International Journal of Medical and Pharmaceutical Sciences
Open access peer-reviewed Journal
Volume 1, Issue 12, Page 34-43.
https://doi.org/10.5281/zenodo.17958977

Review Article

Advances in Proniosome-Based Topical Drug Delivery: Formulation and Therapeutic Potential

Jeevan Kore*[1], Mahesh Kore[2], Shraddha Kothale[3], Shweta Mohite[2]

[1]*Department of pharmaceutical chemistry, Appasaheb Birnale College of Pharmacy, Sangli 416416*
[2]*Department of Pharmaceutics, Annasaheb Dange College of B Pharmacy, Ashta. 416301*
[3]*Department of pharmacology, Dr. Shivajirao Kadam College of Pharmacy, Kasbe Digraj, Sangli. 416305*

Proniosomes are emerging as a stable and efficient provesicular drug-delivery system designed to overcome the limitations of conventional vesicular carriers in topical therapy. Composed of non-ionic surfactants, cholesterol, and water-soluble carriers, proniosomes form niosomes upon hydration, offering enhanced stability, improved encapsulation efficiency, and controlled drug release. Their ability to increase skin penetration through mechanisms such as stratum-corneum lipid fluidization, vesicle fusion, and hydration-driven permeation makes them particularly valuable for delivering poorly soluble or locally acting drugs. Recent advances including nano-proniosomes, elastic proniosomes, and hybrid systems integrated with microneedles or transdermal patchesh ave expanded their therapeutic potential across dermatological, anti-inflammatory, antifungal, wound-healing, and cosmetic applications. Despite their advantages in stability, ease of storage, and enhanced dermal deposition, challenges remain regarding large-scale manufacturing, regulatory standardization, and long-term safety assessment. Overall, proniosomes represent a promising and versatile platform capable of improving topical drug delivery and providing sustained, targeted therapeutic action.

Keywords: Proniosomes, Topical drug delivery, Niosomes, Vesicular carriers, Skin permeation enhancement, Controlled release, Dermatological therapy, Provesicular systems, Nano-proniosomes, Transdermal delivery.

INTRODUCTION

Topical and transdermal drug-delivery systems have gained significant prominence due to their ability to deliver therapeutics directly to the skin or systemic circulation while avoiding first-pass metabolism, reducing gastrointestinal side effects, and improving patient compliance. However, effective penetration of drugs through the stratum corneum the outermost and most impermeable layer of the skin remains a major challenge. Conventional topical formulations such as creams, gels, and ointments often fail to deliver adequate drug concentrations into deeper skin layers, particularly for poorly water-soluble molecules, drugs with high molecular weight, or compounds requiring sustained release. To address these limitations, vesicular carriers such as liposomes and niosomes have been widely explored for enhancing dermal delivery. Although effective in improving drug solubility and permeation, these vesicular systems frequently suffer from drawbacks including physical instability, aggregation, fusion, hydrolysis, and drug leakage during storage, which limits their clinical and commercial utility.

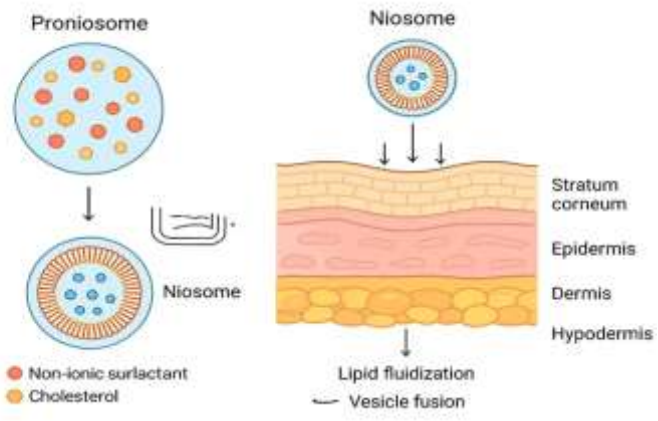


Fig 1: Proniosome drug delivery through skin barrier

Proniosomes have emerged as an innovative provesicular system developed to overcome these limitations by offering improved stability, reproducibility, and ease of handling. Proniosomes are dry, free-flowing formulations composed of non-ionic surfactants, cholesterol, and hydrophilic carriers such as maltodextrin, mannitol, or sorbitol. Upon hydration either during manufacturing or when applied to the skin they are instantly converted into niosomal vesicles capable of entrapping both hydrophilic and lipophilic drug molecules. This hydration-dependent vesicle formation provides significant advantages: enhanced shelf life, minimized leakage, improved stability, and simplified transportation without the need for special storage conditions. Moreover, proniosomes promote drug permeation through mechanisms such as fluidization of stratum-corneum lipids, modulation of skin barrier properties, hydration effects, and vesicle-mediated transport, all contributing to improved bioavailability and therapeutic efficacy. In recent years, proniosome-based topical drug delivery has attracted considerable attention in pharmaceutical research due to its versatility and suitability for a wide range of therapeutic agents, including anti-inflammatory drugs, antifungals, antimicrobials, anti-acne agents, antioxidants, and cosmetic actives. Advances in formulation technology such as nano-proniosomes, elastic proniosomes, hydrogels, transdermal patches, and hybrid microneedle–proniosome system have further expanded their application potential. Additionally, proniosomes allow controlled drug release, enhanced dermal deposition, reduced dosing frequency, and minimized irritation, making them effective candidates for the management of chronic skin disorders. Despite promising preclinical performance, challenges such as process standardization, scalability, regulatory acceptance, and long-term safety evaluation remain areas requiring further research. Nevertheless, the emerging evidence supports proniosomes as a highly promising and innovative platform capable of revolutionizing topical and transdermal drug-delivery strategies. Topical drug delivery has become an essential route for the management of dermatological disorders, pain, wounds, and localized infections due to its ability to deliver therapeutic agents directly to the affected site while minimizing systemic exposure. However, the skin—particularly the stratum corneum—poses significant barriers that limit the permeation of most drugs, especially those with high molecular weight, poor solubility, or limited partitioning ability. These limitations have encouraged the development of advanced vesicular and provesicular drug-delivery platforms capable of enhancing dermal penetration and prolonging drug residence time. Among these systems, proniosomes have emerged as a promising novel approach. Proniosomes are dry, free-flowing, granular or gel-like provesicular systems that transform into niosomes upon hydration. This unique property overcomes the instability issues commonly associated with liposomes and niosomes, such as aggregation, fusion, and drug leakage during storage. Composed primarily of non-ionic surfactants, cholesterol, and a carrier substrate, proniosomes offer improved physicochemical stability, ease of transport, extended shelf life, and scalable manufacturing advantages. The recent scientific Interest in

proniosomal technology is driven by its remarkable ability to enhance topical bioavailability through multiple mechanisms including improved solubilization of hydrophobic drugs, penetration enhancement, occlusive hydration effects, and sustained drug release. Advances in formulation strategies—such as the use of novel surfactants, incorporation of penetration enhancers, and development of nano-sized proniosomes—have broadened their applicability across therapeutic areas including anti-inflammatory therapy, fungal infections, acne management, wound healing, and cosmetic dermatology. Moreover, the adaptability of proniosomes allows for the encapsulation of a wide range of molecules including small drugs, peptides, antioxidants, and herbal extracts, making them suitable for both pharmaceutical and cosmeceutical formulations. With growing evidence supporting their efficacy, improved patient compliance, and ability to deliver drugs transdermally or intradermally, proniosomes are increasingly being recognized as one of the most versatile and future-ready platforms in topical drug delivery. Despite the progress, challenges related to regulatory acceptance, scale-up production, and long-term clinical evaluation remain key areas that require further investigation.

Composition and types of proniosomes:

Composition of Proniosomes

Proniosomes are provesicular systems that convert into niosomes upon hydration. Their composition is similar to niosomes but formulated in a dry or semi-solid form to improve stability and ease of use.

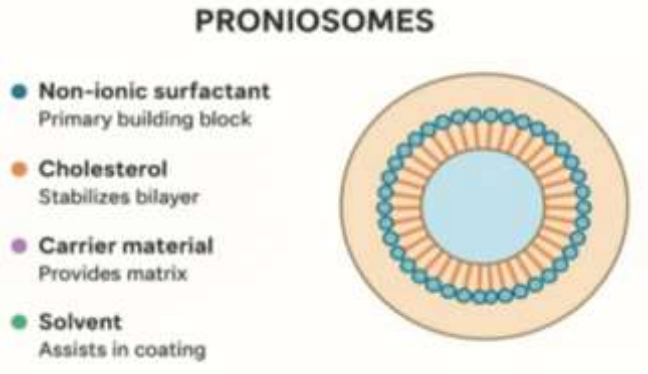


Fig 2: structure of Proniosomes

1. Non-ionic Surfactants: These are the primary building blocks responsible for vesicle formation.

Common surfactants:

- Spans (Sorbitan esters) – Span 20, 40, 60, 80
- Tweens (Polyoxyethylene sorbitan esters) – Tween 20, 40, 60, 80
- Brij surfactants – Brij 52, Brij 76
- Poloxamers

Role:

- Form bilayers upon hydration
- Enhance stability
- Control vesicle size and entrapment efficiency

2. Cholesterol

Cholesterol is included to:

- Increase membrane rigidity
- Improve vesicle stability
- Prevent vesicle leakage
- Typical concentration: 20–30% of total lipid.

3. Carrier Materials / Coating Agents

These are used to convert vesicles into dry, free-flowing proniosomal powders or gels.

Common carriers:

- Maltodextrin
- Sorbitol
- Mannitol
- Sucrose monopalmitate
- Lecithin

- Microcrystalline cellulose (MCC)

Role:

- Provide structural support
- Enhance flow properties
- Extend shelf life

4. Solvents / Hydration Media

Solvents are used during preparation and help distribute surfactants uniformly.

Common solvents:

- Ethanol
- Isopropanol
- Chloroform–methanol mixture
- Water/buffer solutions

Role:

- Dissolve surfactants and cholesterol
- Facilitate uniform coating on carrier particles

5. Additional Components (Optional)

- Penetration enhancers: Oleic acid, isopropyl myristate
- Antioxidants: BHT, BHA
- Humectants: Glycerol
- Drug molecules: Hydrophobic or hydrophilic

Types of Proniosomes

Proniosomes are primarily categorized based on their physical nature and method of preparation.

A. Based on Physical Form

1. Dry, Free-Flowing Proniosomal Powder:

- Prepared by slurry method or spray-coating onto carriers like sucrose or sorbitol.
- Stable and easy to transport
- Converts to niosomes upon addition of water.

Applications: Topical powders, transdermal gels.

2. Proniosomal Gel

- A semi-solid gel prepared by dissolving surfactants in a minimal amount of solvent (ethanol/water).
- Convenient for topical and transdermal applications.
- Hydrates easily to form uniform niosomes.

Applications: Anti-inflammatory gels, antifungal gels, wound-healing gels.

3. Proniosomal Liquid Crystals

- Formed using surfactants with specific hydration levels.
- Show liquid crystalline behavior (lamellar/hexagonal phases).
- Provide very high entrapment and controlled drug release.

B. Based on Method of Preparation

1. Slurry Method

Principle: Coating a carrier (maltodextrin/sorbitol) with surfactant–cholesterol solution.

Procedure:

- Weigh the required amount of carrier material (e.g., maltodextrin).
- Dissolve non-ionic surfactants (Span/Tween) and cholesterol in an organic solvent (chloroform–methanol or ethanol)
- Transfer the carrier material into a round-bottom flask.
- Add the surfactant solution slowly over the carrier.
- Rotate the flask under vacuum using a rotary evaporator at 40–60°C to evaporate the solvent.
- Continue drying until a free-flowing powder is obtained.
- Store the proniosomal powder in an airtight container.
- Hydrate with warm water before use to form niosomes.

Advantages:

- High stability
- Free-flowing uniform powder

- Scalable

2. Coacervation Phase Separation Method

Principle: Separation of surfactant phase from solvent to form a proniosomal gel.

Procedure:

- Dissolve surfactants and cholesterol in ethanol or a suitable solvent.
- Add a small amount of warm water (50–60°C) with gentle mixing.
- A viscous proniosomal gel (coacervate) forms immediately.
- Allow the gel to cool and store in a closed container.
- Hydrating the gel with warm water yields niosomal dispersion.

Advantages:

- High entrapment efficiency
- Suitable for topical gel formulations

3. Spray-Coated Method (Industrial Method)

Principle: Spraying surfactant solution onto carrier particles.

Procedure:

- Prepare a solution of surfactants and cholesterol in a volatile solvent.
- Load carrier particles (sorbitol/maltodextrin) into a spray dryer.
- Spray the surfactant solution onto the carrier while blowing hot air.
- Collect dried proniosomal powder from the chamber.
- Store in airtight containers.

Advantages:

- Suitable for large-scale production
- Uniform coating.
- Fast and reproducible

4. Fluid-Bed Coating Method

Principle: Advanced method for uniform deposition of surfactants onto carriers.

Procedure:

- Suspend carrier particles in upward airflow inside a fluid-bed coater.
- Spray surfactant–cholesterol solution from the top or bottom.
- Allow hot air to evaporate the solvent rapidly.
- Collect coated proniosomal granules.

Advantages:

- Very uniform coating.
- Excellent for industrial manufacturing

5. Ether Injection Method

Principle: Injecting surfactant solution into warm aqueous phase to form proniosomes/niosomes.

Procedure:

- Dissolve surfactant and cholesterol in ether or diethyl ether.
- Heat aqueous phase (buffer solution) to 60–65°C.
- Inject the organic phase slowly into the aqueous phase.
- Ether evaporates, leaving proniosomal vesicles.

Advantages:

- Produces smaller vesicles
- Useful for thermolabile drugs

6. Ethanol Injection Method.

Principle: Ethanol diffuses into the aqueous phase forming vesicles.

Procedure:

- Dissolve surfactant and cholesterol in ethanol.
- Inject this solution into warm water (around 60°C).
- Immediate formation of proniosomes occurs.
- Evaporate excess ethanol if necessary.

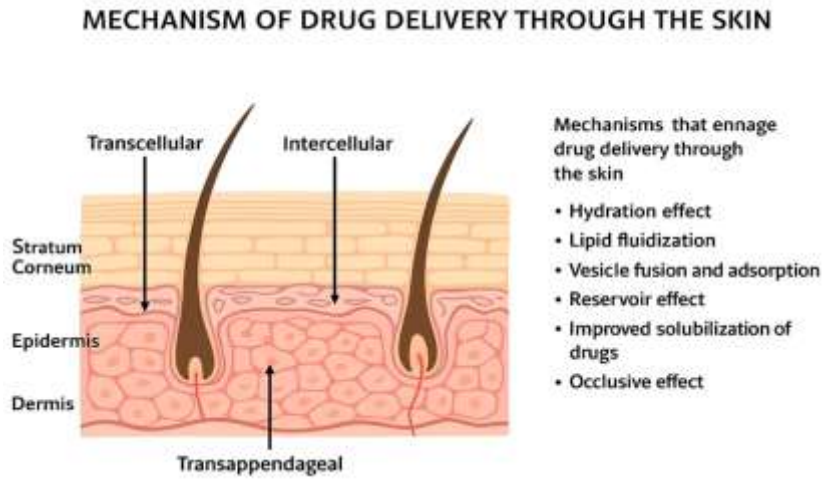
Advantages:

- Simple and fast

- Produces uniform vesicles

Mechanism of Drug Delivery Through the Skin:

The skin acts as both a protective barrier and a route for drug absorption. For topical and transdermal delivery, drugs must penetrate various layers of the skin to reach their target site or systemic circulation. The primary barrier is the stratum corneum, a dense layer of dead keratinized cells embedded in lipid bilayers. Drug molecules cross this layer by passive diffusion through multiple pathways.



Pathways of Drug Penetration Through the Skin

1) Transcellular (Across the Cells) Pathway:

- Drug molecules pass directly through the corneocytes (keratin-filled cells).
- Requires the drug to alternate between hydrophilic and lipophilic environments.
- Suitable for small, moderately lipophilic drugs.

Limitation: Highly tortuous path; low permeability.

2) Intercellular (Between the Cells) Pathway

- Drugs move through the lipid-rich spaces between corneocytes.
- Dominant route for lipophilic drugs.
- Lipid matrix (ceramides, cholesterol, fatty acids) plays a major role in controlling permeation.

Importance: This is the most common pathway for proniosomal and vesicular systems.

3) Trans appendageal (Appendageal) Pathway

Drugs enter through:

- Hair follicles
- Sebaceous glands.
- Sweat ducts

Advantages:

- Provides a shunt pathway bypassing stratum corneum.
- Useful for large molecules, peptides, and nanoparticles.

Contribution: 0.1–1% of total skin area, but highly permeable.

Mechanisms Enhancing Drug Delivery Through the Skin :

Proniosome-based delivery systems enhance skin penetration through several mechanisms:

1) Hydration Effect

- Proniosomes hydrate and form niosomes on the skin surface.
- Increases moisture content of stratum corneum.
- Hydration swells lipid layers, reducing barrier resistance.

2) Lipid Fluidization

- Surfactants (Spans/Tweens) interact with skin lipids.

- Disrupts or loosens the rigid lipid structure.
- Creates transient channels for improved drug permeation

3) Vesicle Fusion and Adsorption

- Niosomal vesicles fuse with skin lipids.
- Transfers encapsulated drug into deeper layers.
- Enhances dermal deposition.

4) Reservoir Effect

- Vesicles act as a drug depot at skin surface.
- Allows sustained release into the epidermis and dermis.

5) Improved Solubilization of Drugs

- Proniosomes increase solubility of poorly water-soluble drugs.
- Higher concentration gradient enhances diffusion.

6) Occlusive Effect

- Proniosomal gel forms a thin occlusive layer.
- Prevents water loss → increases hydration → increases permeability.

Application and Therapeutic Potential of Proniosomes

Proniosomes have emerged as a versatile drug delivery system owing to their ability to form niosomes upon hydration, improve drug stability, enhance permeation, and offer controlled and targeted delivery. Their unique physicochemical properties broaden their applications across various routes of administration.

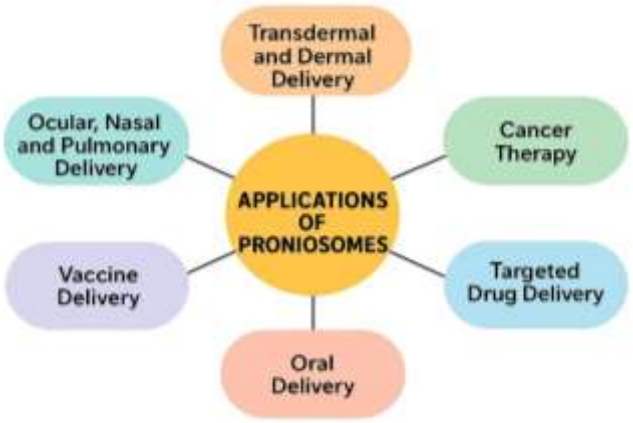


Fig: application of Proniosomes

1) Transdermal and Dermal Drug Delivery

Applications:

- Treatment of skin disorders (psoriasis, eczema, dermatitis).
- Delivery of anti-inflammatory drugs (diclofenac, ketoprofen).
- Topical delivery of antifungal and antibacterial drugs.

Therapeutic Potential:

- Improved skin permeation through hydration and lipid fluidization.
- Higher drug retention in epidermal and dermal layers.
- Reduced systemic side effects and enhanced patient compliance.

2) Cancer Therapy

Applications:

- Delivery of chemotherapeutic agents (doxorubicin, paclitaxel, methotrexate).
- Targeted delivery to tumor tissues via ligand-modified proniosomes.

Therapeutic Potential:

- Enhanced drug accumulation in tumor cells.

- Reduced toxicity to healthy tissues.
- Improved intracellular uptake and sustained release leading to better therapeutic outcomes.

3) Targeted Drug Delivery

Applications:

- Organ-specific delivery (liver, lungs, skin).
- Delivery of drugs with narrow therapeutic windows.
- Gene and peptide delivery when surface-modified.

Therapeutic Potential:

- Precise drug localization at the site of action.
- Lower doses required, minimizing adverse effects.
- Increased bioavailability and therapeutic index.

4) Oral Drug Delivery

Applications:

- Delivery of poorly soluble drugs (aceclofenac, ibuprofen).
- Protection of peptide and protein drugs from degradation.
- Enhanced absorption of low-bioavailability drugs.

Therapeutic Potential:

- Improved stability in gastrointestinal fluids.
- Better intestinal permeability.
- Prolonged drug release and enhanced oral bioavailability.

5) Vaccine Delivery

Applications:

- Delivery of antigens, peptides, and proteins.
- Development of stable vaccine formulations without cold-chain dependence.

Therapeutic Potential:

- Enhanced immune response through depot formation.
- Protection of antigens from degradation.
- Potential for mucosal vaccination (oral, nasal).

6) Ocular, Nasal, and Pulmonary Delivery

Applications:

- Ocular delivery of anti-glaucoma and anti-infective drugs.
- Nasal delivery for migraine therapy and CNS targeting.
- Pulmonary delivery for asthma and infections.

Therapeutic Potential:

- Improved retention time and mucoadhesion.
- Enhanced penetration across mucosal barriers.
- Faster onset of action and increased local bioavailability.

7) Anti-infective Therapy

Applications:

- Delivery of antibiotics, antivirals, antifungals, and antiparasitic agents.
- Used in chronic infections requiring high local concentrations.

Therapeutic Potential:

- Enhanced penetration into infected tissues.
- Protection of unstable antimicrobials.
- Overcomes biofilm-associated resistance.

8) Anti-inflammatory and Pain Management

Applications:

- Delivery of NSAIDs and corticosteroids.
- Transdermal patches and gels for chronic pain.

Therapeutic Potential:

- Sustained release improves long-term relief.
- Reduced gastrointestinal side effects.
- Enhanced skin permeation and faster action.

Advantages of Proniosomes:

1) Improved physical and chemical stability
2) Ease of handling, transport and storage

3) Enhanced drug solubility and entrapment
4) Improved dermal/transdermal permeation and retention
5) Controlled and sustained release
6) Versatility across routes
7) Scalability techniques such as spray-coating and fluid-bed coating enable industrial scale production.
8) Potential for targeting and functionalization

Limitations

1) Surfactant-associated irritation or toxicity
2) Limited loading of very large biomolecules
3) Batch-to-batch variability without strict process controls
4) Regulatory and standardization gaps
5) Stability depends on components

Recent Advances

1) Nano-proniosomes/size reduction strategies: production of sub-200 nm proniosome-derived niosomes for deeper penetration and improved follicular targeting.
2) Elastic / deformable proniosomes: incorporation of edge activators (e.g., Tween 80, bile salts) to produce deformable vesicles that better traverse skin pores and tight intercellular spaces.
3) Stimuli-responsive systems: pH- or temperature-sensitive proniosomes that release drug in response to local cues (early stage but growing).
4) Hybrid delivery platforms: integration of proniosomes with microneedle arrays, transdermal patches, or hydrogel matrices to combine mechanical penetration with vesicular delivery.
5) Spray-coating / fluid-bed manufacturing: improved industrial methods producing more uniform, scalable proniosome powders.
6) Natural/biosurfactant-based proniosomes: move towards biodegradable and biocompatible surfactants for safety and regulatory acceptability.

Future Perspectives

1) Clinical translation and regulatory pathways
2) Process analytical technology (PAT) for manufacturing
3) Personalized topical therapeutics
4) Combination with other technologies
5) Green formulation

CONCLUSION:

Proniosomes are a robust, flexible provesicular platform that meaningfully addresses many limitations of hydrated vesicular systems for topical and other routes of delivery. They combine improved storage stability, tunable release, enhanced permeation and compatibility with scalable manufacturing techniques. Recent innovations including elastic and nano-proniosomes, hybrid microneedle systems, and industrial spray-coating have broadened their therapeutic relevance from dermatology and pain management to ocular, vaccine and targeted anticancer applications. To fully realize clinical potential, focused work on large-scale manufacturing standards, regulatory pathways, and well-designed clinical studies is required. With those hurdles addressed, proniosomes are well poised to become a mainstream platform for advanced topical and targeted drug delivery.

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Cite: Jeevan Kore*, Mahesh Kore, Shraddha Kothale, Shweta Mohite, Advances in Proniosome-Based Topical Drug Delivery: Formulation and Therapeutic Potential, Int. J. Med. Pharm. Sci., 2025, 1 (12), 34-43. https://doi.org/10.5281/zenodo.17958977