



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



Review Article

A Overview of Proniosome Gel: A Versatile Drug Delivery System For Enhanced Therapeutic Efficacy

Sushmita Chavan*, Dr. Sudha Vengurlekar, Sabafarin H. Shaikh

Valmik Naik College Of Pharmacy, Telwadi, Kannad - 431103.

ARTICLE INFO

Published: 13 Dec. 2024

Keywords:

A Overview of Proniosome Gel, Enhanced Therapeutic Efficacy.

DOI:

10.5281/zenodo.14450093

ABSTRACT

Proniosome gel preparations are the semisolid liquid crystal products of non-ionic surfactants that are made by dissolving the surfactant in an aqueous phase (water) and an organic solvent (ethanol) in a minimum amount. Proniosomes are more suitable for transportation, distribution, storage, processing, packing, and sterilisation in their dry powder form as particle carriers. Pro, which means precursor, and niosome combine to form the phrase "proniosome." Proniosomes are essentially mixtures of non-ionic surfactants and a porous inert carrier, such sugar, that flow freely. Generally, nonionic surfactant, alcohol, lecithin, cholesterol, aqueous phase, and miscellaneous (Dicetyl Phosphate, Solulan C24, etc.) components make up proteosomal gel. Proniosomes offer many benefits, like easier distribution, storage, dosage, and transportation. Proniosomes are a type of non-viral vector that has demonstrated beneficial characteristics for gene delivery, including low cost, ease of formulation, good stability, ease of manufacture, and reduced toxicity due to the inclusion of non-ionic surfactant. As such, they may also be used as gene delivery systems. Proniosomes are employed as delivery vehicles for captopril transdermal therapy of hypertension. The study demonstrates that the proniosomal system results in the drug's prolonged release within the body. Lactin, cholesterol, and sorbitan esters are used in the drug's encapsulation. The proniosomes were kept for a year at three different temperatures: room temperature (25° to 0.5°C), refrigeration (2° to 8°C), and high temperature (45° to 0.5°C). For stability tests, the durations ranged from one to three months. . According to worldwide temperature zones and climate conditions, (WHO, 1996) recommends that dry proniosome powders meant accelerated stability at 40 °C/75 percent relative humidity. Proniosomes are proven to have longer and better shelf lives and stability than other vesicular systems. Proniosomes, which are gel-like concentrated niosomes appropriate for topical treatment, were developed for transdermal medication With proniosome use in diabetes.

***Corresponding Author:** Sushmita Chavan

Address: Valmik Naik College Of Pharmacy, Telwadi, Kannad - 431103

Email ✉: Sabafarinhasinshaikh@gmail.com

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.



On the reaction of hydration, proniosomes transform into niosomes and begin to function. Hydration of proniosomes. Either the skin or the addition of aqueous solvents can cause hydration. Drugs that are lipophilic or hydrophilic can both be trapped by proniosomes.

INTRODUCTION

Proniosome gel preparations are the semisolid liquid crystal products of non-ionic surfactants that are made by dissolving the surfactant in an aqueous phase (water) and an organic solvent (ethanol) in a minimum amount (1) Because of their advantages, including low cost, ease of formulation, and outstanding stability, proniosomes are utilised as drug carriers. Because of the greater physical and chemical stability of their forming components compared to lipids, they are far more stable. (2) A appropriate carrier coated with non-ionic surfactants is used to prepare a proniosome, which can be instantly hydrated to become a niosome. The medicine contained in the niosomal vesicles penetrates the skin more quickly than the free drug after proniosomes are briefly agitated in hot water to hydrate them (3) Proniosomes are more suitable for transportation, distribution, storage, processing, packing, and sterilisation in their dry powder form as particle carriers. This form also allows for ideal flexibility, unit dosing as a capsule, and a high degree of stability. (4) Proniosomes are proven to have longer and better shelf lives and stability than other vesicular systems. (5) Proniosome, which means precursor, and niosome combine to form the phrase "proniosome." Proniosomes are essentially mixtures of non-ionic surfactants and a porous inert carrier, such as sugar, that flow freely. Niosomes are formed spontaneously by these proniosomes when they come into touch with water. (6)

Type of Proniosome

According to their physical behaviour proniosomes are classified in to two categories as follows,

1. Dry granular proniosome

2. Liquid crystalline proniosome

1. Dry granular proniosome According to type of carrier and method of preparation, proniosomes are further classified in to two types,

a. Sorbitol based proniosomes b. Maltodextrin based proniosomes (7). Sorbitol based proniosome

: is dry formulation that involves sorbitol as carrier which is further coated with non ionic surfactant and is used as niosome within minute by addition of hot water followed by agitation. These are normally made by spraying surfactants mixture prepared with organic solvent on to the sorbitol powder and then evaporating the solvent. Finally we will get dry free flowing granular powder. In maltodextrin based proniosome maltodextrin acts as carrier. Generally it is prepared by fast slurry method. Time required to produced proniosome by slurry method is independent of ratio of surfactant solution to carry out. Since maltodextrin morphology is preserved, hollow, blown maltodextrin particles can be used for significant gain in surface area. The higher surface area results in thinner surfactant coating, which makes the rehydration process efficient (8). Maltodextrin-based proniosomes are prepared by the fast slurry method. The surface of the proniosome is increased by the use of hollow maltodextrin particles which leads to a thinner surfactant coating that is suitable for rehydration. (9) When surfactant molecules are kept in contact with water, There are three possibilities or way through which lipophilic chains of surfactant can be transformed into disorder liquid state called lyotropic liquid crystalline state (neat phase). These three ways are increasing temperature at kraft point (T_c), addition of solvent which dissolve lipids, and use of both temperature and solvent. Neat phase or lamellar phase contains bilayers arranged in sheet over one another within intervening aqueous layer. For ternary lecithin, non ionic surfactant as monoglyceride and alcohol



system, lamellar liquid crystals are formed at kraft temperature in presence of alcohol. The lamellar crystalline phase can be converted into dispersion on noisome by adding high amount of water.(10) This type of proniosomes are reservoirs for transdermal delivery of the drug. The transdermal patch involves aluminum foil as a baking material along with a plastic sheet. Proniosomal gel is spread evenly on the circular plastic sheet followed by covering with a nylon mesh.(11).

Methods of preparation:

Proniosomes can be prepared by following methods: -

- a. Slurry method
- b. Coacervation phase separation method
- c. The slow spray coating method

1) slurry method

Proniosomes can be prepared by using a solution of cholesterol and surfactants. The non-ionic surfactants used are – span and Brij. The coating carrier used is maltodextrin. The drug and stock solution was added to a 100 ml round bottom flask containing 500 mg of maltodextrin carrier. Then chloroform: menthol solution is added to form a slurry. The flask is attached to a rotary evaporator for the evaporation of the solvent and it is rotated at 60-70rpm, temperature maintained at 45oc and a reduced pressure of 600 mmHg. The process is continuing until the mass in the flask had become a dry free-flowing product. These materials are further dried overnight in a desiccator under a vacuum at room temperature. The dry preparation is referred to as proniosome powder.(12)

2) Co-acervation phase separation method

This is a widely used method for making proniosm gel. Weighed amounts of the drug, lipids and surfactants are placed in a dry, wide-mouth beaker, after which the solvent is added. The ingredients are well mixed and heated in a water bath to a temperature of 60-70 C until the surfactant mixture is completely dissolved. Care must be taken during the process to avoid. (13).

3) The slow spray coating method :

Spray-coating method In this method, proniosomes are prepared by spraying surfactant in organic solvent onto a carrier/coating material followed by evaporation of solvent. The surfactant forms a thin film on the carrier and subsequent hydration cause formation of multi-lamellar vesicles.(14).

2) A 100 ml round bottom bottle containing the desired amount of carrier can be attached to the rotary evaporator. The evaporator must be emptied and the rotary bottle can be rotated in a water bath under vacuum at 65-70°C for 15-20 min. This process is repeated until all the surfactant solutions are used up. Steaming should be continued until the powder is completely dry.(15).

Evaluation of proniosomal gel

Physical appearance and homogeneity

1)Viscosity: The viscosity of the prepared proniosomal gel was measured using a Brookfield viscometer (DV-E). 10 g of the gel composition was measured by rotating the spindle 64 at 12 rpm at 37 °C, because the gel belongs to the category of high viscosity (HA)(16).

2)Measurement of pH : pH measurements are taken in triplicate using a digital pH meter. Before the measurement, the pH meter was calibrated and readings were obtained by immersing the glass electrode in the gel compounds.(17).

3)Spreadability :The Spreadability was identified with the following procedure: 0.5g of gel was placed within a circle of 1 cm diameter premarked on a glass plate over which a second glass plate was placed. A weight of 50g was allowed to rest on the upper glass plate. (18)

$S = m \times L/t$ Where, S: Spreadability;

m: weight of load;

L: length travelled by upper slide;

t: time in seconds

3) Spreadability: Spreadability plays an important role because it indicates the behavior of the gel exiting the tube.(19)



4) Extrudability :As the material flow rate increases, all gel compounds result in higher extrusion pressures. Higher dosage can increase shear stress and flow consistency, resulting in higher extrusion pressure. Table 4 shows the results of the extrudability tests.(20)

1) Standard preparation: Weigh 2 g of gel containing 10 mg of drug, add 1 ml of ethanol and 4 ml of phosphate buffer to a 10 ml volumetric flask and sonicate until dissolved. Fill the final volume with buffer.The resulting solution was filtered using Whatman filter paper and 1 ml of the filtered solution was taken and transferred to a volumetric flask containing 10 ml of phosphate buffer pH 7.4 and the volume was adjusted to the pH 7.4 mark with phosphate buffer. and absorbance was measured at 408 nm(21).

2) Stability study: The stability of the proniosomal suspension was performed as per International Council on Harmonisation (ICH) guidelines for 3 mo. sufficient quantities of the proniosomal gel formulations were sealed in 10g collapsible aluminium tubes in triplicate. The samples were withdrawn at each mo over a period of 3 mo, and leakage of drug from the formulation was analysed for drug content by using a UVvisible spectrophotomete(22).

Morphological Evaluation

1). Physical Appearance: Table shows the color and physical state for each formula, these properties are differ from each other since they depend on the composition(23).

Formulation of proniosomal gel

Generally, nonionic surfactant, alcohol, lecithin, cholesterol, aqueous phase, and miscellaneous (Dicetyl Phosphate, Solulan C24, etc.) components make up proteosomal gel.

Surfactant

The HLB value must to be taken into consideration when choosing a surfactant. Any surfactant Balance (HLB), and a number between 4 and 8 was shown to be compatible with vesicle

production.It has also been reported that the hydrophilic surfactant does not achieve a concentrated state upon hydration due to its high water solubility, which prevents free hydrated units from existing in aggregates and coalescing to create lamellar structures. In the presence of cholesterol, the water-soluble detergent polysorbate 20 also produces niosomes. This is true even though this compound has an HLB number of 16.The HLB of a surfactant influences the degree of entrapment.The entrapment of drugs in vesicles is influenced by the transition temperature of surfactants. The maximum drug entrapment occurs in spans with the highest phase transition temperature, and vice versa.(24)

Vascular 40 and Vascular 60 yield bigger vesicles with more drug entrapment. A high phase temperature and low permeability of the vesicles minimize the amount of medication that leaches out of them. Increased surface free energy from high HLB values of Span 40 and 60 leads to the formation of bigger vesicles, which in turn exposes a wider area to the skin and dissolving media.(25)

The flux value is highest for Span 80 and lowest for Span 60, according to different impacts of non-ionic surfactant on levonorgesterol permeability profile. Due to the greater phase transition

temperature of Span 40 and Span 60, which causes their reduced permeability, there is no discernible variation in the skin permeation profile of these formulations.(26)).

Mechanism action of Proniosomes

PRONIOSOME ACTION:

On the reaction of hydration, protoniosomes transform into proniosomes and begin to nction.Hydration of promethions Niosomes.



Either the skin or the addition of aqueous solvents can cause hydration. Drugs that are lipophilic or hydrophilic can both be trapped by promethiosome. (27)

There exist multiple modes of skin penetration for transdermal medication delivery systems. There are three potential routes: the intercellular road connecting cells and lipids, the path taken by appendages via sweat glands and hair follicles, and the intercellular pathway via the convoluted network of lipids. The appendageal pathway is not a substantial route because skin appendages only make up 0.1% of the total skin surface. (28)

Mechanism of drug transport through skin :

Research conducted on the topical/transdermal use of vesicles has produced inconsistent outcomes. The variables that impact vesicle–skin interactions and are crucial in determining how well drugs are transported through the skin are yet unknown. The interaction takes place in the deeper layers of the skin and its intercellular lipid areas, with a maximum depth of around 10 mm. This is evident through the use of Small Angle X-ray Scattering (SAXS) and Freeze Fracture Electron Microscopy (FFEM). (29).

Advantages of Proniosomes:

A broad variety of active substances may be entrapped by pioniosomes. (30).

improvement in the drug's penetration and bioavailability. (31)

Sustained Release: Drugs that have been encapsulated can be released gradually over a lengthy period of time using proteosomal gels. This may result in longer-lasting therapeutic benefits, a decrease in application frequency, and an increase in patient compliance. (32).

avoids problems with fusion, sedimentation, and aggregation that are connected to stability. (33).

Proniosomes offer many benefits, like easier distribution, storage, dosage, and transportation. (34). **Application of Proniosomes:**

Proniosome in gene delivery: Proniosomes are a type of non-viral vector that has demonstrated beneficial characteristics for gene delivery, including low cost, ease of formulation, good stability, ease of manufacture, and reduced toxicity due to the inclusion of non-ionic surfactant. As such, they may also be used as gene delivery systems. (35).

Anti-neoplastic treatment: Serious side effects are caused by the majority of antitumor medicines. Proniosomes have the ability to change how a drug is metabolised, extend its half-life, and increase its circulation, all of which can lessen its adverse effects. Doxorubicin and methotrexate that were entrapped proniosomally exhibited advantageous properties compared to their untrapped counterparts, including a slower rate of tumour development and increased plasma levels that were followed by a delayed rate of clearance. (36).

Transdermal drug delivery systems:

Drugs work through the skin more effectively thanks to pioniosomes. Primarily, proniosomal technology was utilised in cosmetics. Proniosomal gel enhances the penetration of entrapped drugs relative to un-entrapped drugs, and it also significantly strengthens the immune system. Proniosomal vaccines for transdermal medication delivery are currently being studied (37).

Antibacterial therapy: In order to improve the physical stability and stop the formulation from oxidising, proniosomal preparations are utilised for antibacterial therapy during medication storage. (38).

Non-Steroidal Anti-Inflammatory

drug: Lecithin, cholesterol, spans, and tweens are used to make ketorolac, a strong non-steroidal anti-inflammatory medication, as a proniosome gel with ethanol acting as a solvent. (39).

Applications in cardiology: Proniosomes are employed as delivery vehicles for captopril transdermal therapy of hypertension. The study demonstrates that the proniosomal system results



in the drug's prolonged release within the body. Lactin, cholesterol, and sorbitan esters are used in the drug's encapsulation

Routes of drug administration:-

Proniosomes gel Drug delivery system

Transdermal drug delivery system

Interest in transdermal therapeutic systems has increased because they offer the significant benefit of a non-invasive medication therapy via the parenteral pathway, avoiding first-pass hepatic and intestinal metabolism, and reduced drug adverse effects.(40)

Transdermal medication delivery offers a continuous treatment option as an alternative to traditional oral and parenteral routes.drug levels. Proniosomes present a flexible drug delivery paradigm via vesicles that may be used for transdermal medication delivery.(41)

transdermal medication distribution through the skin eliminates the hazards of intravenous therapy and the difficulties of changing stomach pH, it is advantageous.(42)

Proniosomes, which are gel-like concentrated niosomes appropriate for topical treatment, were developed for transdermal medication With proniosome use in diabetes.(43)

Niosomal vesicles ought to be incorporated into polymeric matrixes such as methylcellulose gels for transdermal administration.(44)

Ocular drug delivery system

The administration of ocular medications should utilize both novel drug delivery methods and the more effective conventional dose form to maximize therapeutic efficacy.(44)

Ocular delivery proniosomal gels are made exclusively or in combinations with Span 60 utilizing various nonionic surfactant types to increase its bioavailability in the eyes for the treatment of bacterial conjunctivitis. (45)

The benefits of administering ocular dose forms frequently are mitigated by maintaining the drug release from proniosomal gel formulations.(46)

high intraocular penetration of topical VRC combined with a concurrent therapeutic concentration that is effective against fungal keratitis and can be reached in many eye tissues.(47)

Due to physiological and anatomical limitations, only a very little portion of the injected drug—roughly 1% or less is accessible for ocular absorption(48).

To increase the ocular bioavailability of lomefloxacin HCl for the treatment of bacterial conjunctivitis, create and assess new ocular proniosomal gels(49)

Stability studies:

The proniosomes were kept for a year at three different temperatures: room temperature (25° to 0.5°C), refrigeration (2° to 8°C), and high temperature (45° to 0.5°C). For stability tests, the durations ranged from one to three months. . According to worldwide temperature zones and climate conditions, (WHO, 1996) recommends that dry proniosome powders meant accelerated stability at 40 °C/75 percent relative humidity. For long-term stability research (RH), it is 25°C/60 percent RH for nations in zones I and II and 30°C/65 percent RH for nations in zones III and IV. (50).

Drug release kinetics :

By exposing in vitro diffusion experiments to various kinetic conditions, the mechanism of drug release from the gels was investigated. these formulas (Higuchi T., 1963).

Zero order kinetics :

$A_0 - K_0t = A_t$. When does the medication release occur at time "t"? A_0 is the first medication. focus. When the data is displayed as cumulative percent drug release vs time, K_0 is the zero order rate

constant (hr⁻¹); if the plot is linear, the data obeys zero-order equal to K.

First order kinetics :

$\log C = \log C_0 - Kt / 2.30$. Where, C is amount of drug remained at time 't', C₀ is Initial amount of drug and K is First order rate constant (hr⁻¹). Graph plotted as log cumulative percent drug remaining versus time yields a straight line indicated the first order kinetics. The constant 'k' can be obtained by multiplying 2.303 with the slope value(51).

For 48 days, the percentage of drug entrapped within the proniosomal formulation vesicles at 4–6°C, 37°C, and 45±2°C was used to assess stability. In light of the vesicular size results, Ratio between drug content and entrapment effectiveness The results of the stability research test demonstrated that the proniosomal formulations remained highly stable both at room temperature and at refrigeration temperature(52).

Sterility testing :-The formulation was sterilised using the membrane filtering process and then incubated for 14 days using various culture media, including soybean casein digest medium and fluid thioglycate medium. To checked any microbial growth was present(53) .

In vitro studies

In vitro release : Determine by Using a dialysis membrane with UV detection at 248 nm, drug release from proniosome hydrocortisone gel was investigated. Also, the formulations were contrasted with a commercially available 1% hydrocortisone cream. When compared to PHG 1%, the marketed formulation's first 1-hour release was shown to be greater. However, in contrast to the 1% PHG formulation, the cumulative percentage release from the 1% hydrocortisone cream was neither consistent or linear with regard to time(54).

In vitro diffusion studies :

Proniosomal gel in vitro diffusion experiments were carried out in a Franz diffusion cell, which

has a receptor compartment measuring around 60 ml in effective volume and an effect. 3.14 square centimeters of permeable surface. Between the donor and receptor compartments, the egg membrane or cellulose membrane was positioned. The receptor media used was phosphate saline buffer, and a measured quantity of Proniosomal gel was applied to one side of the skin. pH 7.4. The temperature within the receptor compartment is kept at 37±0.5°C by surrounding it with a water jacket. A magnetic stirrer is used in conjunction with a thermostatic hot plate to provide heat. A magnetic stirrer loaded with a Teflon-coated bead stirs the receptor fluid(55).

In vitro skin permeation studies :

In Vitro Skin Permeation Studies Preparation of Human cadaver skin: The skin was stored at 0-4oC after collection. The excised human abdomen skin was treated to remove hair and subdermal tissue. The subdermal fat was removed with help of scalpel and swapped with isopropyl alcohol. The treated skin was stored at 0oC in deep freezer for not more than 2 days. To actually mimic the in vitro permeation study, the permeation studies were performed using excised cadaver skin mounted on Franz cell(56). The Franz (vertical) diffusion cell is used to measure the drug's permeation from the proniosome formulation. The skin of the 7–9-week-old wistar rat was adhered to the receptor. compartment into the donor compartment with the stratum corneum side facing up. A piece of paraffin paper covered the top of the diffusion cell. The proniosome formulation was placed into the donor compartment. The receptor compartment was kept at 37°C and agitated at 600 rpm using a magnetic bar(57).

In vivo studies Compared to other formulations, proniosomal gel demonstrated a greater drug permeability of 78.39±0.05% and 80.06±0.01%, respectively, over a 24-hour period through the dialysis membrane. (58).



Each donor compartment was filled with a proniosomal gel formulation equivalent to 5 mg of ketoprofen, while the receiver compartment was used to hold Phosphate buffer with pH 6.8. A magnetic bar spinning at 600 rpm was used to agitate the receptor compartment, which was kept at $37 \pm 1^\circ\text{C}$ (59). transdermal proniosomal gel formulation and contrasted with the Oral Lacipil-4 mg tablet (GlaxoSmithKline, Philadelphia, PA) that is marketed for oral use. For this investigation, six male New Zealand rabbits weighing 3.0 ± 0.3 kg were employed. Two groups of three rabbits each were formed at random from the rabbits. A randomized cross-over design with a single dose, two phases, and a one-week washout period was used. The rabbits were given Lacrivil orally after fasting for the entire night. (60)..

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HOW TO CITE: Sushmita Chavan*, Dr. Sudha Vengurlekar, Sabafarin H. Shaikh, A Overview of Proniosome Gel: A Versatile Drug Delivery System For Enhanced Therapeutic Efficacy, *Int. J. of Pharm. Sci.*, 2024, Vol 2, Issue 12, 1876-1886. <https://doi.org/10.5281/zenodo.14450093>

