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REVIEW ARTICLE

Proniosomes System for Enhanced Topical Drug Delivery: Advancements and Applications

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ABSTRACT
Proniosomes represent an innovative approach to enhance the topical delivery of active pharmaceutical ingredients (APIs) by serving as dry, stable precursors to niosomes. These systems consist of non-ionic surfactants and other excipients in a powder or semi-solid form that, upon hydration, spontaneously form niosomal vesicles. Niosomes are known for improving drug solubility, stability, and controlled release, but they often face limitations such as instability during storage and handling. Proniosomes overcome these challenges by offering improved physical and chemical stability, ease of storage, and transport due to their dry nature. Upon application and contact with moisture, proniosomes are converted into niosomes, which can then penetrate the skin and deliver the encapsulated drug in a controlled manner. The composition typically includes surfactants, cholesterol, and a carrier such as maltodextrin or lecithin, facilitating efficient vesicle formation. This system is particularly advantageous for topical drug delivery, as it enhances drug permeation into the skin, enables localized therapy for dermatological conditions, and can be tailored for transdermal systemic delivery. Various studies have demonstrated the effectiveness of proniosomes in delivering a wide range of drugs including anti-inflammatory, antifungal, and analgesic agents-with enhanced penetration, reduced side effects, and sustained therapeutic action.
Keywords: *Proniosomes, topical drug delivery, niosomal vesicles, controlled Release, drug permeation*

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INTRODUCTION

In recent instances, no single medicament delivery system fulfills all the criteria, but attempts have been made through new strategies. Novel approaches came up covering polychromatic routes of administration, to achieve either controlled or targeted delivery. The prime idea of new drug delivery is feeding of the constant and effective medication in the body and minimizing the side- effects and it also localizes the medicament action by targeting the drug by using drug carriers broadly including liposomes and niosomes [1, 33]. Preferences of liposomes and niosomes over other conventional dosage forms are their vesicular nature, which act as a drug reservoir. Many modifications can also be carried out in order to accommodate the design and drug release. It was moreover found that modified vesicles had properties that effectively deliver drugs into deeper layers of the skin [18, 11, 12].
Niosomes are carrier vesicles, and these are dried to get niosomal dispersion on brief agitation with hot fluid media. This dehydrated form is called as proniosomes, and is an adaptable delivery system because of the ease of dispersion, measuring, transfer, and storage [19, 13].

PRONIOSOMES

Proniosomes are one of the novel pro-vesicular drug delivery systems which are dry formulations coated with carrier such as nonionic surfactants. Proniosomes are defined in such a manner that they can overcome the downsides of niosomes such as physical instabilities, fusion and aggregation. Proniosomes can be administered by various routes like oral, intravenous, buccal, topical, transdermal etc.

Proniosomes are lamellar structures which combine a non- ionic surfactant of the alkyl or di- alkyl polyglycerol ether class and cholesterol followed by hydration in arid media. Similar to liposomes, proniosomes also form a bilayer vesicles but in proniosomes, the bilayer is made of non- ionic surfactant. On the premise of approach of arrangement proniosomes are unilamellar or multi-lamellar [39]. The hydrophilic ends of the surfactant bilayer are exposed on the outside and inside of the vesicles, while the hydrophobic chains within the bilayer face one another. As a result, hydrophilic medications are stored in the vesicle's confined region, whereas hydrophobic substances are embedded in the bilayer as shown in figure 1 [24].

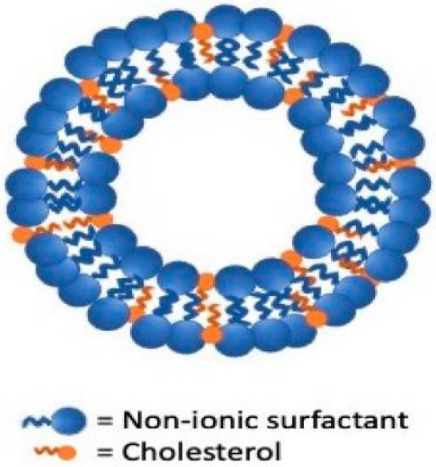

Figure - 1 Structure of proniosomes

Types of Proniosomes:

According to the type of carrier and method of preparation proniosomes may be of two types.

1. Dry granular proniosomes

According to the type of carrier and method of preparation of dry powder proniosomes are

a) Sorbitol-based proniosomes- It represents a class of dry, pre-vesicular delivery systems wherein sorbitol acts as a hydrophilic carrier matrix that is sequentially coated with non-ionic surfactants. Upon exposure to hot aqueous media and mild agitation, these systems rapidly undergo spontaneous hydration, leading to the formation of niosomal vesicles typically within one minute. The preparation involves the gradual deposition of a surfactant phase - dissolved in a volatile organic solvent - onto sorbitol crystals via a fine atomization technique, followed by solvent evaporation under controlled conditions. This deposition - evaporation cycle is repeated iteratively to achieve a uniform and optimal surfactant lamella around each sorbitol particle. A key physicochemical advantage of sorbitol-based proniosomes is their narrow and homogeneous particle size distribution, which enhances vesicle uniformity and stability. These systems are particularly advantageous for the encapsulation and delivery of hydrolytically labile bioactives, offering protection against aqueous degradation [17].

b) Maltodextrin-based proniosomes- These are typically formulated using the rapid slurry method, a technique characterized by its time efficiency and independence from the surfactant solution to carrier ratio. This method facilitates the production of proniosomal systems with a high carrier surface area to surfactant ratio, thereby enhancing formulation efficiency. The conversion of these dry proniosomal powders into niosomal vesicles for drug delivery applications is straightforward, requiring only hydration under mild agitation. In contrast to the sorbitol-based system, which often yields a dense surfactant-sorbitol cake upon solvent evaporation, the use of maltodextrin offers superior structural advantages.

Due to the preserved morphology of maltodextrin - particularly when utilizing hollow, blown maltodextrin particles - the resultant proniosomes exhibit significantly increased surface area.

This elevated surface area facilitates the formation of a more uniform and thinner surfactant lamella on the carrier particles, promoting rapid and efficient rehydration upon aqueous dispersion. Such a configuration not only enhances the vesicle formation process but also improves drug loading and release characteristics [17].

2. Liquid crystalline proniosomes

When surfactant molecules come into contact with water, their hydrophobic alkyl chains can transition into a disordered, fluid-like arrangement known as the lyotropic liquid crystalline phase, or neat phase.

The neat or lamellar phase is characterized by the presence of multilamellar bilayers - repeating lipid bilayers interspersed with aqueous layers - organized in a highly ordered, sheet-like morphology. This supramolecular arrangement produces distinctive X-ray diffraction patterns and exhibits thread-like birefringence under polarized light microscopy, indicative of its anisotropic and crystalline nature.
Upon further hydration or dilution at elevated surfactant concentrations, this lamellar liquid crystalline phase transitions into niosomal vesicles, facilitating encapsulation and controlled release of therapeutic agents.

Advantages of Proniosomes:

- *Versatile drug encapsulation*- Proniosomes are capable of encapsulating both hydrophilic and hydrophobic pharmacologically active agents, enabling broad-spectrum application across diverse therapeutic classes
- *Enhanced logistics and sterility*- As dry, anhydrous formulations, proniosomes offer superior ease in packaging, sterilization, storage, and transportation, with minimal risk of contamination or degradation
- *Chemical stability*- The absence of aqueous content in proniosomal systems eliminates the risk of hydrolysis and oxidative degradation, thereby ensuring extended shelf life and chemical integrity of the formulation
- *Ambient storage compatibility*- Proniosomes not necessitates stringent environmental controls for storage and distribution, maintaining stability under ambient conditions without requiring refrigeration or protective atmospheres
- *Improved physical stability*- These systems exhibit high physicochemical stability, minimizing common vesicular formulation issues such as fusion, sedimentation, leakage, and aggregation
- *Minimal solvent utilization*- Formulated with minimal and pharmaceutically acceptable solvent volumes, proniosomes mitigate the risk of dermal irritation, ensuring safety for topical and transdermal administration
- *Controlled and targeted release profile*- Proniosomes facilitate sustained and site-specific drug delivery, allowing for prolonged therapeutic action and reduced dosing frequency
- *Enhanced bioavailability and safety*- By promoting targeted drug localization and minimizing systemic exposure, proniosomes significantly enhance bioavailability while reducing the incidence of systemic side effects [32, 26].

METHODS OF PREPARATION OF PRONIOSOMES:

The proniosomes are a composition of several ingredients like the non-ionic surfactant, cholesterol or lecithin. Some of the methods, which were reported for the preparation of proniosomes are as follows:

A. Coacervation phase separation method

Proniosomal gels can be formulated using a straightforward and efficient method involving the combination of a non-ionic surfactant, lipid component, and the active pharmaceutical ingredient (API) within a wide-mouthed glass vial, along with a minimal quantity of ethanol or another pharmaceutically acceptable alcohol. This mixture is subjected to gentle heating on a water bath maintained at 60–70 °C for approximately 5 minutes, facilitating the complete dissolution of the surfactant and lipid constituents. Subsequently, a measured volume of aqueous phase (typically phosphate-buffered saline or distilled water) is introduced into the mixture, followed by continued heating until a homogenous and transparent solution is achieved. Upon gradual cooling to ambient temperature, this solution undergoes phase transition to form a semi-solid proniosomal gel. Upon hydration, the proniosomal gel spontaneously forms uniformly sized multilamellar or unilamellar niosomal vesicles, depending on formulation parameters and agitation conditions [34, 4].

B. Slurry Method

Proniosomes can be efficiently formulated using a slurry-based rotary evaporation technique, wherein the carrier material e.g. maltodextrin and the complete surfactant–lipid solution are combined within a round-bottom flask. This assembly is fitted to a rotary flash evaporator, and subjected to reduced pressure (~600 mm Hg) while rotating at 50–60 rpm at a controlled temperature of approximately 45 ± 2 °C. Under these conditions, the organic solvent is gradually evaporated, resulting in the formation of a dry, free-flowing proniosomal powder. The resultant dry proniosomal formulation is then collected and stored in light-protected, airtight containers at 4°C to maintain physicochemical stability and minimize degradation. In this method, maltodextrin, a hydrophilic polysaccharide, functions as a solid-phase carrier owing to its high aqueous solubility and favorable surface morphology. It facilitates uniform deposition of surfactant-lipid films upon solvent evaporation, particularly when delivered as an organic

solution. Importantly, the production time for proniosomal powders via this method is independent of the surfactant-to-carrier ratio, and the resulting formulation demonstrates excellent storage stability and reconstitution behavior [39, 9, 36].

C. Slow spray coating method

This method entails incremental deposition of a surfactant–cholesterol blend, solubilized in an organic volatile solvent, onto a solid-state carrier matrix e.g., maltodextrin or sorbitol through spray-assisted application. Following each spray cycle, solvent evaporation under reduced pressure is performed to facilitate uniform coating. The procedure is iteratively continued until the desired surfactant-to-carrier ratio is attained. Given that the carrier material exhibits partial or complete solubility in the solvent system, controlled surface erosion during the spray phase promotes the eventual formation of multilamellar niosomal vesicles upon aqueous hydration [21, 41]. The resultant dry proniosomal intermediate is characterized by high rehydration efficiency and uniform vesicle size distribution, closely paralleling those generated by classical vesicle-forming protocols [16, 39].

EVALUATION OF PRONIOSOMES

Measurement of angle of repose

The angle of repose of the dried proniosomal powder was determined using the funnel method. The funnel was securely fixed at a predetermined height, positioning its outlet precisely 10 cm above the collection surface. The proniosomal powder was gradually introduced into the funnel, allowing it to flow freely and form a conical mound on the surface beneath. Upon formation of the powder cone, its height and base diameter were accurately measured. These dimensions were then utilized to calculate the angle of repose [25].

Scanning electron microscopy (SEM)

The surface morphology and particle size distribution of the proniosomal powder were meticulously characterized using scanning electron microscopy (SEM). Samples were prepared by affixing a double-sided adhesive tape onto aluminum stubs, onto which the proniosomal powder was uniformly dispersed. The mounted stubs were subsequently introduced into the SEM vacuum chamber for imaging. Morphological analysis was conducted utilizing a gaseous secondary electron detector, enabling high-resolution visualization of the powder's surface topography and microstructural features [19].

Optical microscopy

Proniosomal formulation was deposited onto glass slides and subjected to morphological evaluation via light microscopy. Following suitable dilution, the samples were examined at a magnification of ×1200 to elucidate structural characteristics. High-resolution photomicrographs were acquired using a digital single-lens reflex (DSLR) camera integrated with the microscope, facilitating detailed visual documentation of the proniosomal morphology [31].

Measurement of vesicle size

The mean vesicle diameter and polydispersity index (PDI) of the proniosomal formulations were characterized using dynamic light scattering (DLS) analysis, employing a Zetasizer Nano ZS90 (Malvern Instruments, UK). Prior to analysis, the samples were appropriately diluted with deionized water to ensure optimal scattering intensity. All measurements were conducted at a controlled temperature of 25 ± 0.5°C to ensure reproducibility and accuracy [14, 37].

Zeta potential measurement

The zeta potential of the proniosomal formulation was analyzed at a temperature of 25°C using a zeta sizer. The proniosomal suspension was diluted 100-fold with doubly-distilled water, and the voltage was set to 1.4 V. Electrodes were immersed in the dispersion to determine the zeta potential. Each sample underwent three runs, after which the analysis proceeded at 25°C with a scattering angle of 173° [34, 35, 11].

Drug content

Proniosomes weighing 100 mg were transferred into a standard volumetric flask. They were lysed by adding 50 ml of methanol and shaking the mixture for 15 minutes. The resulting solution was then adjusted to a final volume of 100 ml with additional methanol. Following this, 10 ml of the prepared solution was further diluted to 100 ml using saline phosphate buffer at a specified pH. Aliquots were collected, and the absorbance was measured at a predetermined wavelength, facilitating the calculation of drug content in accordance with the calibration curve [20].

Determination of entrapment efficiency

The quantification of entrapment efficiency of the proniosomal formulation was performed by employing two widely recognized separation techniques: (a) exhaustive dialysis and (b) differential centrifugation.

a) Dialysis method

Proniosomal suspension was transferred into a dialysis membrane (pre-treated osmotic cellulose tubing), sealed at one end, and immersed in 100 mL of phosphate-buffered saline at a defined pH. The system was stirred continuously using a magnetic stirrer to maintain sink conditions. During the 6-hour dialysis process, unentrapped drug molecules diffused across the membrane into the surrounding buffer, whereas vesicle-entrapped drug remained within the dialysis tubing. At the end of the dialysis period, the retained sample was analyzed using UV-visible spectroscopy to determine the concentration of entrapped drug [30].

b) Centrifugation method

In this approach, free drug was separated from the proniosomal suspension by subjecting the sample to ultracentrifugation. The formulation was centrifuged at optimized speed and duration to facilitate sedimentation of vesicular components, while the supernatant containing unentrapped drug was decanted and analyzed. To quantify the encapsulated drug content, the vesicle pellet was lysed using membrane-disrupting agents such as 50% propane or 0.1% Triton X-100. The resultant lysate was then analyzed spectrophotometrically to determine drug concentration. The entrapment efficiency was subsequently calculated by comparing the amount of entrapped drug to the total drug content [5].

***In-vitro* skin permeation study**

A multitude of analytical methodologies is available for assessing transdermal drug permeation and in vitro release kinetics of proniosomal formulations. These include the use of pharmacopeial and non-pharmacopeial apparatus such as the USP dissolution apparatus type I [1], Franz diffusion cells (Puglia et al., 2004) dialysis membrane systems, reverse dialysis configurations [27], and cellophane-based dialysis membranes [7]. Additional diffusion setups include the Keshary–Chien diffusion cell [38] and Spectra/Por® molecular porous membrane tubing [1], each offering unique advantages in simulating physiological conditions for release profiling. For *in-vitro* skin permeation experiments, various animal models are employed to approximate human dermal characteristics. Commonly utilized tissues include dorsal or flank skin excised from albino rabbits [7], abdominal skin of female Sprague–Dawley rats [38], and Wistar rat skin aged 7–9 weeks [13]. These biological membranes serve as diffusion barriers in Franz-type cells or other diffusion systems to evaluate permeation potential.

Stability study

Stability studies of proniosomes were carried out at different temperatures (2–8°C, 25°C, 45°C) for 1 to 3 months by measuring drug content and vesicle size. According to ICH guidelines, accelerated stability should be studied at 40°C/75% RH. Long-term stability is evaluated at 25°C/60% RH or 30°C/65% RH depending on climatic zones. ICH guidelines suggest accelerated stability at 40°C/75% RH, long-term studies at 25°C/60% RH or 30°C/65% RH [22].

ADVANCEMENT AND APPLICATIONS OF PRONIOSOMES:

Topical delivery- Proniosomes are novel drug delivery system have propensity to attach to the stratum corneum, converted to niosomes after hydration and permeate in skin through stratum corneum that results in increased skin permeation [40].

Applications in cardiology- Proniosomes serve as effective carriers for the transdermal delivery of captopril, utilized in the management of hypertension. Research indicates that the proniosomal system facilitates a prolonged release of the medication within the body [14, 15].

Application in diabetes- Type 2 diabetes causes high blood sugar due to insulin malfunction and is linked to male infertility. Proniosomes can enhance the effectiveness of Glibenclamide, a medication that stimulates insulin secretion. In study, male rats with diabetes were treated with Glibenclamide with or without proniosomal for 14 days. Proniosomal formulations-maintained glucose levels prevented weight loss and showed normal testicular tissue [6].

Oral drug delivery - Proniosomes have been extensively explored as a promising platform for oral drug delivery. Numerous studies have demonstrated the efficacy of oral proniosomal powders in significantly enhancing the solubility and bioavailability of poorly water-soluble therapeutic agents [28].

Vaginal drug delivery- Proniosomal gel systems serve as efficient and patient-compliant carriers for vaginal drug delivery, characterized by their superior mucoadhesive properties and the ability to provide sustained and controlled drug release [1].

Oral mucosal drug delivery- Proniosomal gel incorporated into mucoadhesive carbopol base gel to achieve effective therapeutic concentration for longer period of time [2].

CONCLUSION

It can be concluded that the integration of drugs into niosomes for improved targeting to specific tissue sites is widely endorsed by researchers and scholars. Proniosomes, which give rise to niosomes, are recognized as a promising module for drug delivery. They effectively circumvent many issues related to aqueous niosome dispersions, such as physical stability challenges including aggregation, fusion, and leakage. Additionally, they provide enhanced convenience in terms of transport, distribution, storage, and dosing. Proniosomes not only present a viable method for drug delivery but also have the potential to improve the recovery rate of the skin barrier. As a result, proniosomes are regarded as an innovative technology in drug delivery, warranting further research to fully explore the capabilities of these novel systems.

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