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# Transethosomal Gel: A Perspective Approach for Topical Application

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**ABSTRACT**

Transethosomal gel is a type of vesicular drug delivery system that is composed of phospholipids, ethanol and edge activator, designed to enhance drug permeability and residence time, thereby improving therapeutic efficacy. They are also known to be more stable and elastic than other vesicular systems such as liposomes and ethosomes. Transethosomes have small vesicle sizes and are easily able to change the shape of vesicles, allowing them to pass through the layers of skin more efficiently than other vesicular systems. The softness and flexibility of ethanol and edge activator deliver the medication molecules into the systemic circulation. Cold method, hot method, thin film hydration method, and Mechanical dispersion method are involved in the formulation of transethosomes. Evaluation parameters of transethosome are vesicle size, surface charge, entrapment efficiency, surface morphology study, incompatibility, drug content and stability. Transethosomes has different application as it can deliver NSAIDs (Non-steroidal Anti-inflammatory Drugs), hormones, antibiotics, antifungal drugs, Anti-parkinsonism agents, and cosmeceutical application. Transethosomes have achieved high patient compliance. This article examines the many methods used for formulation of transethosomal gel.

## INTRODUCTION:

The primary focus of medication adherence research has been on oral drugs, until now. Now studies have investigated the adherence to topical drugs. The issue of patient adherence to topical drugs is particularly significant about chronic skin diseases, such as psoriasis, atopic dermatitis, and acne, which require long-term use of topical medications.[1]

This review discusses the details of topical formulations, principles, and basic components of drug delivery systems. The clinical evidence suggests that topical gel is a safe and effective treatment option for managing skin-related diseases. Topical preparations are applied to the skin for surface, local, or systemic effects. In some cases, the base may be used alone for its therapeutic properties, such as emollient, soothing, or protective action. Many topical preparations, however, contain therapeutically active ingredients that are dispersed or dissolved in the base. The combination of active ingredients and base provides the opportunity for a wide range of topical preparations, appropriate for many types of drug delivery and therapy. The terms used to classify the bases of topical preparations in which therapeutically active ingredients are incorporated may be based on their physical properties (suspension) or on their intended use (liniments) or on their composition(hydrophilic creams).

**SKIN: The** skin serves as a significant and valid target for drug delivery. However, its inherent limitations restrict its practicality in this context. As the body's largest organ, the skin constitutes 16% of the total body weight and boasts a surface area of 1.8 square meters. Notably, the skin includes various derivatives such as apocrine glands, sweat glands, hair, nails, and oil glands (as depicted in figure). Its primary functions involve safeguarding the body against unwanted substances and microorganisms while maintaining bodily fluids.[3]

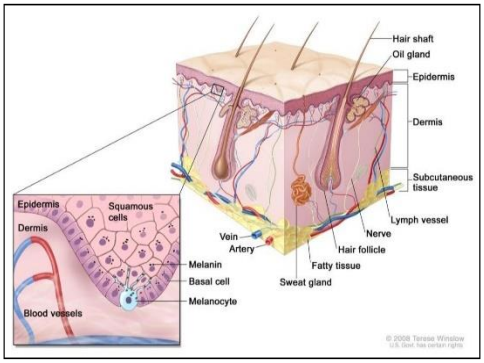


**Figure 1: Structure of skin.**

**Skin layers:** Skin contains three structural layers

- Epidermis
- dermis
- Hypodermis.

**1. Epidermis:**[4]

The epidermis**,** composed of keratinized stratified squamous epithelium**,** plays a crucial role in drug delivery. Keratinocytes, which constitute over 90% of its cells, undergo changes in shape and properties as they move toward the skin surface. The stratum corneum**,** approximately 100–150 mm thick, lacks blood vessels and forms the outermost layer of the epidermis. Beneath the epidermis lies the dermis**,** containing a network of blood vessels that transport blood throughout the body. If a drug can penetrate the stratum corneum, it may enter the bloodstream. This process, known as **passive** diffusion**,** is the sole mechanism for normal drug transfer across this layer. Additionally, the epidermis houses melanocytes, Langerhans cells, and Merkel cells.

**2. Basement membrane**[5]

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. Dermis**[6]

The dermis**,** constituting approximately 90% of the skin's thickness, primarily consists of connective tissue and provides support to the epidermis. It can be divided into two anatomical regions: the papillary dermis (located at the periphery) and the reticular dermis**.** In the papillary region, collagen and elastin fibers are predominantly oriented vertically and connect with the dermal-epidermal junction. Conversely, in the reticular dermis, these fibers are arranged horizontally. Given that the skin plays a crucial role in determining various aspects of drug delivery, such as permeation and absorption, understanding its structure is essential.

**4. Hypodermis[4]**

The hypodermis**,** also known as the subcutaneous layer or superficial fascia, lies directly beneath the dermis and serves to connect the skin to the underlying fascia surrounding the muscles. Although not strictly part of the skin, the boundary between the hypodermis and dermis can be challenging to distinguish. Composed of dense connective tissue and adipose tissue, the hypodermis attaches the skin to underlying structures, provides cushioning, and insulation, and is closely associated with nerve and vascular systems. Its thickness varies depending on the body's surface.

**Factors Affecting Topical Absorption of Drug**

**Physiological Factors[6]**

1. Skin thickness.
2. Lipid content.
3. Density of hair follicles.
4. Density of sweat glands.
5. Skin pH.
6. Blood flow.
7. Hydration of skin.
8. Inflammation of skin.

**Physiochemical Factors[4]**

1. Partition coefficient
2. Molecular weight (<400 daltons).
3. Degree of ionization (only unionized drugs getsabsorbed well).
4. Effect of vehicles

**Factors To Be Considered When Choosing a Topical Preparation[3]**

1. Effect of the vehicle e.g. An occlusive vehicle enhances penetration of the active ingredient andimproves efficacy. The vehicle itself may have a cooling, drying, emollient or protective action.

2. Match the type of preparation with the type of lesions. For example, avoid greasy ointments foracute weepy dermatitis.

3. Match the type of preparation with the site. (e.g., gel or lotion for hairy areas)

4. Irritation or sensitization potential. Generally, ointments and w/o creams are less irritating, while gels are irritating. Ointments do not contain preservatives or emulsifiers if allergy to these agentsis a concern.

**TRANSETHOSOMES:**

Transethosomes are a new type of vesicular nano-carrier systems that were first reported by Song et al. in 2012. They are considered a new generation of ethosomal systems and have the advantages of both transfersomes and ethosomes. These vesicles were designed to share the benefits of both classical ethosomes and deformable transfersomes to introduce transethosomes. Edge activators and permeability enhancers of different types have been used to produce transethosomal systems with better features. According to the review, transethosomes can entrap drugs with molecular weights ranging from 130.077 Da to 200–325 kDa.[7]

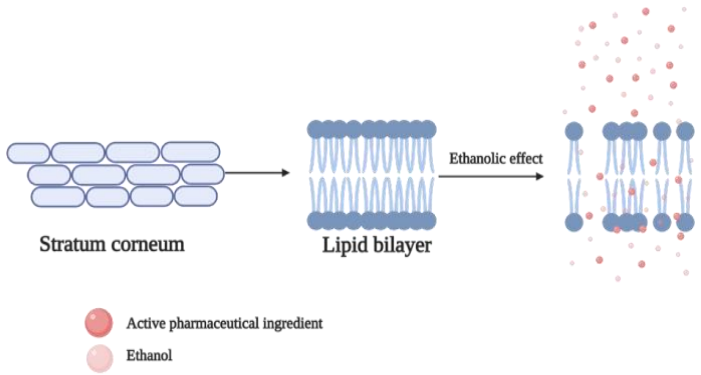


**Figure 2: The penetration mechanism of transethosomes**

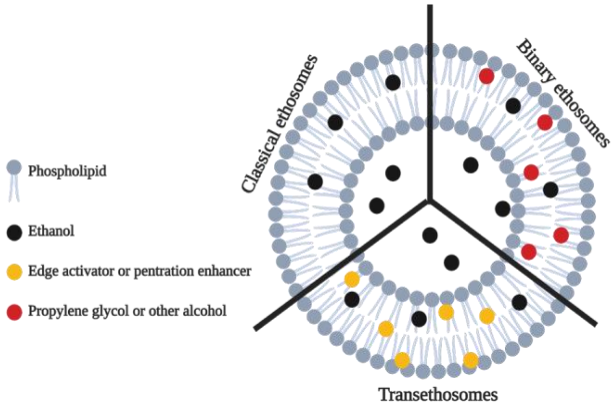


**Figure 3: Different types of Ethosomal system**

## DIFFERENT VESICULAR SYSTEM AND THEIR PRINCIPAL COMPONENTS:

**Transferosomes:** phospholipid and edge activator.

**Liposomes:** phospholipid and cholesterol.

**Niosomes:** non-ionic surfactant and cholesterol.

**Ethosomes:** phospholipid and ethanol.

**Phytosomes:** phospholipid and phytoconstituents.

**Pharmacosomes:** phospholipid.

## STRUCTURE OF TRANSETHOSOMES

Transethosomes are lipid-based vesicles that contain phospholipids, ethanol, edge activator (surfactant), and water**.** These vesicles play a crucial role in delivering drug molecules into the skin. The phospholipids act as carriers, facilitating interaction with the stratum corneum (the outermost layer of the skin).[8] They enhance tissue hydration and merge with the skin's lipid layer. Transethosomes have **a** hydrophilic (polar) hea**d** and a hydrophobic (non-polar) tail**.** The edge activator, a biocompatible surfactant, softens the bilayer structure. It is typically added to improve flexibility and permeability[9]. Ethanol**,** a primary component of the transethosomal system, gives it a distinctive identity as a vesicular system. Ethanol deforms the skin layer, enhancing malleability and flexibility of these nanosystems, allowing them to penetrate through tiny openings in the stratum corneum due to fluidization[10]**.** Water is essential for forming the bilayer when combined with phospholipids and contributes to the

system's flexibility. When ethanol and edge activator are combined, they lead to rearrangement of the lipid bilayer, making it more deformable and enabling deeper penetration into the dermis.[11]

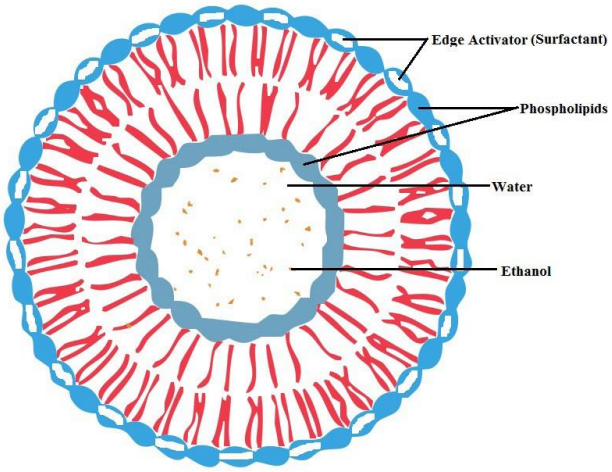


**Figure 4: Structure of Transethosomes**

**ADVANTAGES OF TRANSETHOSOME:**

Transethosomes has greater efficiency when compared to other liposomes in the transportation of activemoieties through the skin.

1. Along 20-50% of ethanol synergic effect is observed hence it is used as a major composition in transethosomes.[12]

2. Noninvasive approach hence better patient compliance.

3. Can be used to deliver the drugs with larger molecular weight this phenomenon makes it an idealcandidate to deliver proteins and peptides through the skin.

4. It's an effective drug carrier to deliver different dosage form.[13]

**Mechanism of action:**

The vesicular system assists in the transdermal drug delivery of the drug moiety by enhancing the permeation of active drug component.[14] The vesicles get penetrated into the skin and the drug gets penetrated through it. The presence of permeation enhancer such as Ethanol, Propylene glycol and Isopropyl myristate increases the fluid content in the lipid bilayer along with lipid content that is present in stratum corneum.[15]

**METHOD OF PREPARATION:**

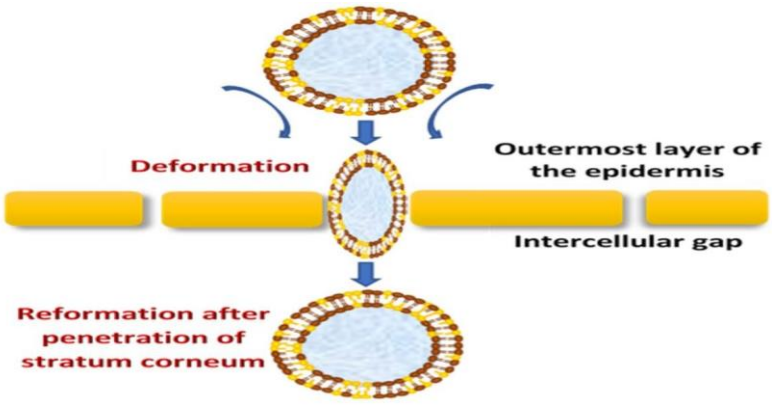


**Figure 5: Mechanism of action of Transethosomes**

- Cold method
- Hot method
- Reverse phase evaporation method
- Mechanical dispersion method

**1. Cold method**

This method is usually used to form transethosomes. Its ability is such that it can be used for thermolabile drugs that are sensitive to heat. It is easily scalable. Phospholipid is dissolved in ethanol as solvent system by vigorous shaking. This mixture is heated up to 30°c in a water bath. Water is heated in a separate vessel up to 30°c and added to the alcoholic mixture slowly. During addition of aqueous solution to ethanolic solution magnetic stirrer is used for uniform mixing (700rpm). Probe sonicator can be used in order to modulate the size of vesicles.[16]

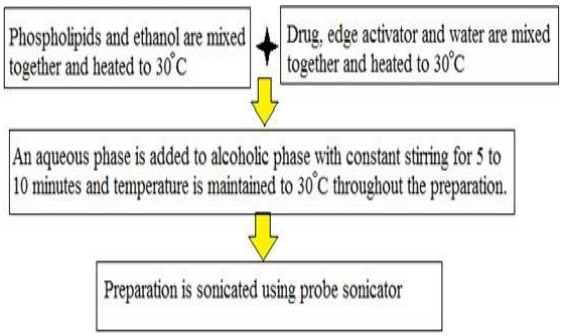


**Figure 6: Cold method.**

## 2. HOT METHOD:

Phospholipid is dispersed in water and heated up to 40°c. A mixture of ethanol and glycol combination is heated up to 40°c. Mix organic phase with aqueous phase with uniform stirring. Based on solubility of drugs solvent system is chosen (water or ethanol). Constant temperature is maintained throughout the process (40°c). Probe sonication can be used to modulate the vesicular size.[17]

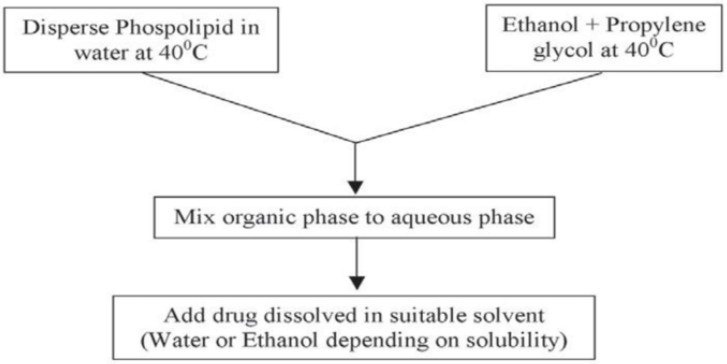


**Figure 7: Hot method.**

## 3. Mechanical dispersion technique:

Round Bottom flask is used in this technique, Liquid and surfactant mixture is dissolved in ethanol. Efficiency of this technique can be enhanced by combination of hydrated thin film and ultrasound homogenization. Using rotary evaporator thin lipid film can be produced, the excess of organic solvent can be removed by keeping it overnight under vacuum. 10%v/v ethanol in phosphate buffer(6.5pH) atm60rpm is used in hydration process. Sonication technique can be employed to modify the vesicular size. [18]

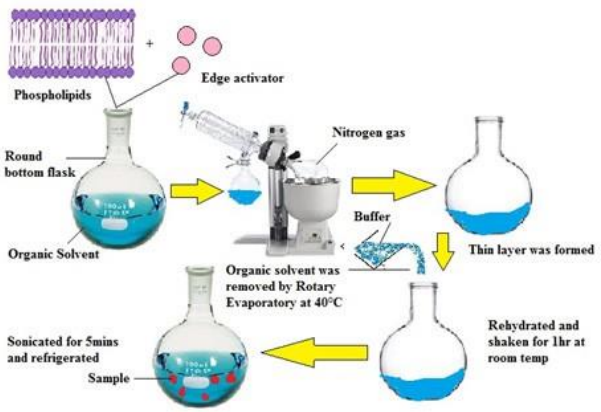


**Figure 8: Mechanical dispersion technique**

### 4. Reverse phase evaporation method

Lipid is dissolved in ethanol; edge activators are added to aqueous phase. Aqueous phase is added into organic phase, and ultrasonication technique is used in separation of two phases at 0°c .Formation of gel occurs under pressure upon removal of organic solvent.[19]

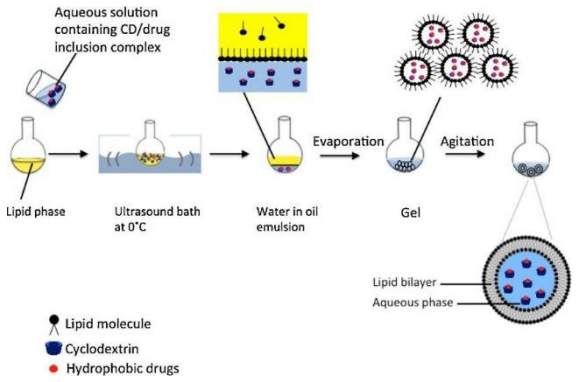


**Figure 9: Formulation of Transethosomes by Reverse Phase Evaporation.**

## Evalution of Transethosomes

### 1. Transmission Electron Microscopy:[20]

TEM was used for imaging of the transethosomes vesicles. Transethosomal dispersion (selected formulation) was diluted tenfold utilizing distilled water, then a drop was placed on a copper grid with a 300-mesh carbon coating and allowed to sit for a minute to allow some of the vesicles to stick to the carbon substrate. A piece of filter paper was used to remove extra dispersion, and the grid was then rinsed twice in deionized water for 3–5 seconds. The sample was then examined under a microscope utilizing 10–100× magnification and an accelerating voltage of 100 kV.

### 2. Entrapment efficiency: [21]

The entrapment efficiency of transethosomes is determined using ultracentrifugation technique. The technique involves performing ultracentrifugation at 1500rpm for 60 minutes at 4°C. The sediment and supernatant liquid are separated, and the amount of sediment is determined. The drug entrapment efficiency is then calculated using an equation.

$$EE = \frac{Amount\ of\ entrapped\ drug}{total\ amount} * 100$$

### 3. Optical Microscopy:[22]

The transethosomes were mounted on glass slides and viewed under a microscope with a magnification of 1200X for morphological observation after suitable dilution. The photomicrograph of the preparation also obtained from the microscope by using a digital SLR camera.

### 4. Vesicle charge: [23]

Vesicle charge is determined by measuring zeta potential for morphological observation after suitable dilution. The photomicrograph of the preparation also obtained from the microscope by using a digital SLR camera.

### 5. Interaction studies by using FTIR spectroscopy:[24]

The drug-excipients interaction was studied using a Fourier transform infrared spectrophotometer (FTIR). IR spectra for drug and powdered transethosomes were recorded in a Fourier transform infrared spectrophotometer (FTIR 1615, Perkin Elmer, USA) with Potassium Bromide (KBr) pellets. The spectra were scanned over the 3600 to 400 cm-1 range.

### 6. Stability study:[25]

The stability testing is done to guarantee the quality, safety, and effectiveness of the active medication ingredient in dosage forms throughout storage. For six months in a stability chamber, transethosomal gel formulations were kept in tightly closed, amber-colored glass containers sealed with aluminum foil at three different temperatures: room temperature (25°C±2°C/60%RH±5%), refrigerator temperature (4.0 °C±1. 0 °C), and accelerated temperature (40°C±2°C/75% RH ± 5%). The samples were taken out at the end of the first, second, third, and six months to assess the in-vitro drug release, pH, entrapment efficiency, and drug concentration.

### 7. Drug content:[26]

Drug concentration in transethosomal gel was measured by HPLC. By accurately weighing 5 gm and dissolving it in 50 ml of transethosomal gel in purified water, the amount of drug present in the gel was determined using sonication with phosphate buffer at pH 7.4.

Sonication for 15 minutes and heating for 5 minutes. The test was conducted into the triplicate, and the average percentage of drug content was calculated.

The % drug content of transethosomal preparation was determined by using the following formula:

% drug content = Sample absorbance /standard absorbance

**Application:**

When compared to liposomes, ethosomes and nanoethosomes; transethosomes are more effective. They distribute drugs 65% more effectively than liposomes do because they can pass through more layers of human skin with ease. The effectiveness of these vesicular systems is being investigated using a small number of bioactive compounds [27].

**Delivery of NSAIDs (Non-steroidal Anti-inflammatory Drugs):[28]**

When taken orally, non-steroidal anti-inflammatory drugs (NSAIDs) can cause gastrointestinal side effects. However, a transethosomal formulation of ketorolac tromethamine has shown improved penetration, while a piroxicam transethosomal gel has demonstrated greater stability and elasticity compared to other deformable vesicle systems, according to Garg V et al.

In an experiment, Paolina et al. administered ethosomes containing ammonium glycyrrhizinate to humans. The formulation with 45% ethanol and a lower proportion of lecithin produced better results. The in vitro study showed improved tolerability and percutaneous permeability, while volunteers in the *in vivo* trial exhibited increased anti-inflammatory activity.

**Delivery of hormones:[29]**

Hormones are administered orally, they can cause several problems such as high first-pass metabolism, poor oral bioavailability, and a range of dose-dependent side effects. In an experiment, Touitou et al. compared the skin penetration capacity of testosterone ethosomes to a commercially available testosterone transdermal patch (Testoderm® patch, Alza Corporation, California) through rabbit pinna skin. The ethosomal formulation's testosterone skin penetration was around 30 times greater than that of a commercially available

transdermal patch. Additionally, the ethosomes system's AUC and Cmax were larger than those of Testoderm®.

**Delivery of Antibiotics:**[30]

Topical delivery of antibiotics is a better choice for increasing the therapeutic efficacy of these agents. Conventional oral therapy causes several allergic reactions along with several side effects. Conventional external preparations possess low permeability to deep skin layers and subdermal tissues. Ethosomes can circumvent this problem by delivering a sufficient quantity of antibiotic into deeper layers of skin. Ethosomes penetrate rapidly through the epidermis and bring appreciable amount of drugs into the deeper layer of skin and suppress infection at their root. With this purpose in mind, Godin and Touitou developed a bacitracin and erythromycin loaded ethosomes formulation for dermal and intracellular delivery. The results of this study showed that the ethosomal formulation of antibiotic could be highly efficient and would overcome the problems associated with conventional therapy.

**Delivery of antifungal drugs:**[31]

Verma et al. conducted a study to evaluate the effectiveness of transethosomes as a drug delivery system for antifungal drugs. They used Econazole Nitrate as the active ingredient and compared the efficacy of econazole nitrate loaded transethosomal gel with that of marketed econazole nitrate transdermal cream. The study found that transethosomal gel exhibited high ex vivo skin retention and high in vitro antifungal activity. Moreover, the drug was released in a controlled manner, which helped eliminate cutaneous candidiasis.

**Delivery of Anti-parkinsonism agent:**[32]

Trihexypheni dyl hydrochloride (THP), a psychoactive drug used to manage Parkinson's disease, was formulated into an ethosomal formulation by Dayan and Touitou. They compared it to conventional liposomal formulations and found that the ethosomal-THP formulation had a greater capability for skin penetration. This suggests that the ethosomes-THP formulation may be more effective in managing Parkinson's disease.

**Cosmeceutical application:**[33]

Cosmetic formulations have effectively incorporated ethosomes due to their advantages such as improved transdermal penetration, increased stability, and less skin irritation from harsh cosmetic chemicals. Ethosomal creams containing curcuma longa extract have also been

created and studied for their potential to have anti-aging and photoprotective properties. The use of C.longa extract-loaded ethosomal creams as a photoprotective and antiwrinkle treatment on human volunteers produced good results in both studies. Yeh et al. developed a transethosome-based hair dye that has been demonstrated to be more effective than a hydroethanolic solution at delivering and enhancing the absorption of black tea extracts to the hair surface.

**Delivery of Anticancer drugs:[29]**

Lei et al. conducted experiments using dual drug loading and transethosomal formulation while treating cutaneous melanoma. They found that dacarbazine and tretinoin worked better together than other formulations and had less cytotoxicity. Dual loaded transethosomes showed improved antitumor efficacy compared to a single-loaded drug. They also discovered that skin penetration can be increased. Shaji et al. found that encapsulating 5-Fluorouracil into a transethosomal gel led to improved deformability, higher skin penetration, and deeper skin targeting compared to ethosomes.

**FUTURE PROSPECT:**

Transethosomal vesicular carriers are a new and innovative technology for delivering medication that researchers are currently studying. The creation, production, importation, export tion, and distribution of drugs should be regulated to adhere to set standards, which makes the future look promising. Manufacturers should ensure that their transethosomal formulations meet the required standards. The excipients used by researchers are “Generally regarded as Safe” and clinically non-toxic.[33]

Transethosomes are a new and innovative technology for delivering medication that researchers are currently studying. They offer a superior carrier system to guarantee the stability of various proteins and medications. Both hydrophilic and hydrophobic medicines can be loaded with it. Transethosomes can be used to deliver many drug types, including antivirals, anti-diabetics, and anticoagulants. Transethosomal administration of an anticancer medication combination is possible with minimal cytotoxicity. To boost a drug’s efficacy, combinations of different medications can be given as transethosomes. Although there isn’t a lot of clinical trials literature available because it’s not commercially available, transethosomes have a lot of potential for usage as a delivery system for topical or transdermal drugs.[34]

## CONCLUSION

The development of ethanol-based ultra deformable vesicular (UDV) systems has made it possible to overcome the barriers that prevent some bioactive chemicals from penetrating the skin. Ethosomes, transferosomes, and anastomoses are components of this new vesicular system. The transethosomal vesicular system is particularly noteworthy due to its improved compatibility with both hydrophilic and hydrophobic therapeutic molecules, which can offer enhanced solubility, penetration, and flexibility. Alcohol and edge activators make up the transethosomal system, which aids in improved topical medication administration to the intended spot. The transethosomal system has the ability to deliver medications with enormous molecular weight, such as peptides and protein molecules, due to high carrier capacity. High patient compliance is achieved when transethosomal gel or cream is used topically. Moreover, ethosomes systems are employed to deliver cosmeceuticals, anticancer, antiviral, antifungal, and anticancer medications. The transethosome vesicular system is more effective than other traditional transdermal permeation approaches because it delivers safety, efficacy, and patient compliance.

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