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A REVIEW ON ETHOSOMES PROMISING AS NOVEL DRUG DELIVERY SYSTEMS

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Abstract

Ethosomes are new lipid-based vesicular carriers that improve medication penetration across the stratum corneum due to their high ethanol concentration. Because of this special characteristic, ethosomes may efficiently transport hydrophilic and lipophilic medications via topical or transdermal routes deep into the skin or even into the systemic circulation. Improved skin penetration, adaptability in drug loading, and biocompatibility are only a few benefits of ethersomes. Vesicle stability issues, such phospholipid oxidation and vesicle fusion during storage, are still problematic, nevertheless. To describe ethosomal formulations and guarantee their quality, effectiveness, and safety as drug delivery vehicles, a range of assessment techniques are used.

Keywords: Ethosomes, vesicular carriers, skin permeation, transdermal drug delivery, topical application, phospholipids, ethanol, drug delivery systems, stability, characterization.

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Introduction

The administration of systemic and topical medications, the skin is the most comprehensive and versatile administration route. The stratum corneum, which is the outermost layer of the skin, acts as the most lasting barrier to drug penetration in the skin. This barrier restricts the bioavailability of medication when it is applied topically when it is applied. Because of this, it is of the utmost importance to conduct research and comparisons on the numerous carriers that are required for systemic medicine delivery in order to get across the natural surface barrier of the skin [1]. In the field of drug delivery, innovative nanocarriers have demonstrated a great amount of potential. Pharmacological complexes known as ethosomes are created when a medicine is combined with a carrier, which is often an alcohol or a derivative of alcohol. This carrier is comprised of an active alcohol component, which, in comparison to standard liposomes, offers superior permeability and drug loading capability [2]. Ethosomes are a type of advanced vesicular delivery system that are based on lipids. In contrast to traditional liposomes, ethosomes include a high amount of ethanol, which increases their flexibility and their ability to penetrate the skin. Ethosomes are predominantly utilized in the pharmaceutical industry for the purpose of enhancing transdermal drug delivery for both localized and systemic therapeutic effects. Additionally, they are being investigated for usage in the cosmetics industry with the intention of enhancing the penetration of active chemicals into the top layers of the skin. In comparison to other types of vesicular systems, such as liposomes, which function as a penetration enhancer, ethosomes have a greater ethanol concentration, which causes them to have an effect on the intracellular level in the stratum corneum [3]. It is significant because ethosomes contain a large percentage of ethanol (usually between 20 and 45 percent) in addition to phospholipids and water. Ethosomes are lipid vesicles that are extremely efficient, highly sophisticated, and highly flexible. Ethosomes were developed to overcome the limits of conventional vesicular carriers. They make it possible to improve the transport of hydrophilic and lipophilic medicines through the dermis and transdermal routes. Initially presented by Touitou in 1997, ethosomes have developed into an essential component in the administration of drugs both

topically and systemically. They have uses in a wide variety of industries, including cosmetics, medicines, and more. Due to the fact that they are able to escape the strong barrier qualities of the stratum corneum, they are now the topic of research and therapeutic attention [4-5].

Benefits of Ectosomes [6-7]

Improved Skin Permeation

Drugs can be delivered deeper into the skin and circulated throughout the body thanks to the stratum corneum being fluidised by a high ethanol content.

Versatility

Exceeds the constraints of molecular weight and solubility, making it appropriate for a wide range of medications, including peptides, proteins, and macromolecules.

Non-Toxic, Biocompatible

Ethamomes, which are made of GRAS materials, have outstanding safety profiles that lower the possibility of negative reactions.

High Patient Compliance

Ethosomal medications, which are often made into gels or creams, provide a practical, non-invasive way to administer treatment.

Easy and Scalable Manufacturing

The techniques used for preparation are simple and flexible enough to be used in large-scale manufacturing.

Passive and Non-Invasive

The system is easily commercialized because it does not require iontophoresis or phonophoresis.

Stability and Efficiency: Because ethanol causes vesicular flexibility and negative charge repels aggregation, it exhibits high entrapment efficiency and stability.

Debenefits of Ectosomes [8-9]

Potential for Irritation

Ethanol may irritate or cause dermatitis, especially in people with sensitive skin.

Formulation Restrictions

Unsuitable for medications requiring large dosages or having physicochemical properties that are inappropriate for skin penetration.

Low Yield & Cost Issues

Scaling up may result in a loss of yield; cost-effectiveness needs to be assessed individually.

Restricted to Dermal and Transdermal Use

Mostly acts topically or transdermally; systemic applications outside of these routes are minimal. Concerns about stability include the possibility of phospholipid oxidation or vesicle fusion during prolonged storage.

Excipient Safety

A thorough toxicological analysis is necessary for certain surfactants or enhancers used in sophisticated systems.

Structure [10-12]

Ethosomes are lipid vesicles that are very flexible and only a few nanometres wide.

Phospholipid Bilayer

This structure has vesicles that hold both hydrophilic (core) and lipophilic (bilayer) drugs.

High Ethanol Content

It gets into phospholipid bilayers, making them more fluid and flexible, and giving them a negative surface charge for stability.

Water Phase

Keeps the vesicle hydrated, which makes it easier for the core to get trapped.

Additives (Optional)

In advanced systems, cholesterol (for stability), surfactants, penetration enhancers, antioxidants, and targeting ligands are used. This special structure lets ethosomes change shape and move through narrow channels between cells in the skin, getting around the stratum corneum barrier that slows things down.

Methods of Preparation of Ethosomes [13-15]

1. Cold Method

- At room temperature, ethanol (and sometimes a polyol like propylene glycol) dissolves phospholipids, drugs, and other lipid parts.
- Add water (which has been heated to about 30°C) while stirring.
- To make vesicles smaller, they are sonicated or extruded.
- The product is kept in the fridge.

2. The hot method

- When phospholipids are mixed with water and heated to about 40°C, they become a colloidal solution.
- We mix ethanol and propylene glycol and heat them up separately.
- When the temperature reaches 40°C, the aqueous phase is added to the organic phase.
- Depending on how well it dissolves, the drug can be dissolved in water or ethanol.
- The process is finished with sonication/extrusion, and vesicles are kept in the fridge.

3. Classic Mechanical Dispersion

- In a round-bottom flask, phospholipids are mixed with organic solvents like chloroform and methanol in a 3:1 ratio.
- Rotary evaporation removes the solvent until only a thin film of lipid is left.
- A hydroethanolic solution with drugs in it is used to hydrate the film.
- Vesicles are made by gently stirring and rotating the mixture.

4. Injecting ethanol and other methods

- Lipids in the organic phase are injected into the water phase while mixing very hard. Sonication and/or extrusion determine the size of the final vesicle.

Mechanism of ethosomes

Advanced lipid-based nanocarriers called ethersomes have completely changed how hydrophilic and lipophilic medications are delivered topically and transdermally. Their distinct mode of action, which depends on the interaction of phospholipid vesicle structure and high ethanol content, accounts for their superior performance over conventional vesicular systems. The ethanol effect and the ethosome (vesicle) effect are the two synergistic phases that can be used to broadly summarise the mechanism [16-19].

1. The Effect of Ethanol

There are different varieties of them:

Damage to skin lipids

High quantities of ethanol (20–45%) in ethosomes modify the way the lipids are distributed in the stratum corneum, which is the outermost layer of skin that protects the body. Ethanol lowers the transition temperature and makes the lipids more fluid by interacting with the polar head groups of the lipid bilayers. This procedure makes the barrier less stiff and more porous, which also makes it less dense.

Better penetration

Ethanol is a strong substance that makes penetration easier. It not only makes pharmaceuticals more soluble in ethosomal vesicles, but it also increases thermodynamic activity, which creates a concentration gradient that drives the drug deeper into the skin. Ethanol breaks down the stratum corneum barrier, which makes it easier for vesicles and drugs that are inside them to get through.

How Ethosomes (Vesicles) Work

Vesicles that can bend and change shape easily

When ethanol gets inside ethomomes, the phospholipid bilayer becomes less stiff and more flexible. Ethosomes can bend and fit through the tiny gaps between skin cells, something many other vesicles can't do.

Release of drugs and fusion of vesicles

When they are inside or outside the stratum corneum, ethosomes vesicles might join with the lipid matrix of the skin. This fusion makes it possible for the carrying medicine to be released straight into the epidermis and maybe even the dermis, or in some formulations, into the systemic circulation. In short, ethosomes act as storage containers that release drugs in a controlled and long-lasting way to the right place.

Penetration between and inside cells

Confocal microscopy and molecular study show that ethosomes mostly use the intercellular lipid pathway to move across corneocytes without harming the cells. Some vesicles may break open and let their contents out as they penetrate deeper, while others may stay together, keeping the medicine under the skin for a longer time.

Looking at things from a thermodynamic and molecular point of view

- Ethosome treatment lowers the melting point (Tm) and enthalpy of lipids, which means that they are more fluid and less ordered.
- Ethosomes do not severely harm or delaminate the skin like harsh chemical enhancers do; instead, they make small, reversible changes that let things through while keeping the skin barrier's overall integrity, as shown by electron microscopy.

Applications of Ethosomes in Drug Delivery Systems

The capabilities of transdermal, cutaneous, and even systemic administration routes have been significantly increased by ethosomes which have become a crucial nanocarrier in drug delivery. They are effective tools for delivering a variety of medicinal medicines because of their special structure, which consists of a soft, flexible vesicle with a high ethanol content. Which are discussed as [20-23]

Transdermal Administration of Medicine

Enhanced Permeation and Controlled Release

Because ethanol disrupts lipids and fluidizes vesicles, ethersomes are especially well-known for helping to transport medications past the stratum corneum, the skin's primary barrier. This makes it possible for medications that are hydrophilic or lipophilic to penetrate deeper layers of the skin and, in certain cases, enter the bloodstream. When compared to more traditional carriers like liposomes and creams, drugs contained in ethosomes frequently exhibit better deposition, higher penetration, and sustained release.

For example:

Glimepiride ethosomes Films: Designed to help manage diabetes, these films effectively transport glimepiride and extend systemic medication levels while causing less side effects than oral treatment.

AceclofenacEthosomal Gels: Show better medication penetration and efficacy than conventional gels when used for localized pain and inflammation (such as arthritis).

Topical and Dermal Administration

Treatment of Skin Conditions: Ethosomes have shown promise in the management of microbial skin infections, alopecia, eczema, psoriasis, and acne. For conditions needing targeted and long-term treatment, their capacity to deposit medications in the epidermis and dermis is crucial.

For example:

Compared to conventional formulations, Acyclovir Ethosomal Gels have better treatment results for herpes

infections because of their increased bioavailability and deeper drug penetration.

Minoxidil Ethosomal Formulations: Improve hair follicle accumulation, offering an improved treatment for androgenic alopecia/baldness.

3. Skin-Based Systemic Delivery

Chronic Disease Management: Transdermal distribution of drugs for long-term systemic disorders where oral or injectable routes are difficult has been made possible via ethersomes. By avoiding first-pass metabolism, this tactic enhances patient adherence.

These consist of anti-cancer pharmaceuticals, antidiabetic compounds, cardiovascular meds, and hormones (insulin, testosterone, and oestradiol).

4. Macromolecule Delivery

Peptides, Proteins, and Genes: Because ethanol gives ethosomes their flexibility, macromolecules (peptides, proteins, and nucleic acids) that are typically challenging to administer transdermally can be transported. The application of ethosomal systems for the topical administration of DNA, vaccinations, and bigger protein medications has expanded the potential of gene therapy and non-invasive vaccination.

5. Antiviral and Antimicrobial Substances

Improved Treatment Results: Antibiotics and antiviral drugs that are otherwise challenging to treat topically can be delivered using ethersomes with remarkable effectiveness.

Examples include acyclovir (for herpes lesions), ketoconazole (for fungi), erythromycin (for bacterial infections), and bacitracin.

6. Applications in Cosmetics

Skin Care and Beauty: In cosmeceuticals, ethosomal carriers have enhanced the stability, skin penetration, and efficacy of antioxidants (such vitamin E and C), whitening agents, hair growth actives, and anti-aging chemicals.

The enhanced bioavailability raises customer satisfaction and lowers the risk of discomfort.

7. **Special and Veterinary Uses**

Additionally investigated in veterinary medicine and other specialized fields, ethersomes can administer medications to animals for systemic effects or skin conditions, as well as facilitate the dermal distribution of phytoconstituents and herbal extracts.

Evaluation of Ethosomes in Drug Delivery Systems [24-32]

The safety, effectiveness, and stability of the system are guaranteed by thorough evaluation, which is essential to the success of ethosomal drug delivery. Ethosomal formulations are characterized by evaluating a number of analytical, physicochemical, and biological criteria.

1.Physicochemical Characterization

A. Size Distribution and Vesicle Size

Instrument: Photon Correlation Spectroscopy (PCS) or Dynamic Light Scattering (DLS).

Relevance

Ascertains homogeneity and aids in permeation and stability prediction. For reliable drug release, ideal ethosomes usually have particle sizes under 200 nm and a restricted size distribution.

Homogeneity is evaluated using the Polydispersity Index (PDI). A uniform population is indicated by PDI values less than 0.3.

B. Surface Morphology and Vesicle Shape

Methods: Scanning electron microscopy (SEM) and transmission electron microscopy (TEM).

The goal is to visualize surface smoothness, lamellarity, and shape—typically spherical—in order to verify nanoscale size and structural integrity.

C. Potential Zeta

Method: DLS equipment or zeta meter.

Significance: Surface charge has an impact on stability; values generally greater than -30 mV indicate strong physical stability and aggregation resistance.

Temperature of Transition

Differential Scanning Calorimetry (DSC) is the instrument.

Use: Examines the phase transition of lipid bilayers and validates the effects of ethanol on the fluidity of vesicles and the breakdown of lipid structure in the skin.

E. Viscosity and pH

Essential: Guarantees skin compatibility (pH ideal: 4.5–6.5) and topical compositions' ease of use.

2. Parameters Associated with Drugs

A. Efficiency of Entrapment (EE%)

Method: HPLC or UV spectrophotometry for drug quantification, after ultracentrifugation or dialysis.

Function: Indicates the percentage of medication that was successfully loaded into vesicles. In order to provide proper dosage and regulated release, a high EE% (often >80–90%) is preferred.

B. Content of Drugs

Method: HPLC or UV spectrophotometry.

Function: Ensures a continuous therapeutic effect and precise dosage.

3. Research on Drug Permeation and Release

A. Drug Release in Vitro

Setup: Franz diffusion cells and the dialysis bag method.

Data: Assists in predicting drug availability and evaluating release kinetics (first-order, zero-order, Higuchi, or Korsmeyer–Peppas models).

B. Skin Permeation Ex Vivo

Model: Skin from a human or animal cadaver in Franz diffusion cells (e.g., rat, mouse).

Measurement: Indicates lag time, comparative flux, and cumulative drug permeation, all of which are directly related to clinical efficacy.

C. Preservation of Skin

Analysis: The quantity of medication that remains in the skin after penetration, which is important for local-acting treatments.

4. Safety and Biological Assessments

A. Biocompatibility and Skin Irritation

Test: Applying to animal skin and periodically rating any negative reactions, such as redness or oedema.

Result: Ethosomal safety for topical application is validated by a zero or absent score.

B. Pharmacokinetic and Pharmacodynamic Studies in Vivo

Goal: Verifies the duration of action, systemic absorption, and therapeutic efficacy when used in animal models.

5. Research on Stability

Conditions: Formulations are kept at different humidity levels and temperatures (4°C and room temperature, 28°C). Particle size, drug content, zeta potential, visual appearance, and aggregation are all parameters that are tracked throughout time.

Objective: Verifies that ethosomes retain their effectiveness and integrity during realistic shelf lifetimes.

6. Sophisticated Methods of Analysis

FTIR and DSC: Lipid phase shifts and drug-excipient compatibility.

Confocal Laser Scanning Microscopy (CLSM): Shows the distribution and depth of vesicle penetration inside epidermal layers.

The behavior of ethosomal gels and creams is determined by rheological tests, which are pertinent to the performance of topical products.

Table 1: Key Assessment Specifications

Methods for evaluations	Parameter	Application
DLS, PCS	Vesicle size, PDI	Uniformity, stability, permeation
TEM, SEM	Vesicle shape	Structural confirmation
Zeta meter, DLS	Zeta potential	Stability assessment
Ultracentrifugation, HPLC/UV	Entrapment efficiency	Drug loading efficiency
HPLC, UV	Drug content	Dose accuracy
Dialysis, Franz cell	In vitro drug release	Release kinetics, availability
Franz cell, CLSM	Skin permeation/ retention	Predicts clinical performance
Animal models	Skin irritation	Safety screening
Size/zeta/pH, visual inspection	Stability	Shelf life, practical usability
DSC	Transition temperature	Membrane fluidity
Viscometer	Rheology (for gels/creams)	Topical performance

Conclusion

In the drug deliveryethosomes have great promise, especially for topical and transdermal applications. Their higher ethanol concentration causes them to fluidize the stratum corneum, which improves medication penetration and boosts therapeutic effectiveness. Even though ethosomes are biocompatible and non-toxic, resolving stability issues during storage and guaranteeing steady drug release patterns are crucial to their therapeutic effectiveness. The creation of safe and efficient ethosomal compositions requires thorough assessment techniques. Ethamomes have the potential to increase the range of medications delivered via the skin and solve a number of drug delivery issues with more study and optimization.

Disclosure Satamente

There are no conflicts of interest.

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