World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(REVIEW ARTICLE)

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Redefining drug delivery paradigims: Proniosomes as revolutionary tools for enhanced efficacy

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World Journal of Biology Pharmacy and Health Sciences, 2025, 23(02), 053-065

Publication history: Received on 22 June 2025; revised on 29 July 2025; accepted on 01 August 2025

Article DOI: https://doi.org/10.30574/wjbphs.2025.23.2.0719

Abstract

Proniosomes represent an innovative drug delivery system that enhances therapeutic effectiveness through controlled release, improved stability, and decreased toxicity. These carriers, based on non-ionic surfactants, are able to contain both hydrophilic and lipophilic drugs, thereby overcoming the limitations associated with traditional carriers that are lipid-based, including niosomes and liposomes. Upon hydration, proniosomes transform into niosomes, facilitating targeted and sustained drug delivery while minimizing adverse effects. They enhance drug stability, bioavailability, and patient compliance, particularly in oral and transdermal delivery methods. Proniosomes effectively tackle challenges like fusion, aggregation and leakage, ensuring physical stability on storage. Their applications span various therapeutic fields, including antibacterial treatments, anti-neoplastic therapies, gene delivery, and ocular drug administration. However, challenges persist, including the complete toxicity profile of non-ionic surfactants, fusion issues, and complexities in preparation. In summary, proniosomes serve as a versatile and effective platform for controlled drug delivery, providing significant advantages across a broad spectrum of medical and pharmaceutical applications.

Keywords: Proniosomes; Structure; Applications; Methods

1 Introduction

Proniosomes are a novel approach that depends on controlled drug administration mechanisms to enable targeted release features. Proniosomes are a type of targeted system that selectively absorbs drugs to prolong their circulation and lessen their harmful effects [1].When proniosomes are agitated in water for hydration, their dry powder formulation turns into an easy-to-use drug release solution. Because the system encapsulates both polar and non-polar active agents, it functions as a functional response to liposomes and vesicular drug delivery platforms [2]. By lowering medication-related side effects and boosting therapeutic benefits, proniosome design improves therapeutic results. By undergoing an initial breakdown process, the medication format shows compatibility with the gastrointestinal tract, reducing the frequency of deliveries and improving patient adherence to treatment. [3]. Proniosomes, which are made up of non-ionic surfactants, can contain both hydrophilic and hydrophobic medication. Drug delivery system based on surfactants were developed in order to overcome the drawbacks of lipid-based carriers. One well- known example is niosomes, which are more economical and chemically stable because non-ionic surfactants are used in their formulation. During storage, niosomes experience physical stability problems like agglomeration, fusion, aggregation, and leakage, despite their chemical stability. By using proniosomes, these difficulties are lessened. Proniosomes are free-flowing powders of non-ionic surfactants or liquid crystalline (gel) vesicular structures [4]. When they are hydrated right before application, they can easily transform into niosomes. Due to the non-ionic surfactants' intrinsically higher level of physical stability, pronisomes offer a number of benefits, such as improved chemical stability and decreased toxicity [5].

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2 Structure

Microscopic lamellar formations that might appear black and hexagonal are known as proniosomes. The semi-solid gel should be translucent and partial-transparency. Proniosomes can be categorized as either unilamellar or multilamellar based on how they are prepared. They have a bilayer structure, with hydrophobic chains facing inward within the vesicle's bilayer and hydrophilic ends directed outward on the surface. Surface-active compounds that are not ionic make up this bilayer [6]. The bilayer's surfactant molecules are arranged so that the hydrophobic ends of the non-ionic surfactants point inward and the hydrophilic ends outward. While hydrophobic medications are embedded in the bilayer, hydrophilic pharmaceuticals are positioned selectively within the vesicle's confined area [7]. Proniosomes have the ability to quickly change into niosomes when hydrated, resulting in a flexible system for the precise and regulated delivery of medications. They are useful in pharmaceutical applications, especially in the development of innovative therapeutic formulations, due to their stability, ease of storage, and adaptability to particular drug release profiles [8].

2.1.1 Proniosomes structure

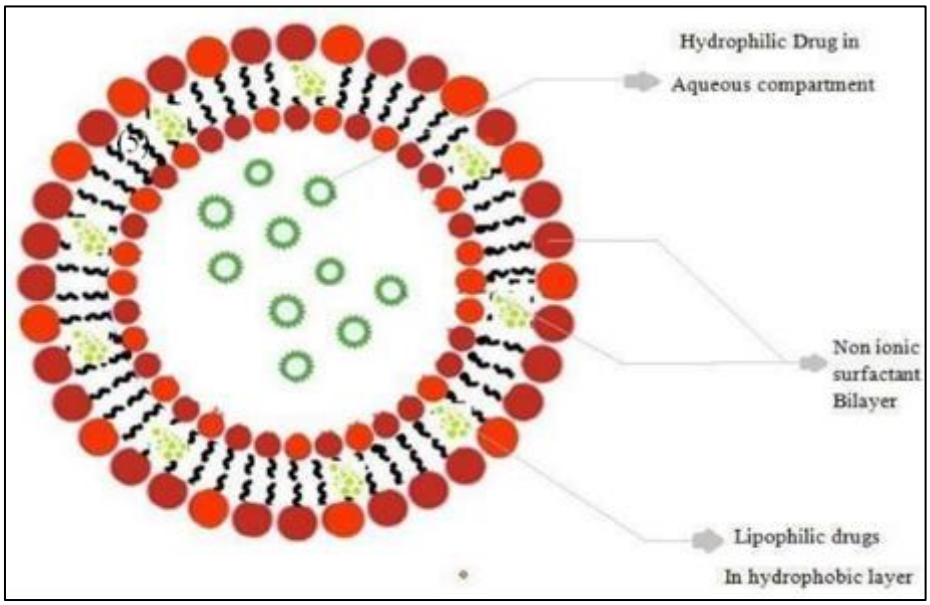

Figure 1 Structure of Proniosomes

3 Comparison: [9-12]

Various composition, entrapment efficacy, such as their size, structure, preparation, and encapsulation efficiency and application.

Table 1 Comparative Characteristics of Different Formulations

Features	Niosomes	Liposomes	Proniosomes
Composition	Nonionic Surfactants	Phospholipid bilayer	Non-ionic Surfactants In Dry Form
Entrapment efficiency	High level	High level	High level
Size(nm)	214 ± 10.7	221 ± 11.5	180-300
Structure	Spherical Vesicles	Spherical Vesicles	Dry, and Free Flowing Powder
Preparation	Sonication ,Micro Fluidization, Film Hydration, Ether Injection, Thin Film Hydration	Sonicaion, Extrusion, Reverse Phase Evaporation	Coacervation Method, Slurry Method, Spray Coating Method

Encapsulation Efficacy	High	High	High
Applications	Among other medications, niosomes can help deliver insulin, siRNA, and other drugs. Gene delivery is another use for them. Niosomes are also good at carrying hydrophilic, lipophilic, and amphiphilic.	Many drugs, such as insulin, si-RNA, and other pharmaceutical agents, can be efficiently transported by niosomes. Applications involving gene delivery also make use of them.	Ketorolac is administered transdermally using proniosomes as a drug delivery vehicle. Pharmaceuticals that are hydrophobic or hydrophilic may be transported by niosomes, which are vesicles made of non-ionic surfactants.

4 Advantages

- Proniosomes reduce problems like aggregation, fusion, and leakage, which enhances physical stability.
- They successfully keep encapsulated medications from becoming overly hydrated, extending the dispersions' shelf life [13]
- They are a great system because of non-immunogenic, biodegradable, and biocompatible[14].
- Additionally, proniosomal formulations can be easily incorporated into transdermal patches without requiring the dispersion of vesicles within a polymeric matrix, and they do away with the need for hazardous solvents.
- Proniosomes' ability to remain stable in storage makes them a versatile delivery system suitable for a wide range of active substances [15]
- Preventing the hydrolysis of encapsulated pharmaceuticals, which restricts the shelf life of the dispersion.
- Eliminate first-pass metabolism and reduce adverse effect.
- Enhance bioavailability and address stability issues [16]

5 Disadvantages: [17-19]

- Less shelf life may be occur due to hydrolysis of medications in capsule form.
- When stored, proniosomes can lead to physical instability complications like accumulation, fusion, and leaking.
- The complete toxicity profile of nonionic surfactants is still not well understood.
- Additionally, heat-based sterilizing methods like steam or dry heat sterilization may damage the bilayers and allow the encapsulated medicine to leak out of the niosome bilayers when temperatures increase above the surfactants' gel-liquid transition point.
- Additionally, multilamellar vesicle preparation is time-consuming and requires specialized equipment are required.

6 Types

Depending on the carrier and preparation technique, proniosomes can be divided into three types.

6.1 Dry Granular Proniosomes

- Sorbital-based proniosomes
- Maltodextrin-based pronisomes

6.1.1 Sorbitol -based Proniosomes

After using sorbitol as the carrier, a non-ionic surfactant is applied on top. By adding hot water and then stirring, this mixture can be turned into a noisome in a matter of minutes. Proniosomes based on maltodextrin are made by a quick slurry process [20]

Uses

This particular kind of proniosome uses sorbitol, a polyol, as a carrier. The drug and surfactant mixture is adsorbed onto the sorbitol particles in the first step. In addition to being extremely stable, these dried granules are also easy to store and transport [21]

Benefit

Proniosomes made from sorbitol have several merits, like better drug stability, better controlled release characteristics, and more resistance to degradation. Their actual strength is their ability to increase drug solubility and bioavailability. [22]

6.1.2 Proniosomes based on Maltodextrin

The polysaccharide maltodextrin, which is made from starch, acts as an additional proniosome carrier. Both the drug and surfactant bind to the maltodextrin particles and produce dry granular proniosomes. Maltodextrin-formulated proniosomes function similarly to sorbitol-based ones. These proniosomes have the ability to hydrate when exposed to water or other body fluids, which produces niosomes [23]

Benefits

Proniosomes based on maltodextrin have several benefits, including increased drug loading efficiency, better drug stability and drug is released in controlled manner. In pharmaceutical formulations that call for targeted delivery or sustained release, they are especially beneficial [24]

6.2 Liquid Crystalline Proniosomes

A state of matter that combines the properties of liquids and solids is referred to as liquid crystalline. Proniosomes are more complex than typical proniosomal formulations because they are advanced formulations that include liquid liquid crystals crystalline characteristics. With anisotropic characteristics and well-ordered molecular configurations, their architecture displays a systematic arrangement similar to that of liquid crystals Drug delivery [25, 26]

6.3 Lecithin-Based Proniosomes

Lecithin can be used as a carrier to increase permeability and biocompatibility.

7 Drug delivery with biodegradable polymers

The incorporation of biodegradable polymers, which are essential for improving therapeutic efficacy while guaranteeing safety and compatibility for living things, has been a prominent feature of recent developments in drug delivery systems.

The incorporation of biodegradable polymers, which are essential for improving therapeutic efficacy while guaranteeing safety and compatibility for living things, has been a prominent feature of recent developments in drug delivery systems. Stearates are among the biodegradable polymers used in modern drug delivery formulations [27]

Through enzymatic or non-enzymatic processes, these polymers are broken down within the body to produce biocompatible byproducts that can be processed through normal metabolic pathways. Biodegradable polymers have proliferated in controlled drug delivery systems throughout the last ten years.

The two main categories of biomaterials used in drug delivery systems are naturally occurring polymers and synthetic biodegradable polymers [28]

7.1 Synthetic Biodegradable Polymers

This group includes substances like polylactic-co-glycolic acid (PLGA), polyanhydrides, and α-hydroxy acids. These polymers are designed to break down into non-toxic byproducts inside the body and have a comparatively hydrophobic nature.

7.2 Naturally Derived Polymers:

These comprise inorganic materials like hydroxyapatite and complex carbohydrates like chitosan and hyaluronan. These polymers meet particular requirements in drug delivery applications by offering a variety of functionalities and biocompatibility.

8 Applications

- Antibacterial Therapy: Proniosomal formulations are used in antibacterial therapy to improve the antibacterial agents' physical stability while they are being stored and to stop the formulation from oxidizing [29]
- Anti-neoplastic Treatment: A number of anti-neoplastic drugs shows serious side effects. By altering these medications' metabolism, proniosomal carriers can prolong their half-life and duration of circulation, reducing side effects. Furthermore, proniosomes are widely used in cancer treatment regimens [30]
- Hemoglobin is transported through proniosomes in the blood. They can act as efficient hemoglobin carriers due to their permeability to oxygen, especially in pathological situations [31]
- Proniosome-assisted drug delivery promotes localized drug action, increasing the medication's potency and effectiveness. At the same time, this approach reduces the drug's systemic toxic effects.
- The use of proniosomes as carriers for cardiotropic drugs is one of their cardiovascular applications. Notably, captopril, an antihypertensive medication, is applied transdermally, which allows for a longer duration of the drug's release within the body [32]
- Proniosomal technology has been widely used in the cosmetics industry, and new research is looking into the possibility of using it to create transdermal vaccines.
- Research on hormonal therapy has shown that proniosomes can be used to deliver levonorgestrel transdermally as an emergency contraceptive [33]

8.1.1 Proniosome hormonal therapy

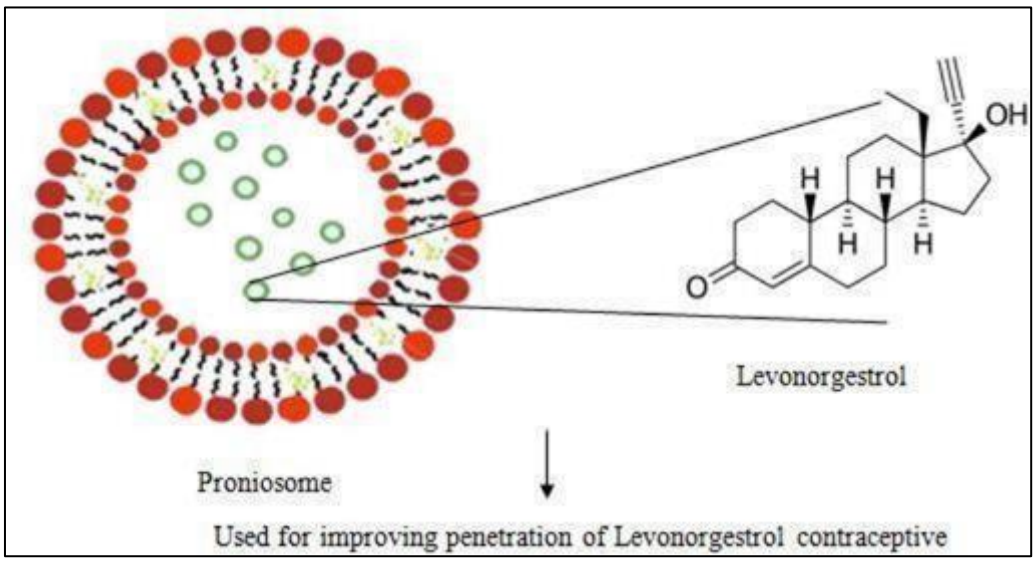

Figure 2 Hormonal Therapy with Proniosome

- Proniosomal encapsulation effectively retains drugs in the bloodstream, the sustained release characteristics of proniosomes are especially advantageous for drug with a low therapeutic index and limited water solubility .
- Oral Drug Delivery: By increasing bioavailability, guaranteeing sustained release, and boosting patient adherence, proniosomes hold great promise for oral drug delivery. Both hydrophilic and hydrophobic drugs can be encapsulated in oral proniosome formulations, protecting them from enzymatic degradation and promoting absorption in the gastrointestinal system. These proniosomes offer flexibility in drug release profiles and site-specific targeting because they can be made for targeted delivery, controlled release, or immediate release [34]

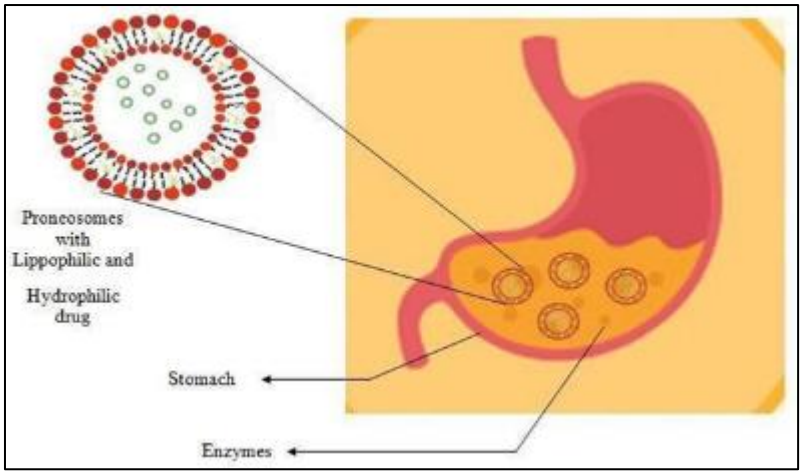

Figure 3 Hydrophilic and hydrophobic drugs can be encapsulated in oral proniosome formulations, protecting them from enzymatic degradation

- Proniosomes are used in topical drug delivery to increase therapeutic efficacy, improve drug deposition, and improve skin penetration. Topical proniosome formulations can contain drugs intended to treat a range of dermatological conditions, including infections, inflammation, and skin diseases. Proniosomes are perfect for the topical administration of both hydrophilic and lipophilic medications because of their enhanced stability, prolonged drug release, and reduced skin irritation.

8.1.2 Proniosomes for topical drug delivery

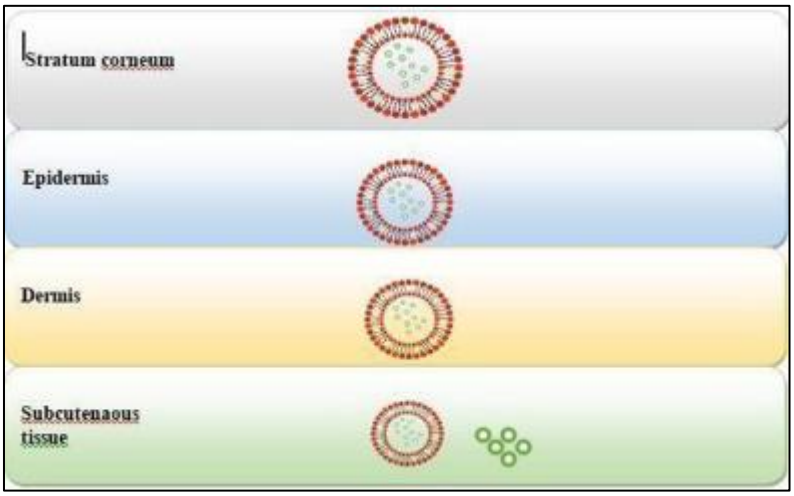

Figure 4 Topical delivery of proniosomes

- Transdermal Drug Delivery: Proniosomes have been identified as efficient drug delivery vehicles that facilitate effective drug absorption through the epidermal barrier. Transdermal proniosome- based formulations enhance drug solubility, permeability, and retention in the skin, enabling prolonged therapeutic effects and sustained release. Proniosomes are perfect for the transdermal delivery of medications with low skin permeability because of their many advantages, which include improved skin penetration, reduced systemic exposure, and improved patient adherence [35]
- Ocular Drug Delivery: The drug bioavailability is improved by prolong the amount of time a drug is present in the eye, and enhance therapeutic results, ocular drug delivery systems employ proniosomes. Drugs intended to treat a range of eye disorders, including glaucoma, cataracts, and eye infections, can be contained in these formulations. Proniosomes are useful for the ocular delivery of both hydrophilic and lipophilic drugs because of their enhanced corneal penetration, reduced drug loss from tear dilution, and increased patient comfort [36]
- Gene Delivery: Proniosomes have been identified as efficient gene delivery vehicles that offer improved stability, safety, and transfection efficiency. Nucleic acids such as plasmid DNA, siRNA, and mRNA can be

encapsulated by gene delivery proniosome formulations to facilitate their intracellular delivery and expression. Proniosomes are suitable for therapeutic uses like gene therapy, gene editing, and RNA interference because of their advantages, which include protection against nuclease degradation, enhanced cellular uptake, and reduced cytotoxicity [37]

9 Method of preparation

Several components are needed to make proniosomes, including a membrane stabilizer, a non-ionic surfactant, a tiny amount of water, and an alcoholic solvent (such as liquid PEG, 1- propyl alcohol, butyl alcohol, PG, or pure ethanol) - which is necessary for creating proniosomal gels. The selection of the carrier material improves the surface area, facilitates efficient drug loading within the proniosomes, and increases the flexibility of the surfactant and other ingredients. Because of its function in stabilizing the cell membrane, cholesterol is primarily used as a membrane stabilizer. The surfactant has several uses, such as as an emulsifier, wetting agent, solubilizer, and permeability enhancer. Phosphate buffer (pH 7.4), hot water, and a 0.1% glycerol solution are the vehicles used to reconstitute proniosomes [38]

9.1 Coacervation - Phase Separation Technique

The technique used to prepare the proniosomal gel. In glass vials, precisely measured surfactants are mixed with the necessary amount of cholesterol. After that, a tiny amount of absolute ethanol—roughly half the total lipid weight—is added to the surfactant or surfactant/cholesterol mixtures in order to dissolve the lipids. After being tightly sealed, the vials are shaken for five minutes at a temperature between 55 and 60 °C in a water bath until the lipids are fully dissolved. A tiny quantity of distilled water—roughly 40% of the total solvent added—is then added to the heated lipid solution, which is then kept in the water bath at 55 to 60 °C for three to five more minutes, or until a clear or translucent solution is obtained. Following the mixtures' cooling to room temperature, they are analyzed to determine whether a transparent solution, two-phase liquids, or translucent, transparent, or white creamy proniosomal gels have formed [39]

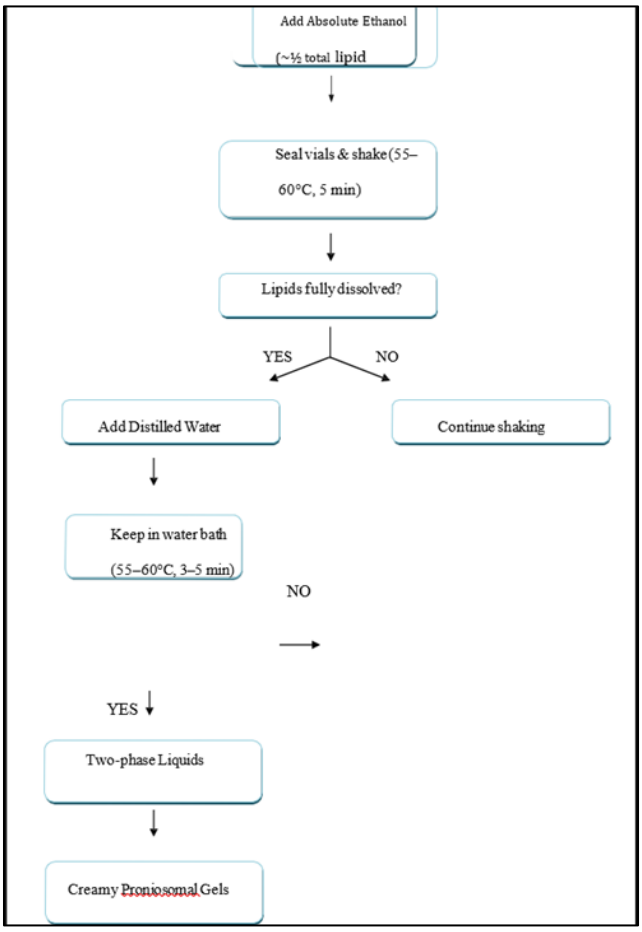

Figure 5 Coacervation - Phase Separation Technique

9.1.1 Drug loading into proniosomal gel formulations:

There are multiple steps involved in incorporating the drug into proniosomal gel formulations. If the drug is lipid-soluble, it can be added to a mixture of cholesterol and non-ionic surfactant, where it is dissolved with absolute ethanol and heated to between 50 and 60 degrees Celsius in a water bath. Alternatively, depending on the drug's physicochemical properties, the drug may be dissolved in either alcohol or distilled water before being mixed with the heated lipid solution. Prior to gelation, it is crucial to ensure that the drug does not induce turbidity or precipitated crystals in the liquid preparations, nor does it precipitate during the gel phase [40]

The incorporation of drugs into zinc oxide nanoparticles (ZnO NPs) can be accomplished via methods of incorporation or adsorption/absorption. The efficiency and capacity of drug loading are influenced by both the specific drug and the technique employed.

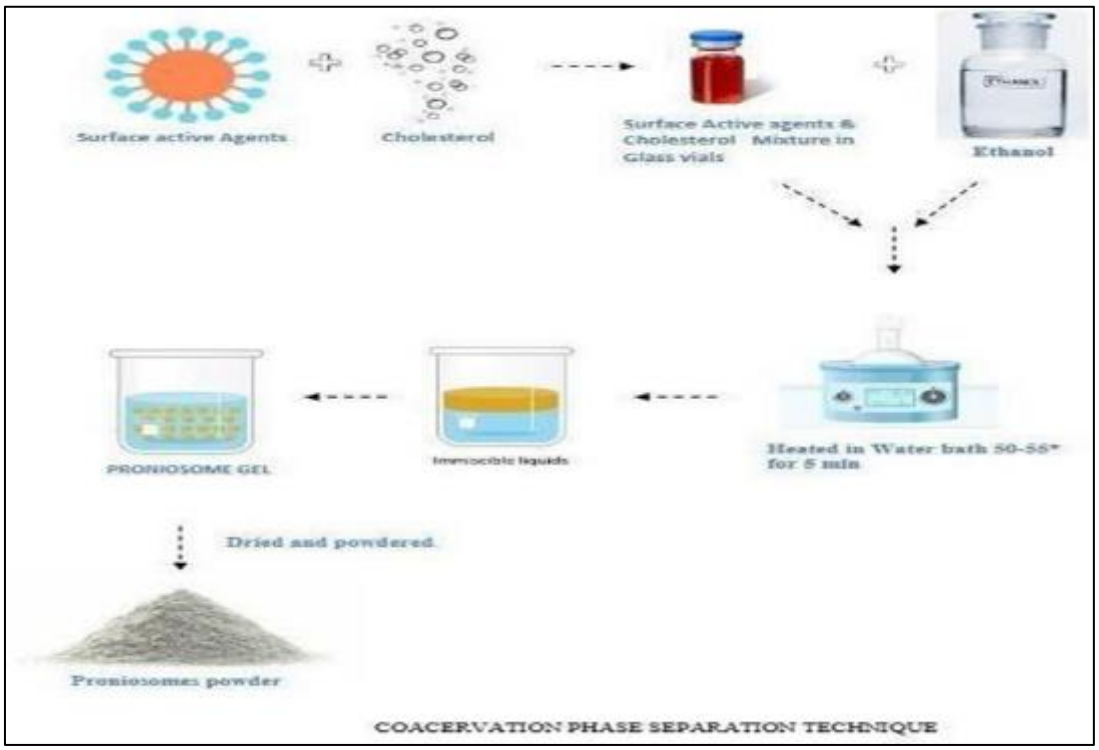

Figure 6 Coacervation - phase separation technique

9.2 Slurry method - free-flowing proniosomal dry powder

The slurry technique is one way to make free-flowing proniosomal dry powder. Using a round-bottom flask, the carrier is added with a drug solution or surfactant to form a slurry. To aid in the formation of a slurry, an extra organic solvent may be added if the surfactant loading is inadequate. After that, the flask is attached to a rotating evaporator, which applies vacuum until the powder is dry and has free-flowing properties. It is imperative that the powder be kept at 4°C in airtight containers. There is some procedural flexibility as the time required to generate proniosomes is unaffected by the ratio of surfactant solution to carrier material. [41]

9.2.1 Slurry method

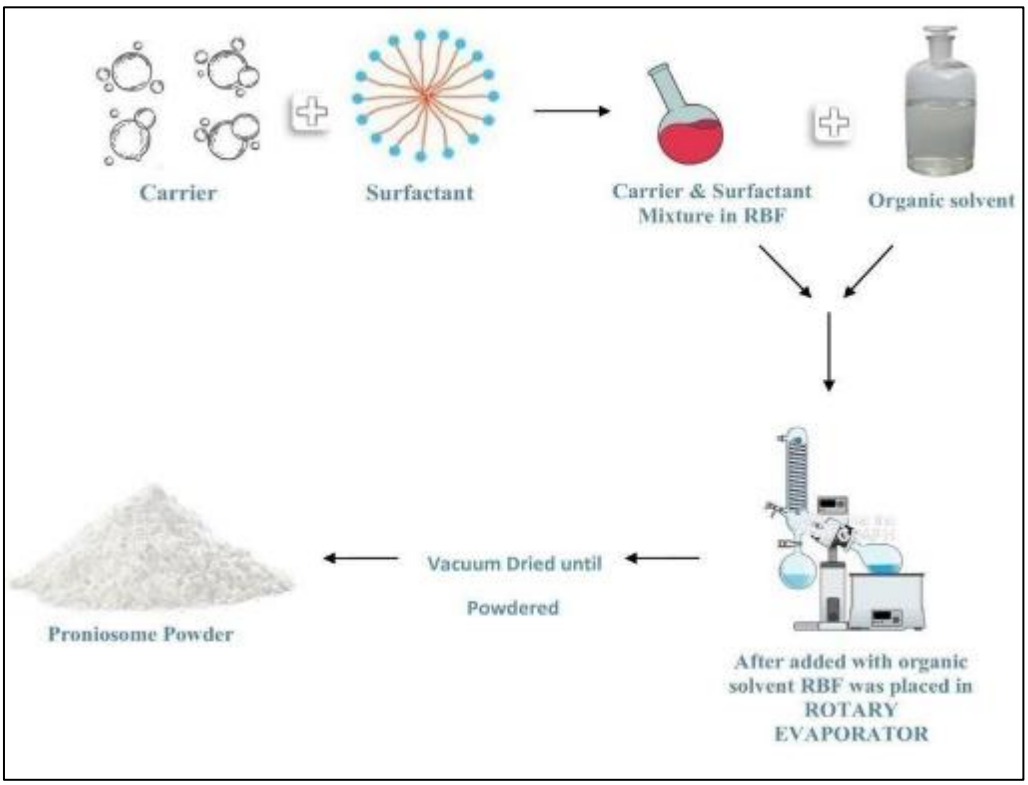

Figure 7 Preparation of Proniosome Powder by Slurry Method

9.3 Spray-coating method

- By applying a drug or surfactant dissolved in an organic solvent onto a substrate or coating material and then allowing the solvent to evaporate, the spray-coating technique produces proniosomes.
- The carrier dissolves in the organic solvent, thus this process must be repeated until the necessary surfactant loading is obtained.
- Upon hydration, the resulting thin layer of surfactant on the carrier promotes the formation of multilamellar vesicles as the carrier dissolves. [42]

9.3.1 Spray-coating method

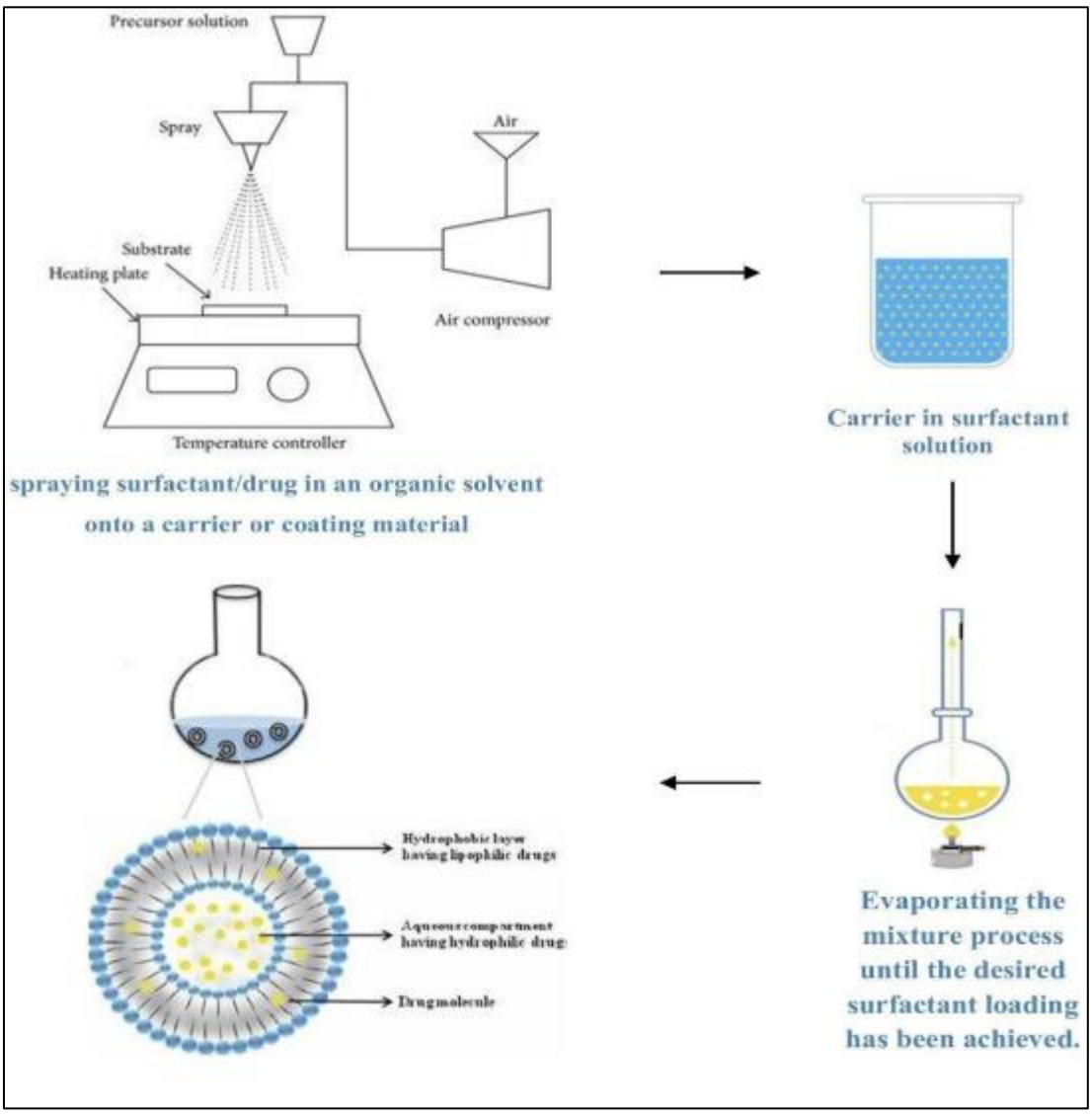

Figure 8 Spray Coating method of Preparation of proniosome

9.4 Niosome from proniosome by hydration

- Through this process, the drug-containing aqueous phase is agitated before to being added to the proniosomes at a temperature higher than the non-ionic surfactant's usual transition phase temperature. [43]

10 Conclusion

Proniosomes represent a promising advancement in drug delivery systems, offering significant improvements over traditional lipid-based carriers such as liposomes and niosomes. Their ability to encapsulate both hydrophilic and hydrophobic drugs, combined with their stability, ease of storage, and controlled release properties, makes them ideal for a wide range of pharmaceutical applications. Proniosomes help overcome challenges like aggregation, fusion, and leakage, enhancing drug stability and bioavailability, while minimizing adverse effects. Their versatility in transdermal, ocular, gene delivery, and topical applications demonstrates their potential in diverse therapeutic areas. However, further research is needed to fully understand the toxicity profiles of non-ionic surfactants and optimize production methods to address existing challenges. Overall, proniosomes offer a promising, flexible platform for the future of targeted and controlled drug delivery, with the potential to improve patient outcomes and therapeutic efficacy.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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