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TWO LAYER MODEL TO SIMULATE TRANSDERMAL DRUG DELIVERY FOR SKIN PSORIASIS

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ABSTRACT: Psoriasis is a non-infectious, dry, inflammatory skin disorder. It results in patches of thick, red skin covered with silvery scales. Transdermal drug delivery is used to deliver drugs through the skin, but the skin is an effective barrier and provides resistance to drug delivery. To improve drug delivery through the skin, permeation enhancers are used. The simulation using the COMSOL software will help to treat the psoriasis skin in a non-invasive manner. The main objective is to create a psoriasis skin model that replicates skin psoriasis properties. Designing a psoriasis skin model using COMSOL Multiphysics software helps to understand the biomechanical properties of the skin when the transdermal drug and the permeation enhancer are delivered. Transepidermal water loss (TEWL or TWL) is one of the causes of psoriasis. It is the loss of water that passes from inside a body through the epidermis to the surrounding atmosphere through diffusion and evaporation processes. To reduce the Transepidermal water loss, the transdermal drug carriers like Liposomes, Niosomes, and Ethosomes are delivered inside the skin along with the drug Calcipotriol. Our results showed that the Niosomes has a better capacity to reduce the amount of water lost in the epidermis than the Ethosomes and conventional Liposomes. Accordingly, it can be put forth that the Niosomes show a lesser recovery period for the psoriasis disease. Thus, the niosome can be used as a future transdermal drug carrier for the treatment of psoriasis.

INTRODUCTION: Psoriasis is a lifelong condition that is caused by the negative signals produced by the immune system, which leads to hyper-proliferation and other inflammatory reactions on the skin.

In this case, keratinocytes, which are the outermost layer of skin, possess a shortened lifecycle and results in the alteration of the desquamation process where the cytokines will come out through lesions of affected patients and as a result, scaling marks appear on the skin.

Psoriasis causes proliferation and abnormal differentiation of keratinocytes and epidermal changes ¹⁻⁵. The trans-dermal drug is accepted as a non-invasive route of drug administration. It enhances the permeability of stratum corneum ⁶⁻⁷. Liposomes and niosomes are transdermal drug

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carriers that are used for the treatment of psoriasis⁸. It has been explained that psoriasis occurs because of barrier function derangement. This may be due to altered stratum corneum and defective water barrier function. Thus it has been investigated that transepidermal water loss values will be higher, and hydration values are less in psoriatic affected skin⁹.

It has been proposed that there is progress in the treatment of psoriasis through novel drug delivery systems. The outermost layer of skin, called keratinocytes, possesses a shortened life cycle, and the cytokines will emerge through the lesions of affected patients, and it causes the scaling marks to appear on the skin. This condition causes psoriasis. The list of drugs used to treat the skin affected by psoriasis includes methotrexate, cyclosporin, clobetasol propionate, calcipotriol, betamethasone, tazarotene, temoporfin, tretinoin¹⁰. Hence, the present work is to create a psoriasis skin model that replicates skin psoriasis properties. Thus the drug that can reduce the recovery time can be found, and the skin model helps to treat the skin in a non-invasive manner.

MATERIALS AND METHODS:

Flow Diagram: The work involves four steps, as shown in **Fig. 1**, and thereby, the skin response can be observed. The skin exhibits viscoelastic material properties, and as a result, the mechanical response loading involves both a viscous component associated with energy dissipation and an elastic

component associated with energy storage. Skin stimulation is a technique in which a mechanical model of the human skin can be created using simulation software, COMSOL¹¹.

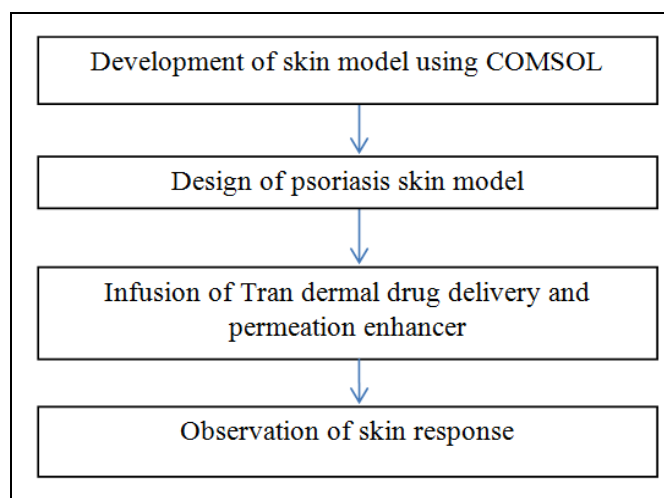


FIG. 1: FLOW DIAGRAM

Design of Transdermal Drug Delivery: A drug delivery system was designed with the laminar flow found in COMSOL. Physics of transport of dilute species were used where the drug will start to flow uniformly. The process of diffusion takes place, and the drug will flow from the region of higher concentration to the region of lower concentration. The drug will have a higher concentration, and the epidermal layer of the skin will have a lower concentration. Thus the drug will start to flow in the epidermal layer of the skin.

TABLE 1: PROPERTIES OF LIPOSOME, NIOSOME, ETHOSOME

No.	Author	Transdermal Drug	Density Rho (Kg/m ³)	Dynamic viscosity Mu (Pa.s)	Young's modulus E (Pa)	Poisson's ratio Nu (1)
12	Louise, Prashant, Megan D	Liposome	70	1.5	1	0.25
13	Baillie AJ	Niosome	80	0.3	1.2	0.5
14,15	Ibrahim M Abdulbaqi	Ethosome	70	1.5	1	0.25

Note: the number (No.) corresponds to the numbering in the list of references; Density, Dynamic viscosity, Youngs modulus and Poisson's ratio

The enhancers designed were liposome, ethosome, niosome and the drug used was calcipotriol. Liposomes and niosome are used as topical drug carriers for dermal and transdermal drug delivery in the treatment of psoriasis¹⁹⁻²⁴. Micro-needles are used for transdermal drug delivery. The micro-needles increase the permeability of the drug by

bypassing the stratum corneum, but the micro-needles can cause damage to the skin²⁵⁻³³. Thus the liposome, ethosome, and niosomes are used as topical drug carriers³⁴⁻³⁶. These drug carriers and the drug was placed above the epidermal layer of the skin, and the drug will flow through the process of diffusion and the response of the skin was found.

The transdermal drug carriers exhibit certain viscoelastic properties³⁷⁻³⁸, and their corresponding properties are shown in the following **Table 1**.

Collagen: Collagen is the significant structural protein found in all living organisms. It is the most available protein in the human body. The epidermis is made with the material called collagen, and the corresponding properties are shown in **Table 2**

Calcipotriol: The drug calcipotriol is efficient in the treatment of psoriasis. Calcipotriol was developed along with the transdermal drug carriers. The properties of this drug are listed below in **Table 3**.

TABLE 2: PROPERTIES OF COLLAGEN

No	Author	Density rho (Kg/m ³)	Bulk modulus K (N/m ²)	Young's modulus G (GPa)
16,17	Albert L., Arul jothy	1.09	0.5	5

Note: the number (No.) corresponds to the numbering in the list of references; Density, Bulk modulus and Young's modulus of Collagen.

Transepidermal Water Loss (TEWL): Transepidermal water loss (TEWL or TWL) is the loss of water that passes from inside a body

TABLE 3: PROPERTIES OF CALCIPOTRIOL

No.	Author	Name of the Drug	Elasticity Rho (Pa)	Dynamic viscosity Mu (Pa.s)	Young's modulus E (Pa)	Poisson's ratio Nu (1)
18	JP Marty	Calcipotriol	70	1.3	1.46	0.5

Note: the number (No.) corresponds to the numbering in the list of references; The Elasticity, Dynamic viscosity, Young's modulus and Poisson's ratio of Calcipotriol

RESULTS:

Development of Skin Layers: Epidermis, Dermis, and the Hypodermis layer of the skin was developed using COMSOL. The uppermost layer was the epidermis and the underlying layers are the dermis and hypodermis. The drug was injected in the epidermis, and its response was studied. So the thickness of the epidermal layer was made higher than the dermis and the hypodermis layer.

Stress & Strain Characteristics for the Developed Skin Model: In the stress-strain characteristics of the skin, the strain is increased with the increase in stress. Stress-strain characteristics exhibit the toe region and the linear region. The toe region typically lies below 3% strain, a region in which specimen elongation is

through the epidermis to the surrounding atmosphere *via* diffusion and evaporation processes.

Psoriasis is a chronic skin disease that affects an estimated 125 million population worldwide. Research has shown that the epidermal permeability barrier function varies with skin pigmentation. The barrier function is deranged in psoriasis.

When the temperature is increased from 28 degrees Celsius to 36 degrees Celsius, the loss of water occurs, which proves that the skin is prone to infection, and thereby, because of this water loss, the skin can be identified as psoriasis affected skin. The water loss through the skin when sweat glands are absent or inactivated is known as trans-epidermal water loss (TEWL).

In normal skin, increasing skin temperature from 25 °C to 39 °C raises the TEWL rate exponentially. It is likely that the filtration properties of normal skin, which determine this exponential relationship with skin temperature, would be different from those of pathologic skin.

accompanied by very low stress. The linear region is evident beyond approximately 2 to 3% tensile strain. The slope of this linear portion of the curve has been used to define the "Young's modulus".

Design of Model Transdermal Drug Delivery: The transdermal patch was designed with the liposome as the enhancer and the calcipotriol as the drug. This patch is placed above the epidermal layer of the skin. The psoriasis is a chronic disease that affects the epidermal layer of the skin, and hence the transdermal patch containing the drug and the enhancer are placed above the epidermis.

Diffusion vs. Time Plot: The drug and the enhancer are diffused inside the epidermal layer of the skin. **Fig. 1** shows the diffusivity of the drug

and the enhancer concerning time. The red line indicates the diffusion at the initial state with the diffusivity of the drug as zero. The green line indicates the diffusion of the drug, and the blue indicates the diffusion of permeation enhancer inside the epidermis.

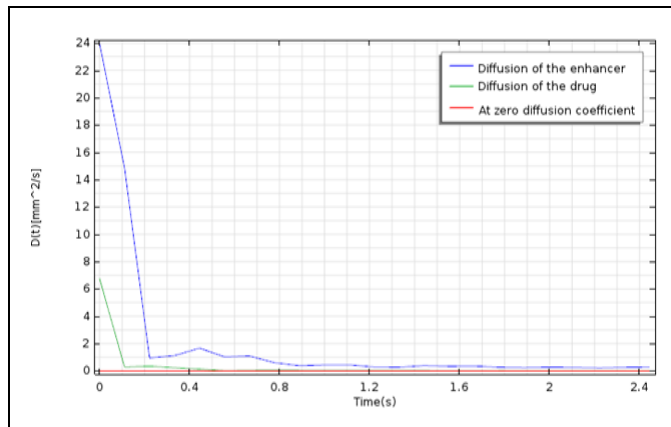


FIG. 1: DIFFUSION OF DRUG AND LIPOSOME ON THE EPIDERMIS

Viscosity vs. Shear Rate: The viscosity of the drug decreases, which indicates that the penetration of the drug is increased. When the penetration of the drug is increased, the skin can regain its original shape and it is shown in Fig. 2. Shear rate indicates the rate of change of velocity at which one layer of fluid passes over an adjacent layer. Viscosity is a property of the fluid which opposes the relative motion between the two surfaces of the fluid that are moving at different velocities

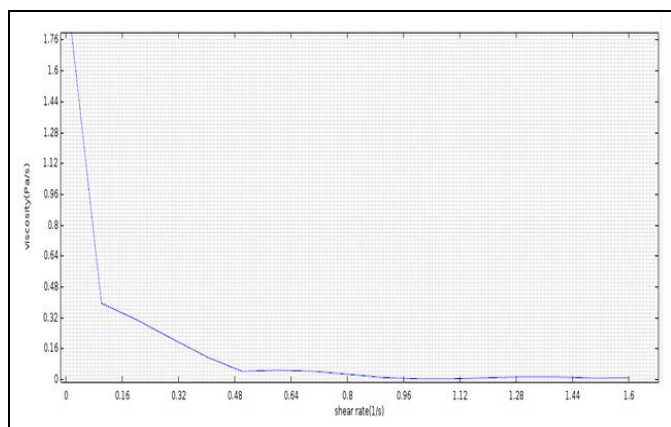


FIG. 2: VISCOSITY vs. SHEAR RATE

Response of the Skin for the Drug and Enhancer: Liposome has better structural recovery on the skin. Yield stress will become lower; thereby small stress is needed to initiate the flow, which may be better in terms of applicability of the formulation of skin, and it is shown in Fig. 3. On

the application of the transdermal drug and the enhancer, the following inferences are made: Liposome has better structural recovery on the skin. Yield stress will become lower, thereby small stress is needed to initiate the flow, which may be better in terms of applicability of the formulation of skin.

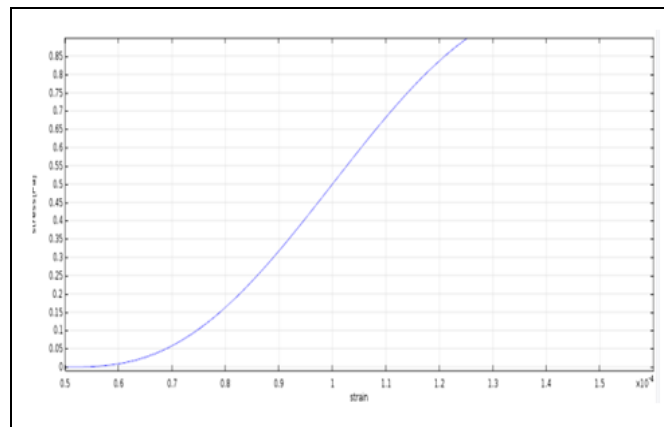


FIG 3: STRESS vs. STRAIN CURVE

Design of Psoriasis Skin: Barrier function is deranged in psoriasis. The epidermal layer of the skin has the loss of water, and thereby it is prone to infection and gets affected by psoriasis. Thus the designed infected layer of the epidermis is shown in Fig. 4.

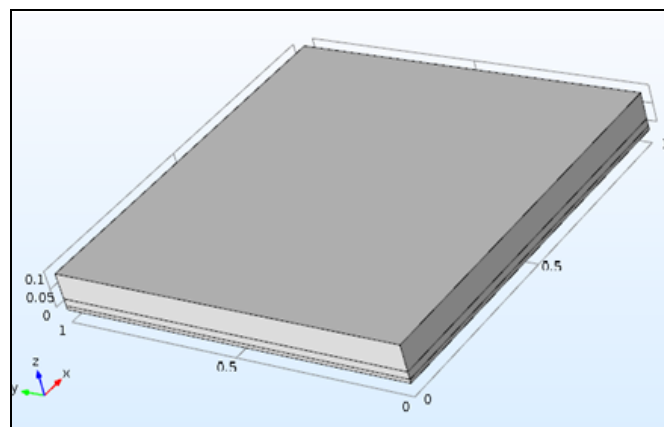


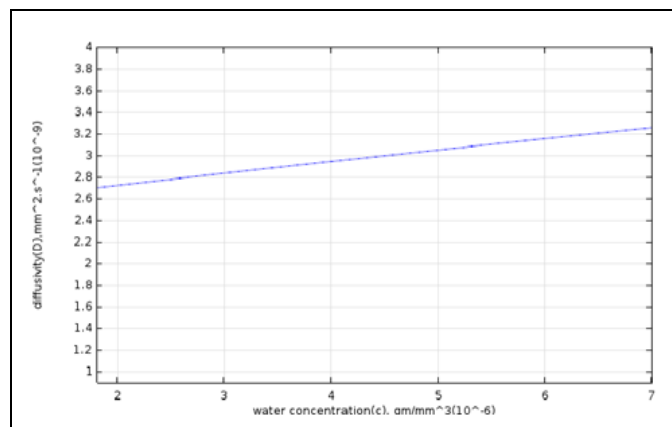
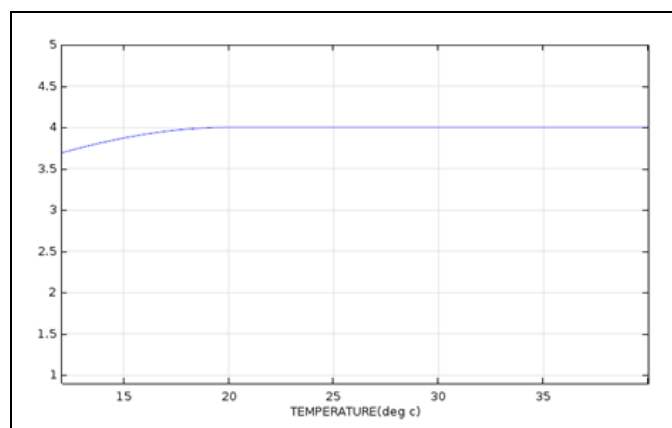
FIG. 4: PSORIASIS SKIN MODEL

Significant differences are observed in skin hydration, TEWL because of barrier function derangement. TEWL in involved psoriatic skin is around 2.5 times than that of normal skin. Thus the designed model of skin has a loss of water, and it is affected by psoriasis. The concentration of the water at the dermal layer is given as 1000 mol/mm³. Thus due to the process of diffusion, the amount of water that is diffused inside the epidermis with its diffusivity is shown in Fig. 5.

Transepidermal Water Loss vs. Temperature:

The level of water loss in the layer of the epidermis is shown in **Fig. 6**, and this shows that the epidermal layer of the skin is affected by psoriasis. At the temperature of 28 °C the level of water loss is $4.3\text{E-}2 \text{ cm}^{-2} \text{ hr}^{-1}$.

For the normal skin, the water loss will be low. But due to the high level of water lost in the epidermis, there is a derangement of barrier function, which proves the presence of psoriasis in the epidermis.

**FIG. 5: DIFFUSION vs. CONCENTRATION****FIG. 6: TEWL vs. TEMPERATURE**

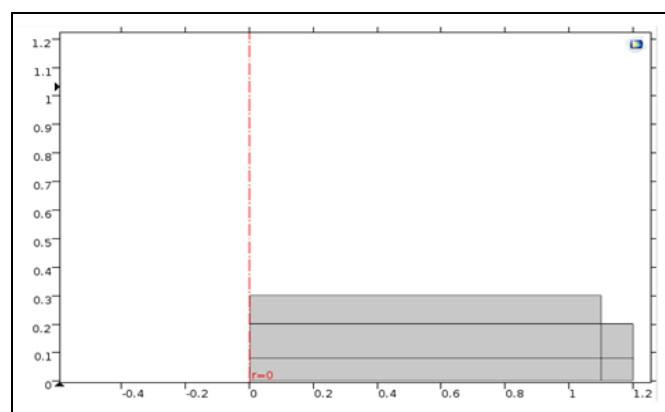
Diffusion vs. Concentration: The dermal layer of the skin has a higher concentration of water and hence the process of diffusion takes place. The level of diffusion of the water to the epidermis is shown in **Fig. 5**.

Transepidermal Water Loss vs. Temperature:

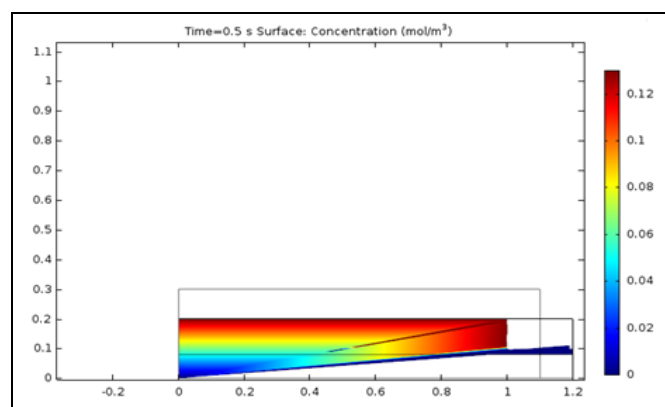
At the temperature of 28 °C the level of water loss is $4.3\text{E-}2 \text{ cm}^{-2} \text{ hr}^{-1}$. For the normal skin, the water loss will be low. But due to the high level of water lost in the epidermis, there is a derangement of barrier function, which proves the presence of psoriasis in the epidermis.

Design of Patch Containing Liposome on Psoriasis Affected Skin:

The patch containing liposome is placed above the affected epidermal layer of the skin, and it is shown in **Fig. 7**.

**FIG. 7: TRANSDERMAL PATCH ON THE LAYERS OF THE SKIN****Concentration of Drug in the Epidermis:**

After placing the patch containing the drug and the enhancer, it takes 0.5s to diffuse inside the epidermal layer of the skin, and it is shown in **Fig. 8**. The concentration of the drug is higher in the epidermal surface, and it gets reduced when it reaches the dermal layer. Thus the derangement of barrier function can be recovered, and the loss of water is reduced.

**FIG. 8: DIFFUSION OF DRUG AND THE LIPOSOME INSIDE THE EPIDERMIS AND DERMIS****Transepidermal Water Loss vs. Temperature for Liposome:**

After the diffusion of drug calcipotriol and the enhancer liposome inside the skin, the level of water lost is reduced and it is shown in **Fig. 9**. At the temperature of 28 °C, the level of water lost is $0.18\text{E-}2 \text{ cm}^{-2} \text{ hr}^{-1}$. Thus, the level of water lost after the diffusion of the drug is reduced, and the barrier function is arranged to recover the skin from psoriasis.

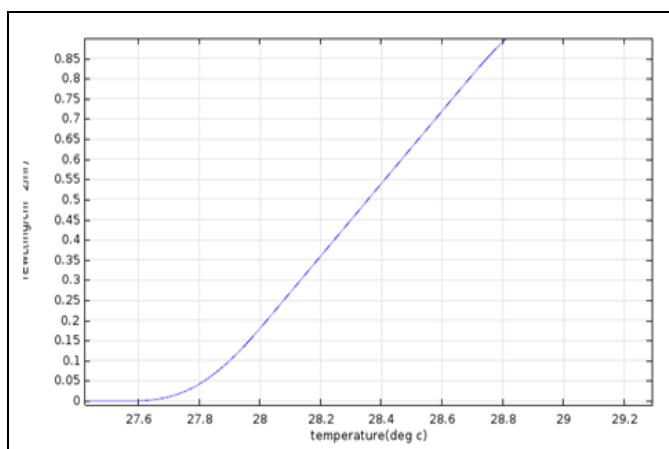


FIG. 9: TEWL vs. TEMPERATURE FOR LIPOSOME

Transepidermal Water Loss vs. Temperature for Ethosome: After the diffusion of drug calcipotriol and the enhancer ethosome inside the skin, the level of water lost reduced is less than the liposome drug but not less than the niosome, and it is shown in Fig. 10.

At the temperature of 28 °C, the level of water lost is $0.14\text{E-}2 \text{ cm}^{-2} \text{ hr}^{-1}$. Thus, the level of water lost, after the diffusion of the drug ethosome, is found to be lesser than the drug liposome.

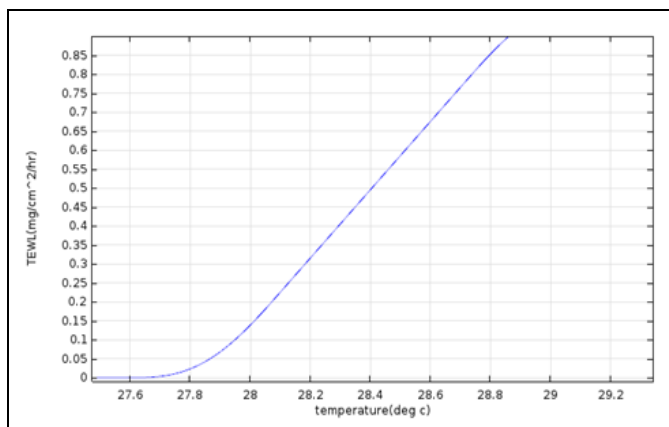


FIG. 10: TEWL vs. TEMPERATURE FOR ETHOSOME

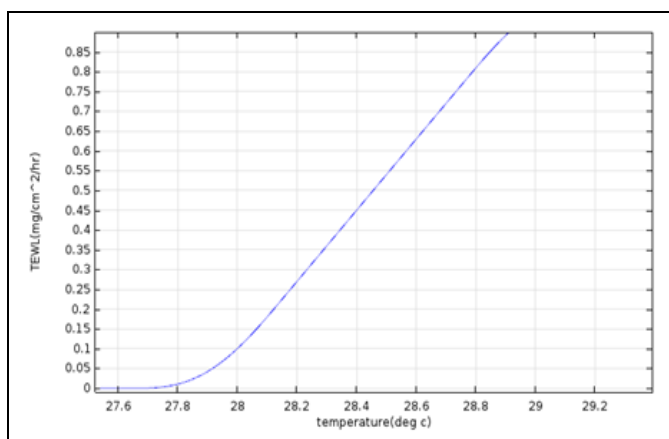


FIG. 11: TEWL vs. TEMPERATURE FOR NIOSOME

Transepidermal Water Loss vs. Temperature for Niosome: After the diffusion of drug calcipotriol and the enhancer niosome inside the skin, the level of water lost is reduced lesser than the liposome, and it is shown in Fig. 11. At the temperature of 28 °C, the level of water lost is $0.1\text{E-}2 \text{ cm}^{-2} \text{ hr}^{-1}$. Thus, the level of water lost after the diffusion of the drug niosome, is found to be lesser than the drug liposome, and it can be inferred that the niosome is efficient in its penetration property, and thereby it can cure psoriasis than the ethosome and the liposome.

DISCUSSION: Psoriasis is a chronic skin disease that affects an estimated 125 million population worldwide. Many factors cause psoriasis, one of the factors is Transepidermal water loss (TEWL or TWL), which is the loss of water that passes from inside the body through the epidermis to the surrounding atmosphere *via* diffusion and evaporation processes³⁹. The epidermal permeability barrier function varies with skin pigmentation. Thus, Psoriasis occurs because of barrier function derangement. The skin is not a uniform sheath covering the body, but a specialized organ with several functions changing from site to site. When the temperature is increased (*i.e.*, 28 degrees Celsius to 36 degrees Celsius), the loss of water occurs, which proves that the skin is prone to infection and thereby, because of this water loss, the skin can be identified as psoriasis affected skin³⁹⁻⁴¹.

The stratum corneum exhibits the permeability barrier for the skin. The transdermal drug delivery through skin is preferable for both local and systemic therapy. Topical treatment targets the site of disease, and henceforth it minimizes the side effects within the body. Thus our work is aimed to deliver the drug-using topical treatment. The demonstration has proven that the drug carriers may serve as a local depot for sustained release of dermal active compounds. Topical drug delivery systems can act superficially on the skin surface, locally in the dermal layer of the skin or transdermally to provide successful delivery of drug molecules to the systemic circulation avoiding the limitations of conventional routes of drug delivery⁴²⁻⁴³. According to a study, liposomes, ethosomes, transfersomes, niosomes and catezomes act as topical drug delivery systems.

One of the major advances in vesicle research is the finding that some specially designed vesicles possessed properties that allowed them to successfully deliver drugs in a deeper layer of skin. Ethosome is one of the specially designed lipid carriers recently developed. It shows enhanced skin delivery. Ethosome is characterized by prolonging physical stability concerning liposomes. Liposomes are made of phospholipids, and niosomes are made of surfactants. Hence, niosomes have greater stability and lack many of the disadvantages associated with liposomes such as high cost, low availability and the variable purity problems associated with phospholipids. Niosomes do not require special conditions such as low temperature or an inert atmosphere during preparation and storage; these features make niosomes more attractive for industrial manufacturing⁴⁴. Niosomes have been demonstrated to be promising controlled delivery systems for the percutaneous administration of both hydrophilic and lipophilic drugs. Our results also show that niosome has a better recovery effect as compared to liposome and ethosome.

CONCLUSION: Examined together, all these observations strengthen our conclusion that niosome has a better recovery effect as compared to liposome and ethosome. Further, our results show niosomes to be promising controlled delivery systems for the percutaneous administration of both hydrophilic and lipophilic drugs. Thus, collectively our findings indicate that the niosome can be used as a transdermal drug carrier for the psoriasis. Further, different combinations of drugs with different types of enhancers can be used, find a suitable drug for psoriasis.

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CONFLICTS OF INTEREST: The authors declare that there is no conflict of interest regarding the publication of this paper.

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