



Invasomes: A Novel Vesicular Nanocarrier for Transdermal Drug Delivery – A Comprehensive Review

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ABSTRACT:

Invasomes are emerging as a promising class of vesicular drug delivery systems designed to overcome the formidable barrier posed by the stratum corneum in transdermal drug delivery. These soft, deformable lipid vesicles are composed of phospholipids, ethanol, and terpenes, which synergistically enhance both carrier flexibility and skin permeability. Compared with conventional liposomes and ethosomes, invasomes exhibit superior penetration into and through the skin, enabling improved local or systemic delivery of poorly permeable drugs. This review article summarizes the structure, composition, and mechanisms of action of invasomes, highlights major preparation techniques, discusses critical physicochemical and biological characterization parameters, and outlines current therapeutic applications and translational prospects, including formulation and regulatory considerations. The compilation aims to consolidate available knowledge and identify key research gaps and future directions for invasome based drug products.

Key Words: Invasomes, Nanocarrier, drug delivery systems, ethosomes

Introduction:

Transdermal drug delivery systems (TDDS) offer several advantages over conventional oral and parenteral routes, including avoidance of firstpass metabolism, relatively steady drug levels, improved patient compliance, and reduced systemic toxicity. 1–3 However, the outermost layer of the skin, the stratum corneum (SC), acts as a highly effective barrier that severely limits the permeation of most drugs, especially hydrophilic and high molecular weight molecules. 2,4

To overcome this barrier, various physical and chemical methods have been explored, including iontophoresis, microneedles, ultrasound, and use of chemical penetration enhancers.^{4–6} among these, nanovesicular carriers such as liposomes, niosomes, and ethosomes have gained attention for their ability to modulate drug partitioning and diffusion across the skin. Within this class, invasomes have emerged as a next generation vesicular system that combines the advantages of lipid vesicles with the permeation enhancing properties of ethanol and terpenes. 1,3,7

This review aims to provide a comprehensive overview of invasomes as a novel nanocarrier system for transdermal delivery. It covers their structural and compositional features, mechanisms of skin penetration, methods of preparation, key physicochemical and biological characterization parameters, therapeutic applications, and future prospects with regulatory considerations.

2. Concept and Historical Background

The concept of invasomes was introduced as an evolution of traditional liposomes and ethosomes, aiming to address limitations in deformability and skinpenetration efficiency. 1,3,7 Early liposomal systems were found to be relatively rigid and poorly deformable, which restricted their ability to squeeze through the dense lipid matrix

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of the stratum corneum. 1,7 Ethosomes, which incorporate high concentrations of ethanol into the lipid bilayer, improved flexibility and skin penetration but still showed limitations in stability and penetration enhancement for certain drug classes. 3,7

Invasomes were developed by combining the vesicular architecture of liposomes with permeation enhancing components such as terpenes and ethanol, thereby creating a more flexible, deformable, and penetration efficient vesicular system. Early studies demonstrated that invasomes could significantly increase the transdermal flux of model drugs compared with conventional liposomes and ethosomes, sparking interest in their use for both dermatological and systemic delivery applications. 1,3,7

3. Structure and Composition

Invasomes are soft, deformable lipid vesicles composed of three main components:

1. **Phospholipids** (e.g., phosphatidylcholine) that form the vesicular bilayer.
2. **Ethanol**, which modulates membrane fluidity and assists in drug solubilization.
3. **Terpenes** (e.g., limonene, menthol, cineole), which act as potent penetration enhancers.

Some formulations may also include lysophospholipids or other surfactants to further optimize vesicle flexibility and drug loading. 5,7 The overall composition is typically an aqueous dispersion of spherical or near spherical vesicles with a diameter generally in the nanometer range (100–300 nm), although particle size can be tuned by changing lipid concentration, sonication time, and solvent composition.

The vesicular structure allows encapsulation of both hydrophilic drugs in the aqueous core and lipophilic drugs within the lipid bilayer, making invasomes suitable carriers for a wide range of therapeutic agents. The presence of ethanol and terpenes imparts greater fluidity and elasticity to the bilayer, enabling the vesicles to deform and penetrate the intercellular lipid domains of the stratum corneum more efficiently than conventional liposomes. 1

4. Mechanism of Skin Penetration

The superior skin penetration of invasomes is attributed to a combination of vesicle deformation, lipid fluidization, and skin barrier modulation. 1,3,5,7 Several mechanisms have been proposed:

1. **Deformability and “vesicle squeezing”:** The soft, flexible nature of invasomes allows them to deform and traverse the tortuous intercellular lipid pathways of the stratum corneum, similar to, but more efficient than, ethosomes.
2. **Lipid fluidization:** Ethanol and terpenes intercalate into the lipid bilayers of both the vesicles and the SC, increasing membrane fluidity and reducing the packing order of lipids, thereby facilitating drug diffusion.
3. **Disruption of lipid and protein organization:** Terpenes can disrupt the supramolecular organization of intercellular lipids and keratin domains, further weakening the barrier function of the SC.
4. **Enhanced partitioning:** The ethanol–terpene mixture can increase the solubility and partitioning of drugs into the lipid domains of the skin, promoting higher local drug concentrations.

In addition, invasomes may reach deeper skin layers (e.g., dermis) and can even facilitate systemic absorption when designed for systemic delivery, while still offering the potential for localized action with reduced systemic exposure.

5. Methods of Preparation

Several preparation methods have been reported for invasomes, all of which aim to produce stable, homogeneous vesicular dispersions with controlled size and lamellarity. 1,3,10 Common techniques include:

1. **Film hydration method:** Phospholipids and terpenes are dissolved in an organic solvent, the solvent is evaporated to form a thin lipid film, and the film is hydrated with an aqueous buffer containing ethanol and dissolved drug. The dispersion is then subjected to sonication or extrusion to achieve desired vesicle size.

2. **Handshaking / mechanical dispersion:** Lipids are dispersed in an ethanol–terpene–aqueous mixture by vigorous shaking or vortexing, followed by gentle agitation or mild sonication.
3. **Downscaling methods for pilot production:** For larger scale or preclinical preparation, high pressure homogenization or extrusion through polycarbonate membranes of defined pore size are used to produce uniform invasomal dispersions.

Parameters such as lipid concentration, ethanol content, terpene type and concentration, hydration temperature, and sonication time significantly influence vesicle size, polydispersity, and entrapment efficiency, and must be optimized for each drug. 1,3,10

6. Physicochemical Characterization

Standard characterization of invasomes includes evaluation of the following parameters:

1. Vesicle size and polydispersity index (PDI): Typically measured by dynamic light scattering (DLS); invasomes are generally in the range of 100–300 nm with low PDI when optimally prepared.
2. Zeta potential: Indicates surface charge and colloidal stability; values are often in the moderately negative range (–10 to –30 mV), depending on lipid and surfactant composition.
3. Morphology: Transmission electron microscopy (TEM) or scanning electron microscopy (SEM) confirms spherical or near spherical vesicles with a closed bilayer structure.
4. Entrapment efficiency (EE): Determined by separating untrapped drug (e.g., via dialysis, centrifugation, or ultrafiltration) and quantifying the remaining encapsulated drug; EE can often exceed 70–80% for suitable drugs. 1,
5. pH and osmolality: Adjusted to ensure skin compatibility and stability.

In addition, thermodynamic stability (e.g., by centrifugation, freeze–thaw cycles, or storage under different conditions) and invitro release (e.g., using dialysis or Franz diffusion cells) are evaluated to predict invivo performance.

7. InVitro and InVivo Evaluation

Invitro evaluation of invasomes typically involves:

1. **Exvivo skin permeation studies:** Using animal or human skin in Franz diffusion cells to compare drug flux, permeability coefficient, and cumulative amount permeated through invasomal formulations versus control liposomes, ethosomes, or drug solutions.
2. **Skin retention studies:** Quantifying drug deposited in different skin layers (stratum corneum, epidermis, dermis) to assess potential for localized therapy.

Invivo studies (animal models and, in some cases, human volunteers) have demonstrated:

1. Enhanced transdermal flux and higher relative bioavailability compared with conventional vesicular systems and drug solutions.
2. Favorable pharmacokinetic profiles, including prolonged release and reduced peak plasma concentrations, which may lower systemic side effects.

For example, invasomal formulations of drugs such as avanafil and other model compounds have shown severalfold higher bioavailability than conventional transdermal films or solutions, highlighting their potential for systemic delivery.

8. Therapeutic Applications

Invasomes have been explored for a wide range of therapeutic applications, both dermatological and systemic:

8.1 Dermatological and Cosmeceutical Uses

Invasomes are particularly suitable for localized treatment of skin disorders such as:

1. Psoriasis, eczema, and atopic dermatitis (delivery of corticosteroids, calcineurin inhibitors, or anti inflammatory agents).
2. Acne and bacterial infections (delivery of antibiotics or retinoids).
3. Skin cancer and premalignant lesions (delivery of chemotherapeutic or photodynamic agents).
4. Wound healing and scar modulation (delivery of growth factors or anti inflammatory agents).

By enhancing drug retention in the epidermis and dermis while limiting systemic absorption, invasomes can increase local efficacy and reduce systemic adverse effects.

8.2 Systemic Delivery

Invasomes have also been investigated for systemic delivery of drugs via the transdermal route, including:

1. Antihypertensive agents
2. Nonsteroidal anti-inflammatory drugs (NSAIDs)
3. Hormones and erectile dysfunction drugs (e.g., avanafil)

Transdermal invasomal formulations can circumvent first pass metabolism and gastric degradation, thereby improving oral bioavailability limited drugs and offering more stable plasma levels.

8.3 Cosmetic and Anti Aging Applications

Terpene containing invasomes are also being explored in cosmetic formulations for delivery of antioxidants, vitamins, and moisturizing agents into deeper skin layers, potentially improving skin hydration, elasticity, and antiaging effects.

9. Advantages and Limitations

9.1 Advantages

1. Enhanced skin penetration compared with conventional liposomes and ethosomes.
 2. Deformability and flexibility, allowing easier passage through intercellular lipid pathways.
 3. Dual functionality (local and systemic delivery) depending on formulation design.
- Biocompatibility and biodegradability of phospholipids and many terpenes, which are often derived from natural sources.
 - Potential for reduced systemic toxicity by localizing drug action in the skin.

9.2 Limitations

1. Ethanol related skin irritation at higher concentrations, necessitating careful optimization.
2. Terpene induced sensitization or contact dermatitis in some individuals.
3. Formulation stability challenges, including vesicle aggregation, leakage, and oxidation of unsaturated lipids or terpenes.
4. Scaleup and manufacturing complexity, particularly for maintaining consistent vesicle size and drug loading.

10. Safety and Toxicity Considerations

Available invitro and invivo studies suggest that invasomes are generally well tolerated, but local irritation and sensitization potential must be evaluated case by case. Preclinical safety assessments typically include:

1. Invitro cytotoxicity (e.g., on keratinocytes or fibroblasts).
2. Exvivo skin irritation tests (e.g., transepidermal water loss, histopathology).
3. Invivo irritation and sensitization studies in animal models and, eventually, human volunteers.

Ethanol and certain terpenes can act as irritants at high concentrations, so selection of safe terpene types and concentrations, along with appropriate vehicle design, is crucial to maintain invasome efficacy without compromising skin safety.

11. Regulatory and Translational Aspects

Despite promising preclinical data, invasomes have not yet reached widespread clinical use, and regulatory pathways for invasome based products are still evolving. 6,9 Key considerations include:

1. Classification as an advanced drug delivery system or novel excipient, which may require additional stability, safety, and efficacy data.
2. Quality control of critical quality attributes (CQAs), including vesicle size, EE, zeta potential, and sterility/endotoxin levels for parenteral or high risk products.
3. Scaleup and manufacturing validation under current Good Manufacturing Practice (cGMP) standards.
4. Clinical trial design to demonstrate safety, localized or systemic efficacy, and benefit over existing transdermal formulations.

Several recent reviews highlight that invasome technologies hold high translational potential, but interdisciplinary collaboration between formulation scientists, clinicians, and regulatory experts is required to bridge the gap from bench to bedside.

12. Current Research Trends and Future Directions

Current research on invasomes is focused on:

1. Optimization of terpene combinations and ethanol levels to balance penetration enhancement with skin safety.
2. Surface modified or hybrid invasomes (e.g., polymercoated or hybrid invasome niosome systems) to further improve stability and targeting.
3. Combination with physical enhancement techniques (e.g., microneedles or iontophoresis) to achieve synergistic penetration enhancement.
4. Targeted delivery to specific skin compartments (e.g., hair follicles, sebaceous glands) for diseases such as acne or alopecia.

Future directions may include:

1. Personalized transdermal delivery based on individual skin physiology and disease state.
2. Artificial intelligence assisted formulation design to optimize invasome composition and performance.
3. Expansion into vaccine delivery and gene therapy via the skin, leveraging invasome mediated penetration into immune rich skin layers.

12.1 Comparative Positioning of Invasomes among Vesicular Carriers

Invasomes should be compared with other carriers according to the drug, target skin layer, and intended therapeutic effect. Conventional liposomes can encapsulate hydrophilic and lipophilic agents but may show limited passage through intact stratum corneum because they lack strong penetration-enhancing components. Ethosomes use ethanol to increase lipid fluidity and skin permeation. Transfersomes generally incorporate edge

activators to increase deformability, whereas niosomes use non-ionic surfactants and may offer cost or stability advantages depending on composition. Invasomes combine phospholipids with ethanol and terpenes; the added terpene component can further modify skin-lipid organization. These systems are not universally interchangeable: performance depends on drug properties, excipient concentrations, and the intended local or systemic effect. Direct head-to-head studies using the same drug, dose, vehicle, skin model, and analytical method are needed before declaring one carrier superior.

12.2 Formulation Design and Optimization

Invasome development should begin with a target product profile: intended site of action, desired skin depth, dose, release duration, dosage form, and acceptable irritation risk. Critical formulation variables include phospholipid identity and concentration, ethanol proportion, terpene identity and level, drug-to-lipid ratio, hydration conditions, and any stabilizer or coating. These variables can interact; increasing ethanol or terpene content may improve permeation up to a point but can also increase irritation, drug leakage, or vesicle instability. Design-of-experiments approaches, such as factorial designs or response-surface methods, can evaluate interactions more efficiently than changing one variable at a time. Responses should include vesicle size, polydispersity index, entrapment efficiency, drug content, release, skin flux, skin retention, and tolerability. The optimum formulation should balance performance and safety rather than maximize permeation alone.

12.3 Advanced Characterization and Quality by Design

Dynamic light scattering provides hydrodynamic size and polydispersity, but results should be interpreted alongside sample dilution, dispersant, temperature, and instrument settings. Microscopy supports morphology assessment, while zeta-potential measurements indicate surface charge but do not independently prove long-term stability. Entrapment efficiency should be measured with a validated separation method that minimizes vesicle disruption and distinguishes encapsulated drug from free or surface-associated drug. Additional useful tests include differential scanning calorimetry or spectroscopy to investigate component interactions; deformability or extrusion tests where appropriate; in-vitro release; and assay of drug content and degradation products. Stability studies should monitor size distribution, aggregation, leakage, pH, appearance, potency, and oxidation or hydrolysis of susceptible lipids. Quality-by-design principles can connect material attributes and process parameters to critical quality attributes, supporting reproducibility during scale-up.

12.4 Interpreting Permeation Data and Translational Evidence

Franz diffusion-cell studies are useful for comparing formulations under controlled conditions, but results depend on skin source, anatomical site, integrity, storage history, receptor medium, temperature, dose, and sampling design. Reports should state cumulative amount permeated per unit area, steady-state flux where justified, lag time, permeability coefficient, and mass balance. Skin retention should be measured separately from drug that has crossed the skin, because high transdermal flux is not always desirable for a medicine intended to act locally. Human skin is preferable when feasible, while animal or reconstructed-skin models should be justified and their limitations acknowledged. In-vivo pharmacokinetic or efficacy findings should not be inferred from in-vitro release alone. Comparisons should use a relevant control, such as the same drug in a conventional gel or solution, and report variability and statistical analysis.

12.5 Recent Formulation Examples and What They Demonstrate

Recent reports illustrate the range of formulation work but also the need to distinguish proof of concept from clinical validation. A 2025 crisaborole-loaded invasomal gel study reported an optimized vesicle size of 185.65 nm and entrapment efficiency of $82.26 \pm 0.36\%$, with 96.65% in-vitro release over 12 hours; these are formulation and laboratory-release outcomes, not by themselves proof of improved patient outcomes [21]. A 2024 resveratrol-loaded invasome gel study explored topical delivery for skin-cancer applications, providing a preclinical direction that requires careful interpretation of the model and endpoints used [22]. A 2025 study of chitosan-coated tenoxicam invasomes investigated statistical optimization alongside in-vitro, ex-vivo, and in-

vivo assessments, illustrating interest in surface modification and multi-level evaluation [23]. Collectively, these examples suggest movement toward optimized gel systems and coated vesicles, but robust comparisons, independent replication, tolerability data, and well-designed clinical studies remain necessary.

12.6 Research Gaps and Priorities

Several issues should be addressed before invasomes can be considered routine pharmaceutical platforms. First, mechanistic studies should distinguish intact-vesicle transport from vesicle disruption followed by diffusion of released drug and penetration enhancers. Second, standardized methods and reporting are needed so results from different laboratories can be compared. Third, the long-term effects of repeated exposure to ethanol and individual terpenes require systematic assessment, including irritation, sensitization, barrier recovery, and effects on diseased skin. Fourth, stability-indicating methods and scalable manufacturing processes must be established for batches with reproducible size distribution, drug loading, and release. Finally, clinical development should define a meaningful comparator and demonstrate an advantage in efficacy, safety, convenience, or adherence. Recent reviews identify stability, excipient safety, manufacturing, and regulatory requirements as major translational challenges [24,25].

12.7 Review Scope and Evidence Limitations

This article is a narrative review rather than a registered systematic review. The cited studies represent selected literature and should not be interpreted as an exhaustive or quantitatively pooled evidence base. Differences in drug molecules, terpene composition, vesicle preparation, skin models, and outcome measures limit direct comparisons across studies. Future reviews would benefit from a transparent database-search strategy, predefined inclusion criteria, duplicate screening, risk-of-bias assessment, and evidence tables separating in-vitro, ex-vivo, animal, and human findings.

14. Conclusion

Invasomes represent a promising class of vesicular nanocarriers for transdermal drug delivery, combining the structural advantages of liposomes with the permeation enhancing properties of ethanol and terpenes. Their soft, deformable nature allows efficient penetration through the stratum corneum, enabling enhanced local and systemic delivery of a wide range of drugs. While several challenges related to stability, irritation potential, and regulatory approval remain, ongoing research and technological advances are paving the way for invasome based formulations to become viable clinical options. With further optimization and rigorous clinical evaluation, invasomes may play a significant role in the future of noninvasive, patient friendly drug delivery systems.

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