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TRANSETHOSOMES AS ADVANCED VESICULLAR CARRIER FOR ENHANCED TRANSDERMAL DRUG DELIVERY: A COMPREHENSIVE REVIEW

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ABSTRACT

Transethosomes are advanced ultradeformable lipid vesicles designed for enhanced transdermal drug delivery, overcoming limitations associated with conventional oral and topical administration, such as first-pass metabolism and poor bioavailability. Composed of phospholipids, ethanol, edge activators, and water, transethosomes combine the advantages of ethosomes and transfersomes, allowing improved penetration through the stratum corneum and delivery of drugs to deeper skin layers. Incorporation into gel formulations further enables controlled and sustained release, making them suitable for localized treatment of chronic conditions, antifungal therapy, antihypertensive administration, and topical antibiotic delivery. Their unique composition enhances vesicle flexibility, skin hydration, and drug encapsulation efficiency while maintaining biocompatibility and biodegradability.

Preparation methods include cold and hot techniques, thin-film hydration, mechanical dispersion, and reverse-phase evaporation, and evaluation involves particle size, zeta potential, entrapment efficiency, in vitro/in vivo permeation studies, and stability assessments. Despite limitations such as formulation complexity, high production cost, and potential skin irritation, transethosomes show significant promise in pharmaceutical and cosmeceutical applications, including anti-aging and hair care, establishing them as a versatile platform for transdermal drug delivery.

KEYWORDS: Transethosomes, Transdermal drug delivery, Ultradeformable vesicles, Phosplipid vesicles, Topical thereputics, Skin penetration.

INTRODUCTION

First-pass metabolism and interactions in the gastrointestinal tract often reduce drug effectiveness and cause side effects, leading to poor patient compliance. Advanced drug-delivery systems, especially peptide-based and transdermal carriers, are being developed to overcome these problems and improve drug penetration through the skin.[1]

Transethosomes are nanoscale lipid vesicles composed of phospholipids, ethanol, and sometimes surfactants. Unlike conventional liposomes or other vesicular systems, they are designed to be highly deformable, allowing them to easily traverse the stratum corneum—the outermost layer of the skin—and thereby enhance drug absorption. The presence of ethanol in their formulation increases membrane flexibility and improves penetration through the epidermal barrier.[2]

Transethosomal gels are advanced transdermal drug delivery systems (TDDS) that integrate the benefits of gel matrices with ethosomes (lipid-based vesicles) to achieve targeted, controlled, and sustained drug release. These systems have gained considerable interest due to their ability to enhance transdermal drug absorption, especially for medications used in managing chronic conditions such as arthritis, where localized inflammation and pain are common.[3]

Skin

The skin is the largest organ of the human body and serves multiple functions, such as acting as a protective barrier against the external environment. It is composed of three layers, as illustrated in **Figure 1**. The outermost layer, the epidermis, is approximately 0.2 mm thick and primarily consists of keratinocytes. This layer lacks blood vessels and capillaries. Beneath it lies the dermis, which contains capillaries and nerve fibers, with a thickness ranging from 1 to 4 mm. The innermost layer, the subcutaneous layer (also called the hypodermis), is an elastic layer located beneath the dermis, rich in fat cells, and has a thickness of about 4 to 9 mm as illustrated in **Figure 2**.[4]

Skin layers: Skin contains 3 structural layers

1. Epidermis

2. Dermis
3. Hypodermis

Structure of skin

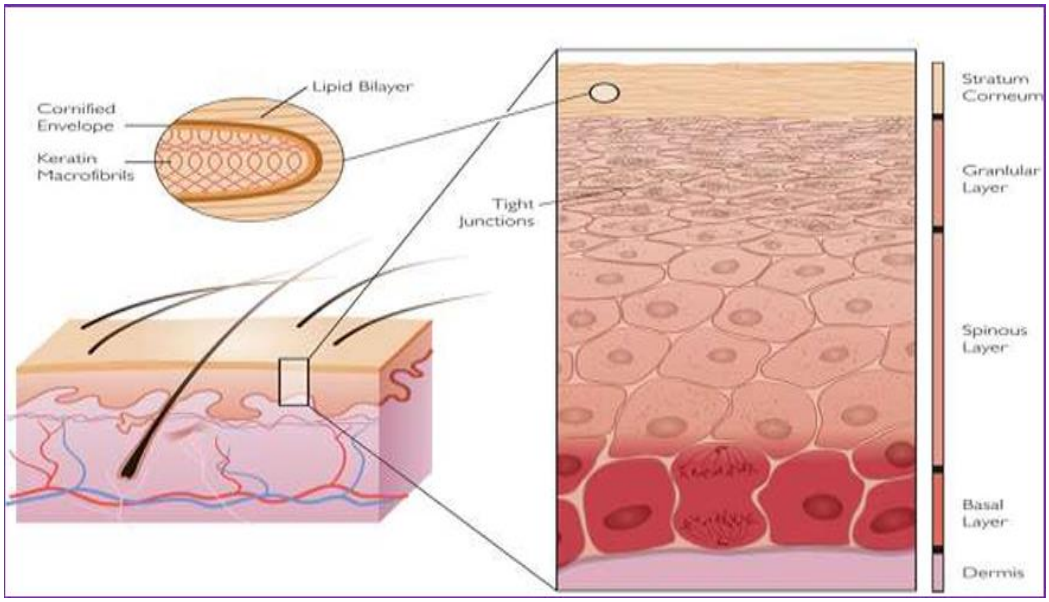

Figure No 1: Layer of Human skin.[5]

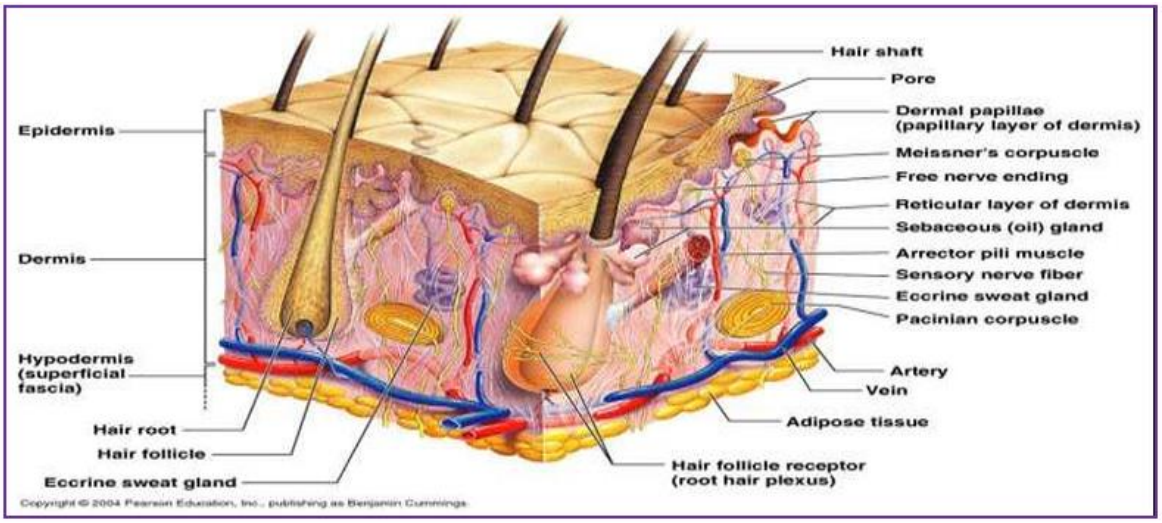

Figure No 2: Anatomy of Human skin.[5]

1 Epidermis

The epidermis is composed of stratified squamous keratinized epithelium, which contains four distinct types of cells. Keratinocytes are the most abundant, forming the bulk of the epidermal layer. Interspersed among them are less common, non-epithelial cells located in specific regions: melanocytes, which produce melanin; Merkel cells, involved in tactile sensation; and Langerhans cells, which function as antigen-presenting immune cells.[6]

2 Basement membrane

The dermo-epidermal junction, formed by a multilayered structure known as the basement membrane, establishes a physical boundary between the dermis and epidermis layers. This boundary restricts the passage of large drug molecules and cells.[3]

3 Dermis

The dermo-epidermal junction, formed by a multilayered structure known as the basement membrane, establishes a physical boundary between the dermis and epidermis layers. This boundary restricts the The dermis is the thick middle layer of the skin, located between the outer epidermis and the inner hypodermis. It contains blood vessels and nerves that support and feed the skin. The dermis has two layers: the upper papillary layer, which is thin and has loose connective tissue, fibroblasts, small blood vessels, nerves, and helps with wound healing; and the deeper reticular layer, which is thick, strong, and made of dense connective tissue with collagen and elastic fibers that give the skin strength and flexibility. As we age, these cells and fibers decrease, making the skin weaker and less elastic.[7]

4 Hypodermis

The hypodermis, also called the subcutaneous fat layer, supports both the dermis and epidermis. It primarily serves as a fat storage area, helps regulate body temperature, provides nutritional support, and offers protection against mechanical impact. This layer also contains the main blood vessels and nerves that supply the skin and may include pressure-sensing organs. In transdermal drug delivery, a drug must pass through all three skin layers to reach the systemic circulation.[8]

Transethosomes

Transethosomes (TEs), first reported by *Song et al. (2012),* are a novel class of ultradeformable vesicles designed for transdermal drug delivery. They are composed of phospholipids, high concentrations of ethanol (30–40%), edge activators or permeation enhancers, and water, allowing them to combine the beneficial properties of both ethosomes and elastic vesicular systems. The phospholipids act as drug carriers and can readily interact with and merge into the stratum corneum, enhancing skin hydration and drug penetration. Ethanol disrupts the lipid structure of the skin's outer layer, while edge activators impart flexibility and softness to the vesicles, enabling them to pass through narrow skin pores. Water contributes to bilayer formation and vesicle deformability are depicted in **Figure 3**. Due to this unique composition, transethosomes, typically ranging in size from 40 to 200 nm

depending on the drug, can effectively penetrate deeper skin layer and improve transdermal drug delivery.[9]

Structure of transethosomes[10]

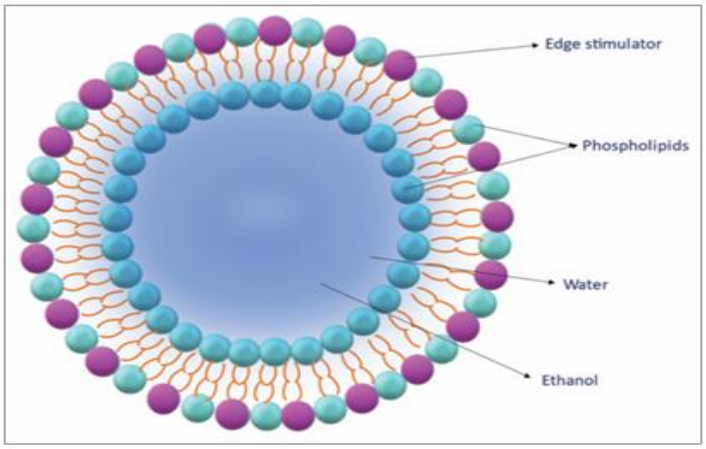

Figure No 3: Structure of transethosomes

MECHANISM OF ACTION

Transethosomes are specialized lipid-based vesicular systems composed of phospholipids, high concentrations of ethanol, edge activators, and water. They combine the advantages of both transfersomes and ethosomes. Depending on the incorporated drug, their size typically ranges from 40 to 200 nm. A distinguishing feature of transethosomes compared to other vesicular carriers is the presence of ethanol. Ethanol intercalates into intercellular lipids, enhancing lipid fluidity and reducing bilayer density, which contributes to the initial stage of their penetration mechanism. In combination with other components, ethanol fluidizes the lipid matrix of the stratum corneum; its high concentration in transethosomes promotes vesicle flexibility and deformability, enabling penetration through microscopic channels formed within the corneum as a result of lipid fluidization. Additionally, the alcohol content affects vesicle size by imparting a net negative surface charge, which leads to a reduction in vesicle diameter. An ethanol concentration of 30–40% is considered optimal for producing stable and uniform ethosomes, while a reduction of approximately 20% in ethanol content may result in larger vesicles. Phospholipids are essential for Bilayer formation, consisting of hydrophobic tails and hydrophilic head groups, as illustrated in **Figure 4.**[11]

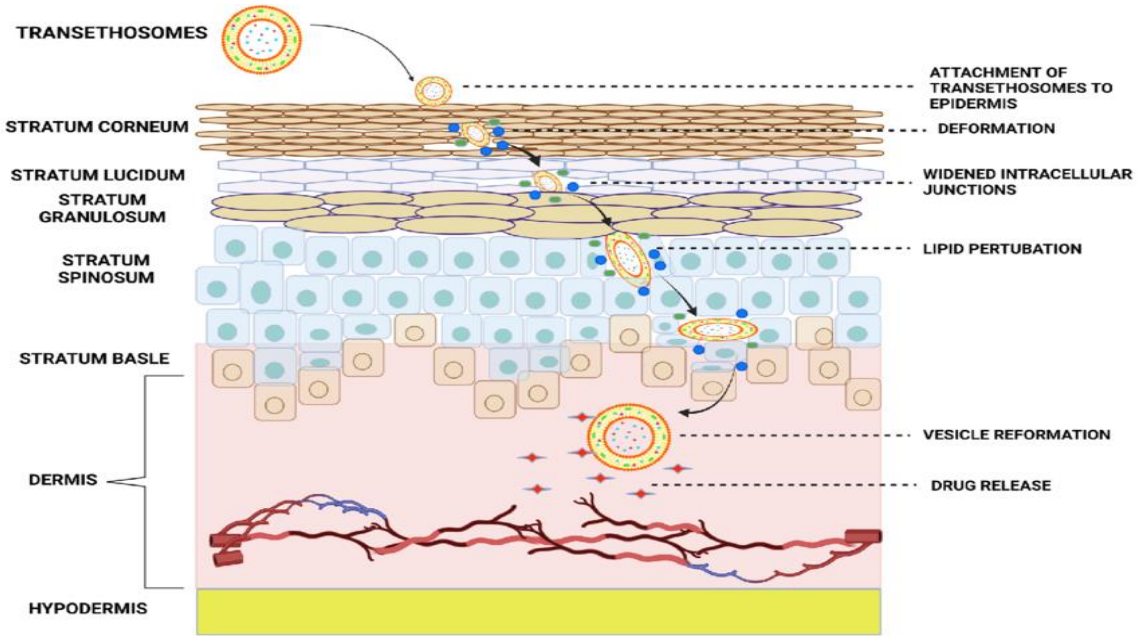

Figure No 4: Mechanism of transethosome-mediated skin penetration.[12]

ADVANTAGES

- Transethosomes enhance the penetration of drugs across the skin**.**
- They can be formulated into semisolid dosage forms, such as gels, for effective transdermal drug delivery.
- Transdermal administration using Transethosomes helps bypass first-pass metabolism**.**
- Transethosomes are biodegradable and biocompatible.
- They provide superior skin permeation compared to conventional formulations.
- Drugs with a molecular weight below 500 g/mol can be efficiently encapsulated and conveniently delivered through the transdermal route.
- Several studies have shown that transethosomes exhibit better transdermal delivery than rigid liposomes.
- However, transethosomes have limited ability to penetrate the deeper layers of the stratum corneum.
- Transethosomes overcome this limitation by improving penetration into the lower layers of the stratum corneum.[9]

DISADVANTAGES

- Transethosomes have shown considerable effectiveness in transdermal and other drug delivery routes; however, they also possess notable limitations.
- Complex formulation processes.

- Potential stability concerns during storage.
- Limited drug encapsulation efficiency.
- High manufacturing and production costs.
- Possibility of causing skin irritation.[13]

METHOD OF PREPARATION

- Cold method
- Hot method
- Thin flim hydration method
- Reverse phase evaporation method
- Mechanical dispersion method

1. Cold method

The cold method is a simple and widely used technique for preparing transferosomes at low temperatures. In this method, phospholipids, penetration enhancers, and other lipid components are mixed in an organic solvent to form the organic phase, while water, saline, or buffer is used as the aqueous phase. The aqueous phase is then added slowly to the organic phase under continuous magnetic stirring for a fixed time, during which vesicle size is influenced by the stirring speed and duration. Depending on the nature of the drug, it can be dissolved in either phase before mixing. The prepared formulation is finally stored under refrigeration are depicted in **Figure 5**. This method is preferred because it avoids heat exposure and reduces the risk of drug degradation.[14]

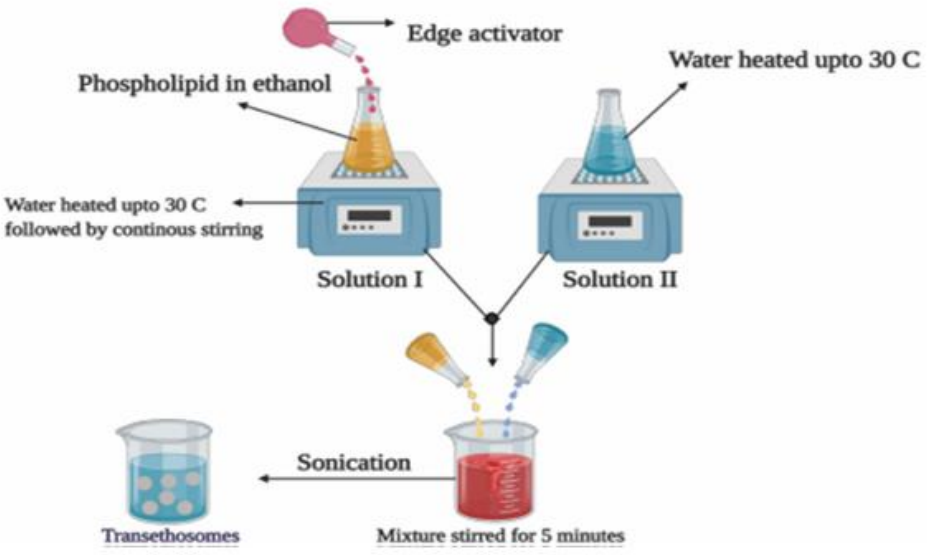

Figure No 5: Cold method.[9]

2. Hot method

This method involves dispersing phospholipids such as phosphatidylcholine and phosphatidylserine in water and heating the dispersion to 40 °C to form a colloidal solution, while ethyl alcohol and a dihydric alcohol are separately mixed and maintained at the same temperature. The aqueous phase is gradually added to the alcoholic phase under continuous stirring for 7–10 minutes, after which the drug, dissolved in either ethanol or water depending on its solubility, is incorporated into the system. The process is carried out at a constant temperature of 40 °C, followed by sonication to obtain smaller transethosomal vesicles, are illustrated in **Figure 5**.[12]

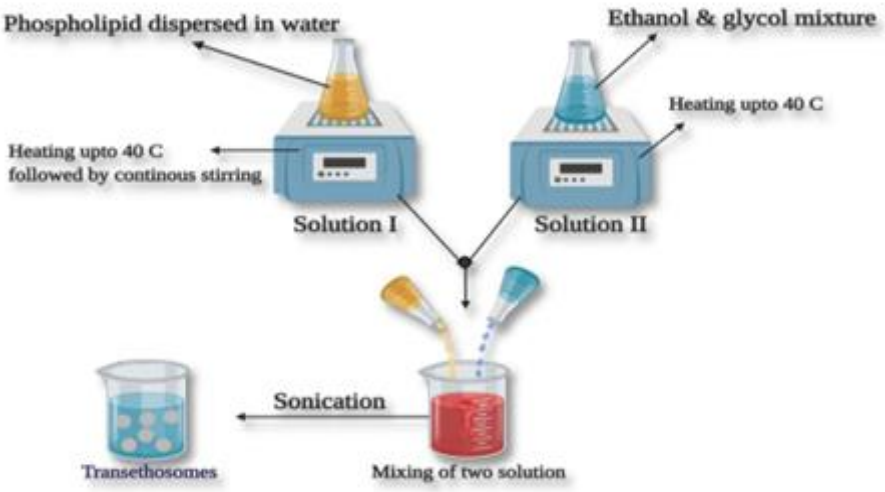

Figure No 5: Hot method.[15]

3. Thin flim hydration method

Series of lipids and edge activators will be employed for the formulation of the vesicles. The lipids, edge activators, and drug will be weighed accurately and dissolved in chloroform/methanol (2: 1 v/v). This solution will be evaporated on a rotary evaporator at controlled temperature under reduced pressure. The thin flim obtained will be hydrated with specified pH (phosphate buffer saline with or without ethanol). The suspension will be kept overnight for the complete hydration of the vesicles are depicted in **Figure 6**.[16]

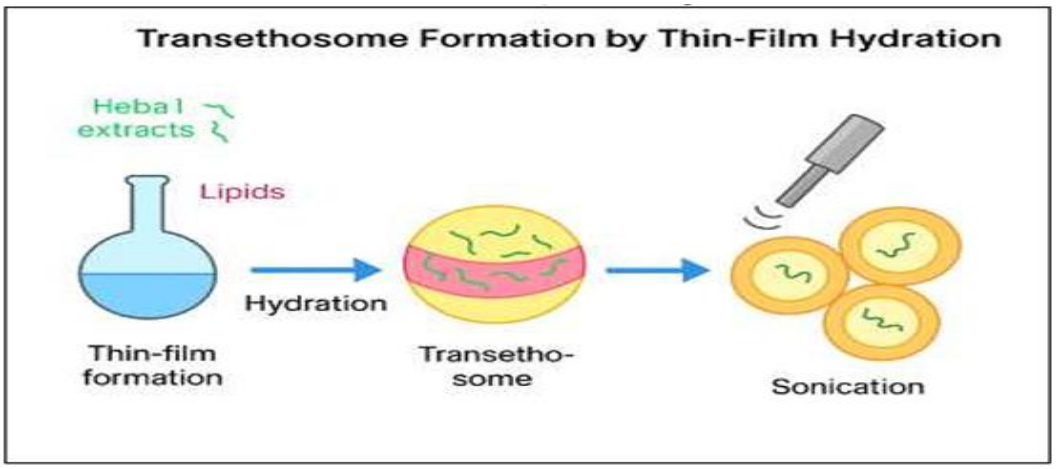

Figure No 6: Thin film hydration method.[17]

4. Mechanical dispersion method

In the mechanical dispersion method for ethosome preparation, lecithin and curcumin were dissolved in ethanol and stirred magnetically. The solution was then poured into a round-bottom flask and evaporated using a rotary evaporator to form a thin film. This film was hydrated to form ethosomes and sonicated for 5 minutes to ensure uniformity. Finally, the ethosomes were filtered through a 0.22 µm membrane filter, are illustrated in **Figure 7**.[18]

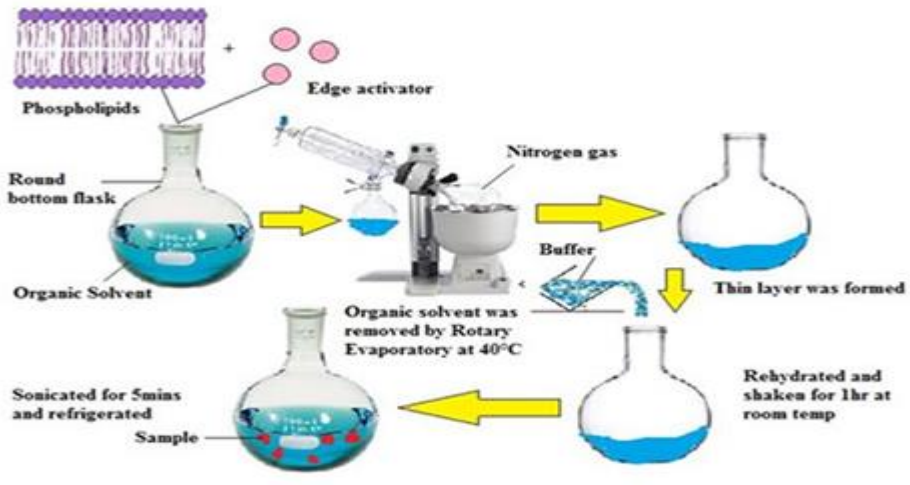

Figure No 7: Mechanical dispersion method.[15]

5. Reverse phase evaporation method[15]

This method involves dissolving lipids in ethanol as the organic solvent, while the aqueous phase contains edge activators. The organic phase is gradually mixed into the aqueous phase, and the resulting mixture is placed in an ultrasonic bath at 0 °C to promote phase separation. The organic solvent is then removed under reduced pressure, leading to gel formation.

Subsequently, the lipid layer becomes encapsulated, and the dispersion is stirred and filtered are depicted in **Figure 8**. This process is known as the reverse phase evaporation method.[16]

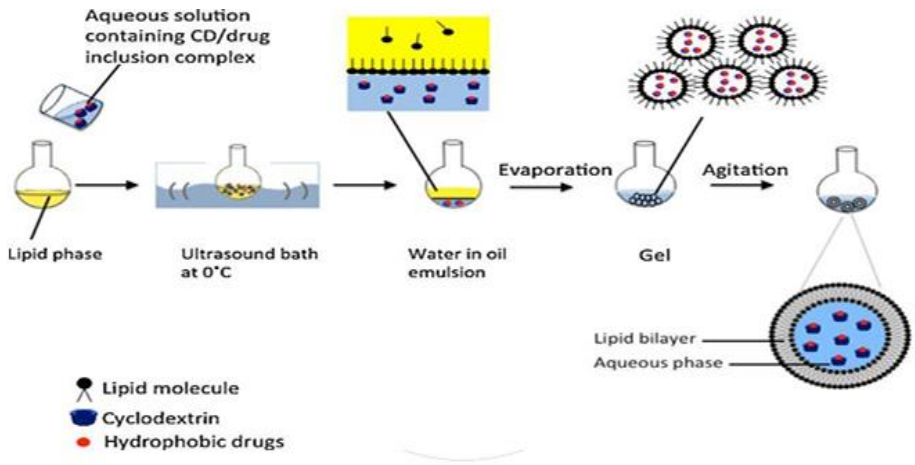

Figure No 8: Reverse phase evaporation method.[19]

EVAULATION OF TRANSETHOSOMES

1. Invitro drug release studies[20]

The study utilized a Franz diffusion cell. A pre-soaked diffusion membrane in pH 7.4 phosphate buffer was positioned between the donor and receptor compartments. The receptor compartment was filled with phosphate buffer, while 1 mL of the formulation was placed in the donor compartment. The assembly was maintained on a magnetic stirrer at 100 rpm, with the temperature controlled at 37 ± 2 °C. At hourly intervals for 12 hours, 1 mL samples were withdrawn from the receptor compartment, replaced with an equal volume of fresh buffer, and subsequently analyzed under a microscope.

2. Entrapment efficiency[21]

The entrapment efficiency of the transethosomal formulations was determined using the ultracentrifugation method. Briefly, 2 mL of each formulation was transferred into a microcentrifuge tube and subjected to ultracentrifugation at 100,000 × g and 4 °C for 1 hour using an ultracentrifuge (Kubota, Japan). The supernatant was then carefully collected with a micropipette and diluted with methanol to disrupt the vesicles. The amount of drug in the supernatant was quantified using a UV–visible spectrophotometer (Shimadzu UV-1900, Japan) at 295 nm. The percentage entrapment efficiency (%EE) was calculated using the following formula.

$$\%\ \text{Entrapment efficiency} = \frac{Drug\ loading}{\text{Theoretical drug loading}} \text{ x } 100$$

3. Transmission Electron Microscopy (TEM)[22]

Transethosomal vesicles can be observed using a transmission electron microscope (TEM). First, any excess material is removed by filtering the vesicular suspension through filter paper. A small amount of the suspension is then placed onto a copper or carbon grid. The vesicles are stained with an aqueous solution of phosphotungstic acid or 2% uranyl acetate. After partially drying the grid, the sample is examined under the TEM.

4. Determination of drug content[23]

In a 50 mL volumetric flask, 1 g of gel was dissolved in 50 mL of methanol. The mixture was sonicated in a bath until a clear, transparent solution was obtained. It was then filtered through a 0.45 µm filter and diluted with methanol as needed. The drug concentration was determined by measuring the absorbance at 296 nm using a UV spectrophotometer, with methanol serving as the blank.

Drug Content = Actual drug content in vesicles /Theoretical drug content in vesicles × 100

5. Particle Size and Zeta Potential[24]

The particle size of transethosomes can be determined using a particle size analyzer, dynamic light scattering (DLS), or photon correlation spectroscopy. The zeta potential of the formulation can be measured using a zeta meter.

6. Intereaction studies by using FTIR spectroscopy[25]

The interaction between the drug and excipients was studied using Fourier Transform Infrared (FTIR) spectroscopy. IR spectra of the pure drug and powdered tablets were recorded using an FTIR instrument (FTIR 1615, Perkin Elmer, USA) with potassium bromide (KBr) pellets. The spectra were scanned over a range of 3600–400 cm^{-1}.

7. Stability studies[26]

The stability of vesicular carrier formulations is usually assessed by monitoring changes in vesicle size over time, with more uniform (homogeneous) preparations generally being more stable than heterogeneous ones. Techniques like X-ray scattering or differential scanning are used to study membrane stability and molecular arrangement. Particle size analysis is often used as a quality control test, but it may not fully reflect the internal stability of the vesicles, as additives in some liposomal formulations can disrupt the lipid layers and affect the true stability.

8. Measurement of viscosity[27]

Viscosity measurements were performed using a Brookfield viscometer (DV-II+ Pro D220) with spindle T-96 at a speed of 12 rpm18.24

9. Finding unentrapped drug concentration[28]

The sonicated vesicular dispersion was centrifuged at 25,000 rpm for 1 hour at 4 °C using a refrigerated centrifuge. The resulting supernatant was then analyzed with a UV–visible spectrophotometer to determine the amount of unentrapped drug.

The following equation gives the %Entrapment efficiency:

$$\%EE = (\text{Total drug} - \text{Unentrapped drug} / \text{Total drug}) \times 100$$

10. Determination of pH in Transethosomal Formulations[29]

pH was measured using a digital pH meter, as pH can affect drug penetration through the skin. Formulations that are too acidic or too alkaline may cause irritation and reduce drug efficacy. The pH meter was first calibrated with standard buffer solutions at pH 4, 7, and 10. The electrode was then immersed in a small amount of the transethosomal dispersion, or in a diluted sample prepared with deionized water, to record the pH. Transethosomal formulations are generally maintained within a pH range of 4.5 to 6.5 for safe and effective topical application.

11. Ex Vivo Skin Permeation Study[30]

An ex vivo skin permeation study for transethosomes was performed using rat skin as a model for human skin in Franz diffusion cells with a diffusion area of 0.758 cm^2. The excised rat skin was mounted between the donor and receptor compartments, and the receptor compartment was filled with 10 mL of phosphate-buffered saline (pH 7.4) and maintained at 37 ± 1 °C under continuous magnetic stirring. The optimized transethosomal formulation was placed in the donor compartment and compared with a conventional formulation. At predetermined time intervals ranging from 0.5 to 24 hours, 1 mL samples were withdrawn from the receptor compartment, and an equal volume of fresh buffer was added after each sampling to maintain sink conditions. The amount of drug permeated through the skin was analyzed using UV spectrophotometry at 280 nm, using drug-free samples as controls to avoid interference.

APPLICATION

1. Transethosomes can improve drug delivery efficiency by more than 65% owing to their unique ability to penetrate intact human skin. Consequently, transethosomes have been extensively explored as carriers for the transdermal delivery of a wide range of bioactive compounds.[31]

2. Delivery of antifungal drugs

To evaluate the effectiveness of vesicular carriers for antifungal therapy, a transethosome-based delivery system was developed to enhance the skin penetration. The performance of transethosomes was compared with conventional liposomes, deformable liposomes, ethosomes, and polyethylene glycol-based controlled formulations.[32]

3. Delivery of Anti-hypertensive Drug

Antihypertensive drugs are commonly administered via the oral route; however, several agents exhibit poor bioavailability due to extensive first-pass metabolism. The study was incorporated into a transethosomal delivery system, which significantly enhanced transdermal drug permeation and improved systemic absorption.[33]

4. Delivery of antibiotics

Topical application of antibiotics can improve their effectiveness while reducing side effects associated with oral therapy, such as allergic reactions. Conventional topical formulations often struggle to reach deeper layers of the skin, limiting their ability to treat infections effectively. Ethosomes, a type of lipid-based carrier, can overcome this problem by penetrating the skin more efficiently and delivering drugs to the deeper layers where infections occur. For example, Godin and Touitou developed an ethosomal formulation containing bacitracin and erythromycin, which was shown to be more effective than conventional treatments in targeting skin infections.[34]

5. Cosmeceutical application

Transethosomes have gained significant attention in cosmetic formulations due to their superior skin penetration capability, enhanced stability, and reduced irritation compared with conventional delivery systems. Transethosome-based creams containing *Curcuma longa* extract have been developed and investigated for their anti-aging and photoprotective effects. Studies conducted on human volunteers demonstrated that *C. longa* extract–loaded transethosomal creams produced notable improvements in wrinkle reduction and protection

against photoinduced skin damage. Furthermore, Yeh et al. developed a transethosome-based hair dye formulation, which exhibited more efficient delivery and greater deposition of black tea extracts on the hair surface than a hydroethanolic solution.[35]

CONCLUSION

Transethosomes are an advanced and promising transdermal drug delivery system that effectively overcome the limitations of conventional oral and topical formulations by enhancing skin penetration, bypassing first-pass metabolism, and improving drug bioavailability. Their unique composition of phospholipids, high ethanol concentration, and edge activators provides superior vesicle deformability, enabling efficient transport of drugs across the stratum corneum into deeper skin layers with controlled and sustained release. Transethosomal gel formulations further improve patient compliance due to ease of application and localized therapeutic action. Extensive evaluation studies have demonstrated their stability, safety, and enhanced permeation performance, while successful applications in antifungal, antihypertensive, antibiotic, and cosmeceutical drug delivery highlight their broad therapeutic potential. Although challenges such as formulation complexity, stability issues, limited drug loading, and high production costs remain, continued research and formulation optimization are expected to establish transethosomes as a highly effective and versatile platform for transdermal drug delivery.

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