OC, at this mixture is

blended for 15 seconds using a high shear homogenizer, followed immediately by bubbling (R, 1985).

Micro – Fluidization Method: Recent technologies are utilized to prepare unilamellar vesicles with a precise size distribution. The method of microfluidization is based on the principle of two fluid streams colliding at extremely high velocities, which interact with each other. The impact of the thin liquid sheet along a customary front is arranged so that the energy supplied to the system stays within the realm necessary for niosome formulation. The result in greater uniformity, smaller size, and improved reproducibility of the niosomes formed.

Hand Shaking Method: Surfactant and cholesterol are dissolved using a volatile organic solvent, such as diethyl – ether, choloroform, or methanol, in a round-bottom flask. The organic solvent is eliminated at a temperature of 20Oc with the help of a rotator evaporator, leaving a thin layer of solid mixture on the flask's wall. The dried surfactant film can be rehydrated with an aqueous phase at temperatures between 0OC – 60OC with gentle agitation to yield multilamellar niosomes (Khandare JN., 1994).

Thin- Film Hydration Method: The thin-film hydration technique is a simple approach frequently utilized in the formation of miosomes. In this technique, a combination of surfactant and cholesterol which are the key component in the membrane formation is dissolved in an organic solvent in a round – bottomed flask connected to a rotary evaporator. The organic liquid is subsequently evaporated, resulting in a thin dried film on the bottom of flask. Next, water or a buffer solution is added to the layer at a temperature higher at the surfactants transition temperature. This mixture is then gently stirred for a predetermined duration to form multilamellar vesicles. These vesicles can be processed further through sonication to yield unilamellar vesicles. Depending upon their solubility, either aqueous or organic phases are utilized to dissolve the drug intended for encapsulation. Sonication is generally applied after this procedure to facilitate the formation of niosomes with a consistent size distribution (Hiraskar, 2024).



CHARACTERIES OF NIOSOMES:

- **Particle Size and Shape:** The vesicles are shaped like a spherical. The Zeta sizer instrument is used to determine particle size. Particle size analysis was carried out for 60s at a scattering angle of 165Oc. The sample was filled in cuvettes and then inserted into the instrument by opening the lid of the zeta sizer for analysis (Durak S, 2020).
- **Osmotic Shock:** The alteration in vesicle size can be determined through osmotic studies. The niosome formulations are incubated to hypotonic, isotonic, and hypertonic solutions for duration of 3 hrs. Following this period, any change in the size of vesicles in the formulation can be viewed using optical microscopy (Leitgeb, 2020).
- **Measurement of Angle of Repose:** The angle of repose for dry powder niosome can be determined using the funnel method. The niosome powder is poured into a funnel that is fixed at certain position so that the 13mm outlet orifice is 5cm above a flat black surface. The powder will flow down from the funnel, creating a conical mound on the surface, and the angle of repose is then calculated by measuring the height of the mound and the diameter of its base (Hu C., 1999).
- **Stability Studies:** The stability of Niosomes can be evaluated by measuring the average vesicle size, size distribution, and entrapment efficacy. This evaluation is conducted by examining the niosomal suspension under various temperature conditions. Niosomes are collected at intervals during storage, and UV spectroscopy and HPLC are utilized to quantify the amount of medication retained in the niosome (Mawazi SM, 2024).
- **Entrapment Efficacy:** The drug – loaded Niosomes entrapment efficacy was determined using Cooling Centrifugation. To separate the unentrapped drug, 1ml of niosomal dispersion was measured into a 1.5 ml capacity Eppendorf tube and centrifuged at 17000rpm for 30 minutes at 4^{o}C. Following centrifugation, the supernatant, which contained the unentrapped drug, was collected, diluted with PBS, and analyzed using a UV spectrophotometer.

The calculation for entrapment efficacy is determined by (Kamboj S, 2014):

Entrapment efficiency = Total amount of drug – The amount of drug in supernatant liquid /Total amount of drug × 100

- **Zeta – potential analysis:** We need to conduct zeta potential analysis because to know the colloidal properties of the formulation we have developed. The zeta potential of the diluted niosomes, which are derived from proniosomes dispersion, was assessed using a zeta potential analyzer based on electrophoretic light scattering and laser Doppler velocimetry techniques. The temperature was set at 25^{o}C, and the charge on the vesicles along with their mean zeta potential values, including standard deviations of the measurements, were obtained directly from the measurement (Harwood., 1995).
- **In – vitro Release:** The release of the drug from the niosomal suspension in vitro was assessed through the dialysis bag method. In vitro drug release experiments were performed utilizing various pH buffers to stimulation gastric condition and blood pH, in order to analyze the impact of pH on drug release. Prior to use, the dialysis sac was soaked in distilled water. One end was sealed with a clip, and 5 ml of the niosomal suspension was introduced into the dialysis bag, which was then

sealed at the other end with another closure clip to avoid any leakage (Ravalika V, Formulation and evaluation of etoricoxib niosomes by thin film hydration technique and ether injection method, 2017) (Ruckmani K, 2011). The dialysis bag was then placed in a beaker containing 100 ml of PBS at pH 7.4, while the beaker was placed on a magnetic stirrer set to 100 rpm and kept at a temperature 37 1^{o}C (Asthana GS, 2016). The dialysis membrane served as the donor compartment, while the surrounding medium acted as receptor compartment. Every hour, 5ml sample were taken from the PBS, with each sample being replaced with fresh PBS. The diluted samples were then analyzed for absorbance using a UV spectrophotometer (Kaur D, 2018).

- **Number of Lamellae:** The quantity of lamellae in Niosomes can be determined by using the techniques such as electron microscopy, NMR spectroscopy, or X-ray scattering methods (Kapse PH, 2024).

APPLICATIONS OF NIOSOMES:

Niosomes as Carrier for Hemoglobin: Hemoglobin is carried by niosomes. Like non – capsulated haemoglobin, these vesicles easily permeable to oxygen and can alter the haemoglobin dissociation curve. It is possible to overlay the vesicle spectrum of niosomal suspension with that of free haemoglobin (S:, 2024).

Anti – neoplastic treatment: Many antineoplastic drugs have significant adverse effect. The use of niosomes can alter drug metabolism, extending the half – life and circulation of medication while reducing the side effects. Niosomes inhibit tumour growth and increase plasma level by retarding clearance (VS, 2022).

Study of Immune System: Niosomes have been utilized to study the immune response induced by antigen. Their ability to specifically target the immune system, along with their minimal toxicity and improved stability make them an excellent option (Rasul RM, 2020).

Transdermal Delivery: Niosomes were investigated for their ability to improve drug absorption and reduce skin irritation while occur through the unbroken stratum corneum and well as serve as a method for transdermal drug delivery. Researchers investigated the absorption of ketorolac, a potent non – steroidal anti- inflammatory drug, into excised rabbit skin using various proniosome gel formulations and Franz diffusion cells. The penetration of drug and the lag time were significantly enhanced to generate the proniosomes.

Treatment of Leishmaniasis: Leishmaniasis occurs when the parasite infiltrates cells and the liver. Antimonial medications are commonly utilized for treatment. Research demonstrated that the on mice indicated form was improved. Administering two doses on consecutive days produced an additive effect. As drug-encapsulated liposomes, niosomes are also useful in the study of experimental leishmaniasis (. Gunda RK, 2023).

Delivery of Peptide Drug: Researchers are exploring niosomes as a potential method to protect peptides from degradation in the gastrointestinal tract, An in – vitro study was investigated using an oral – vasopressin derivative encapsulated in niosomes, demonstrating that the encapsulation of the drug enhances the stability of the peptides (Khambalkar SM, 2024).

Cosmetics: Non – ionic surfactant vesicles were first associated with cosmetic application by L'Oreal. During the 1970s and 1980s, L'Oreal developed and secured patents for niosomes. In 1987, Lancôme launched "Niosomes, their first product. In the realm of cosmetics and skin care, niosomes offer several benefits, including the ability to enhance the stability of encapsulated medications, increases the bioavailability of poorly absorbable ingredients, and improve skin penetration (Sharma S, 2024).

Sustained Release: The sustain release capabilities of niosomes can be applied for

medications that possess a low therapeutic index and poor water solubility, since those can be retained in circulation through niosomal encapsulation (Navneet Kumar Verma, 2014).

Localized Drug Action: Niosomal drug delivery is an effective method for attaining localized drug action since their size and limited ability to penetrate through epithelium and connective tissues maintain the drug concentration at the administration site (Navneet Kumar Verma, 2014).

CONCLUSION AND FUTURE ASPECTS OF NIOSOMES:

Niosomes have been suggested as a liposome substitute. They have a few advantages over liposomes, including better chemical stability, higher purity, and reduced cost. Non-ionic surfactant vesicles interfere with drug metabolism, plasma clearance kinetics, tissue distribution, and cellular contact. Given all of the improvements made to niosome formulations and drug delivery systems, it is clear that niosomes are a safe and effective drug delivery method that can improve patient compliance. One kind of drug delivery molecule that can safely distribute medications with the ability to target specific sites is niosomes. Toxic anti-cancer, anti-infective, anti-AIDS, anti-inflammatory, antiviral, and other medications can be encapsulated in niosomes and used as drug carriers to increase bioavailability and targeting qualities while lowering toxicity and adverse effects. Niosomal drug carriers are less dangerous and inappropriate than ionic drug carriers. Niosome handling and storage don't require any particular circumstances. Therefore, there is a great deal of room for the researcher to study niosomes in their field of expertise for the benefit of society.

Declaration by Authors

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