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Review Paper

Niosomal Drug Delivery Systems: Emerging Trends in Dermatological Applications

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ABSTRACT

Dermatological disorders such as acne, psoriasis, eczema, and fungal infections remain major global health concerns, often requiring long-term therapy. Conventional topical formulations face significant challenges, including poor skin penetration, rapid drug degradation, and low patient compliance. To overcome these limitations, nanocarrier-based delivery systems have emerged as promising alternatives. Among these, niosomes—vesicular carriers composed of non-ionic surfactants and cholesterol—have attracted considerable attention due to their biocompatibility, stability, and ability to enhance dermal drug delivery. Recent studies demonstrate that niosomes can improve skin retention, sustain drug release, and protect labile molecules, making them highly suitable for dermatological applications. This review highlights the structural aspects, preparation methods, and advantages of niosomes, with a particular focus on their role in treating various skin conditions. Comparative insights with other vesicular systems, current challenges, and future directions for clinical translation are also discussed. Overall, niosomes represent a versatile and effective platform with strong potential to advance the field of topical and transdermal drug delivery.

INTRODUCTION

Dermatological disorders, including acne, psoriasis, atopic dermatitis, fungal infections, and others, impose significant burdens worldwide in terms of morbidity, psychological impact, and health-care costs. Conventional topical therapies such as creams, ointments, lotions, and gels are often limited by poor drug penetration across the skin barrier, rapid drug degradation, low drug retention, frequent dosing requirement, and poor patient adherence (1,2,3).

The skin's stratum corneum (SC) is the principal barrier to drug permeation; its lipid-rich intercellular matrix particularly restricts hydrophilic or large molecule penetration (4,5). Moreover, many active pharmaceutical

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ingredients are chemically unstable or suffer from low solubility, limiting their formulation into conventional vehicles without loss of efficacy or premature degradation (6,7). Additionally, factors such as irritation potential, cosmetic acceptability, and vehicle-related discomfort can further reduce patient compliance (8).

To overcome these limitations, advanced drug delivery systems have been pursued. Among these, nanocarriers (including liposomes, solid lipid nanoparticles, nanoemulsions, polymeric nanoparticles, micelles, ethosomes, etc.) have shown promise for enhancing skin permeation, improving drug stability, enabling sustained or controlled release, and achieving targeted delivery (9,10,11). Reviews have reported that nanoparticles, when properly designed (size, charge, hydrophobicity, surface functionalization), can enhance permeation through the SC, accumulate in specific layers of skin (epidermis, dermis), and reduce systemic side-effects while improving local therapeutic outcomes (12,13,14).

Vesicular systems in particular — such as liposomes and niosomes — offer further advantages. Niosomes are non-ionic surfactant based vesicles, often combined with cholesterol, which are more stable, less expensive, and can be easier to scale than some lipid-based vesicles. Their bilayer structure allows entrapment of both hydrophobic and hydrophilic actives, protecting labile molecules from degradation, and enabling sustained or controlled release (15,16).

Film-forming systems (films, film-forming gels, patches, etc.) are another promising vehicle class. They provide continuous contact with the skin, reduce loss of active ingredient (by evaporation or rubbing off), and can improve patient adherence by reducing dosing frequency and improving cosmetic acceptability (17,18). However, despite many promising preclinical studies, translation to clinical practice remains limited. Many nano-formulations face challenges in reproducibility, scale-up, regulatory approval, stability under storage conditions, skin irritancy, and cost of goods (19,20). There is also a lack of comprehensive comparative studies among different vesicular systems, especially in context with herbal bioactives. With this background, the present review focuses on niosomal drug delivery systems in dermatological applications, exploring their fundamentals, advantages, current applications (including anti-acne therapy), challenges, and future directions.

2. Niosomes: Fundamentals

2.1 Structure and Composition

Niosomes are vesicular, bilayered nanocarriers made primarily of **non-ionic surfactants** and **cholesterol**, often with **charge-inducing agents** and a **hydration medium** to stabilize the vesicle and tune its properties (21,22,23). The bilayer structure consists of hydrophobic tails inward, hydrophilic heads outward, forming an aqueous core that can encapsulate hydrophilic actives, while hydrophobic compounds may be embedded in the bilayer membrane (22,23).

Key components include:

- **Surfactants**: such as spans, tweens, alkyl ethers, alkyl glycosyl ethers etc. The type (chain length, polarity) as well as hydrophilic-lipophilic balance (HLB) of surfactants influence vesicle formation, stability, encapsulation efficiency, release profile and skin penetration. (22,24,25)
- **Cholesterol** (or other lipids) to increase rigidity and stability of the bilayer; its presence reduces leakage and improves vesicle integrity (21,23,26).
- **Charge inducers (charge modifiers)**: agents such as dicetyl phosphate, stearylamine etc., used to impart surface charge, improve colloidal stability (reduce aggregation),

influence zeta potential, and thus affect the interaction with skin and drug release behaviour (22,27).

- **Hydration medium**: aqueous buffers or other media; the pH, ionic strength, and inclusion of stabilizers or preservatives can affect niosome formation and stability (22,28).

Other structural parameters include vesicle size (small unilamellar, large unilamellar, multilamellar), lamellarity, bilayer thickness, surface charge (zeta potential), and the encapsulation capacity. These properties are significantly affected by the choice and ratio of surfactant:cholesterol, as well as preparation method (22,29).

2.2 Methods of Preparation

Several methods are used for preparing niosomes; each has its advantages and limitations depending on the active molecule, desired vesicle size, encapsulation efficiency, scale, and cost. Important methods include:

Method	Principle / Steps	Advantages	Limitations
Thin-film hydration (hand-shaking)	Surfactant + cholesterol dissolved in organic solvent → solvent evaporated to form thin film → film hydrated with aqueous phase containing drug to yield vesicles; often followed by sonication or extrusion to reduce size. (22,23,30)	Good entrapment, relatively simple; lamellarity adjustable; widely used in lab scale. (22,30)	Use of organic solvents; possible residual solvent; size control less precise; lamellarity may lead to larger vesicles.
Reverse-phase evaporation	Organic phase (surfactant + cholesterol + maybe drug) emulsified with aqueous phase, then organic solvents removed under vacuum leading to formation of large unilamellar vesicles (LUVs). (22,31)	Higher encapsulation of hydrophilic drugs; suitable for a variety of actives.	More complex; organic solvent removal critical; possible solvent residual; scale-up challenging.
Ethanol (or solvent) injection	Injection of surfactant + cholesterol solution in ethanol (or other solvent) into aqueous phase → spontaneous vesicle formation. (22,32)	Simpler; faster; fewer steps; good for small unilamellar vesicles.	Organic solvent use; maybe smaller encapsulation efficiency; size and polydispersity somewhat harder to control.
Sonication / Probe or Bath Ultrasonication	After initial hydration or mixing, applying ultrasound (bath or probe) to reduce size and polydispersity. (22,33)	Produces small size vesicles; useful for reducing multilamellarity; lower cost equipment.	Heat generation may degrade sensitive drug; possible damage to structure; limited control over exact size distribution.
Microfluidics / Controlled mixing methods	Using microfluidic channels or flow-focussed mixing to control vesicle formation via precise control of flow rates and mixing. (22,34)	Excellent size control; reproducibility; amenable to scale-up; lower polydispersity.	Require specialized equipment; initial cost; optimization needed per formulation.
Bubble method	Dispersing surfactant + cholesterol in buffer, then bubbling nitrogen gas or another inert gas, sometimes with heating, to form vesicles (solvent-free or low solvent). (22)	Fewer/without organic solvents; simpler; potentially more biocompatible.	Less researched; scalability and reproducibility less established; control over size/polydispersity limited.

Method	Principle / Steps	Advantages	Limitations
Heating method	Heating mixture of surfactants, cholesterol, and drug/hydration medium to above gel-transition temperature or melting point, sometimes with agitation, to form vesicles. (22)	Simpler; applicable when drug is heat stable; fewer solvents; can be low cost.	Not suitable for heat-sensitive actives; potential degradation; size may be large; stability issues.

2.3 Key Factors Affecting Niosome Properties

Some of the critical formulation/processing variables include:

- **Surfactant:cholesterol ratio**: More cholesterol increases rigidity, reduces leakage, but too much can reduce flexibility or encapsulation especially of hydrophilic actives. (21,29)
- **Type of surfactant** (chain length, HLB, saturation) — hydrophobic tail length and structure impact bilayer packing and permeability. (22)
- **Charge-inducer presence and amount**: Offers electrostatic stabilization; surface charge can influence aggregation, skin interaction, and release behaviour. (22,27)
- **Hydration medium properties**: pH, ionic strength, buffer type; may affect drug stability, vesicle swelling or collapse.
- **Processing parameters**: Sonication time and intensity, temperature during film formation or hydration, solvent evaporation rate, flow rates in microfluidics; all affect size, polydispersity (PDI), encapsulation efficiency. (22,34)

3. Advantages of Niosomes in Dermatological Applications

Niosomes offer several compelling advantages for skin drug delivery, which make them particularly well-suited for treatments like acne, inflammatory dermatoses, cosmetic therapy and anti-aging. Key advantages include:

3.1 Enhanced Skin Penetration and Retention

- Niosomes can improve skin penetration of both hydrophilic and lipophilic drugs by interacting with the stratum corneum lipids, disrupting intercellular lipid packing, and providing a lipidic vesicular pathway for permeation. (35)
- They tend to increase drug retention in the epidermis and dermis, thereby allowing more localized drug action and possibly reducing systemic absorption and side effects. (36,37)

3.2 Improved Stability and Protection of Labile Actives

- Encapsulation within the bilayer or aqueous core protects drugs from environmental degradation (oxidation, photodegradation, hydrolysis). (38)
- Herbal bioactives (e.g. polyphenols, flavonoids) that are prone to instability benefit particularly, as studies show niosomes help preserve their bioactivity. (39)

3.3 Controlled / Sustained Release

- Niosomal formulations can provide controlled or sustained release profiles, avoiding rapid burst release, which helps in reducing dosing frequency and improving patient compliance. (36,40)
- This slower release also means more stable drug levels in the skin over time, enhancing therapeutic outcomes. (37)

3.4 Biocompatibility, Low Toxicity and Cost-Effectiveness

- Non-ionic surfactants used in niosome formation are generally less irritating and more biocompatible compared to some ionic vesicular systems. (40)
- Compared to liposomes, niosomes are more chemically stable (phospholipids in liposomes are prone to oxidation), and less expensive to manufacture. (35,38)

3.5 Versatility in Encapsulation of Different Types of Actives

- Niosomes can encapsulate hydrophilic, lipophilic, and amphiphilic molecules effectively, allowing broad flexibility in drug/active choice. (35,36)
- They are also useful for botanical or herbal actives, peptides, small molecules, and other therapeutic agents. (39,40)

3.6 Cosmetic Acceptability, Aesthetics and Patient Compliance

- Since niosomal systems can reduce irritation (by controlled release and by protecting skin from high local concentration), improve texture, reduce greasiness, and improve retention on skin, they may be more cosmetically acceptable. (36)
- Film-forming or gel vehicles incorporating niosomes can further aid in adherence, reduce frequency of application, and maintain contact with skin. (37)

4. Comparative Insights

Niosomes are often compared with other vesicular drug delivery systems such as liposomes, transfersomes, ethosomes, and solid lipid nanoparticles (SLNs). Their performance differs across parameters such as skin penetration, stability, drug release, and cost.

4.1 Niosomes vs Liposomes

Niosomes are generally more chemically stable than liposomes, since non-ionic surfactants are less prone to oxidative degradation compared with phospholipids (41). Liposomes may provide better fusion with skin lipids due to their phospholipid composition, but they are expensive and less stable on storage (42). Some studies report liposomes offer higher skin flux, while niosomes tend to retain drugs in the epidermis and superficial dermis (42).

4.2 Niosomes vs Transfersomes, Ethosomes, and SLNs

Transfersomes, due to their high deformability, can squeeze through narrow intercellular channels in the stratum corneum, often outperforming niosomes in penetration depth, though with stability concerns (43). Ethosomes, enriched with ethanol, enhance penetration but may cause irritation; in contrast, niosomes are safer but provide more superficial delivery (44). SLNs, with occlusive and hydrating effects, can sometimes deliver hydrophilic compounds more efficiently than niosomes (42).

4.3 Clinical Effectiveness

A clinical study on **dapsone-loaded niosomes** showed improvement in acne patients after 8 weeks, with minimal irritation, highlighting translational potential (45). Other reports confirm niosomes enhance antibacterial drug deposition in the skin while maintaining safety (46).

4.4 Limitations

While niosomes are cost-effective and stable, they often achieve less deep penetration compared with transfersomes or ethosomes. Optimization of surfactant type, cholesterol ratio, and vesicle size is critical to balance drug entrapment and penetration (41,42).

5. Challenges and Future Perspectives

Despite significant progress, the clinical translation of niosomal drug delivery systems in dermatology remains limited. Several challenges need to be addressed:

5.1 Scale-Up and Manufacturing

Most reported niosomal formulations are developed at laboratory scale. Transitioning to industrial-scale production poses challenges in terms of reproducibility, cost, and maintaining vesicle uniformity. Conventional methods such as thin-film hydration and sonication are not easily scalable (47,48). Advanced techniques like microfluidics offer better control but require specialized equipment and validation (49).

5.2 Stability Issues

Although niosomes are more stable than liposomes, instability can still arise from vesicle aggregation, fusion, leakage of encapsulated drug, or hydrolysis of surfactants. Long-term storage stability, particularly for herbal actives like flavonoids, remains a concern (50,51). Lyophilization and use of stabilizers may improve shelf-life but add complexity and cost (52).

5.3 Safety and Skin Irritation

While generally biocompatible, some surfactants may induce irritation or allergic reactions upon prolonged topical application. High concentrations of cholesterol or charge-inducing agents may alter skin tolerance (53). Systematic toxicological and dermatological safety studies are still scarce (54).

5.4 Regulatory and Translational Barriers

Regulatory approval of nanocarrier-based dermatological formulations is complex. Issues such as classification (cosmetic vs therapeutic), lack of standardized testing protocols, and absence of harmonized guidelines hinder market entry (55). Moreover, few clinical trials have been conducted, limiting clinical evidence (56).

5.5 Patient-Centric Considerations

Formulation must not only be effective but also cosmetically acceptable. Patient adherence depends on non-greasy textures, absence of odor, ease of application, and reduced dosing frequency (57). Integration of niosomes into film-forming gels and patches may help address compliance concerns (58).

5.6 Future Perspectives

Future research should focus on:

- **Hybrid systems**: e.g., niosomes embedded in hydrogels, microneedle-assisted delivery, or stimuli-responsive vesicles for precision therapy (59,60).
- **Herbal actives**: Given the growing interest in natural agents (e.g., baicalin, curcumin, resveratrol), niosomes can provide improved stability and targeted delivery (61).
- **Personalized medicine**: Incorporating AI-driven design, 3D printing, and patient-specific formulations for dermatology.
- **Clinical validation**: Large-scale, randomized clinical trials are urgently required to confirm efficacy and safety.

Overall, while niosomes show strong potential for advancing dermatological therapy, overcoming these scientific, regulatory, and translational hurdles will determine their successful clinical adoption.

CONCLUSION

Niosomes represent a versatile and effective drug delivery platform with significant potential in dermatological therapy. Their ability to enhance skin penetration, sustain drug release, protect

labile compounds, and encapsulate a wide range of actives makes them particularly suitable for conditions such as acne, psoriasis, fungal infections, and inflammatory skin disorders. Compared with conventional formulations, niosomes offer improved therapeutic outcomes and better patient compliance, while also being more stable and cost-effective than many other vesicular systems. despite encouraging laboratory and preclinical results, translation into routine clinical use remains limited. Challenges related to large-scale manufacturing, stability during storage, regulatory approval, and comprehensive clinical validation must be addressed before widespread adoption can occur. Looking forward, integrating niosomes into advanced delivery systems such as film-forming gels, microneedle platforms, and hybrid nanocarriers offers exciting opportunities. With continued innovation, clinical research, and regulatory support, niosome-based formulations have the potential to transform dermatological therapy and bring safer, more effective, and patient-friendly treatments to market.

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