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RECENT ADVANCES IN TRANSFEROSOMAL GEL FORMULATION FOR TRANSDERMAL DRUG DELIVERY

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ABSTRACT

Transferosomes are highly deformable vesicular carriers that have emerged as a promising approach for enhancing transdermal drug delivery. Their unique flexibility enables them to penetrate the stratum corneum and improve drug permeation through the skin. Transferosomal gels combine the advantages of transferosomes with the convenience of topical gel formulations, providing sustained drug release, improved bioavailability, and enhanced patient compliance. This review highlights the composition, preparation methods, mechanisms of skin penetration, characterization parameters, and recent advancements in transferosomal gel formulations. Furthermore, the therapeutic applications of transferosomal gels in the delivery of antiviral, anti-inflammatory, antifungal, and other drugs are discussed. The review also addresses current challenges and future prospects in the development of transferosome-based transdermal drug delivery systems. Overall, transferosomal gels represent a promising and effective strategy for improving the therapeutic efficacy of various drugs through transdermal administration.

KEYWORDS: Transferosomes, Transferosomal gel, Transdermal drug delivery, Vesicular carriers, Skin permeation, Drug delivery systems.

INTRODUCTION

TRANSDERMAL DRUG DELIVERY SYSTEM

Recent research is focused on the creation of novel drug delivery systems with patient compliance as the primary goal and high therapeutic activity. Drugs taken orally encounter a hostile environment in the GI tract, where the majority of medications are destroyed under acidic or alkaline conditions, have solubility problems, and, most significantly,

undergo first pass metabolism. Parenteral preparation has several drawbacks, including a lack of medication reversal, hypersensitive reaction, infection risk, and cost. Some medications are particularly bitter to the taste, making oral administration difficult for patients, and parenteral administration painful due to the necessity for a needle. Because of the variety of benefits of this method, extensive research has been spent on the advancement of topical medication administration during the previous few decades. The skin on an average adult body covers roughly 2 m2 and weighs 3 kg; it gets around one-third of the blood circulating throughout the body.

Topical drug delivery refers to the application of a drug to the skin for a localized effect, whereas transdermal drug delivery systems (TDDS) employ the skin as a potential route for the administration of pharmaceuticals with systemic action. One of the systems with the highest patient compliance is TDDS. Some potential benefits of the transdermal route over other traditional routes include avoiding first- pass metabolism in the same way that oral and parenteral medications do, extending the duration of activity and minimizing unfavourable side effects, using medications with short half-lives, improving physiological and pharmacological response, preventing drug level fluctuations, inter and intra-patient variations, and most importantly, it offers patients convenience.

BASIC COMPOSITION OF THE SKIN

The epidermis, dermis, and subcutaneous tissue, together with sebum and sweat glands, make up human skin. The stratum corneum is formed by the stratified epithelium known as the epidermis, which has layers of spinous and basal granular cells. Compacted with metabolically dormant cells, the stratum corneum is around 15–20 layers deep and contains a complex interlocking structure with proteins and lipids that resembles bricks and mortar. Fatty acids, cholesterol, and ceramides are among the important lipids found in it; ceramides comprise around half of the lipids.

Free fatty acids (10–15 %) are saturated and have a very long chain. The function of the stratum corneum barrier depends on these lipids. About 75–80 % protein, 5–15 % lipids, and 5–10 % unidentified substances make up the stratum corneum. Corneocytes, according to the brick and mortar model, are flat, elongated, and polygonal cells that are 0.2–1.5 µm thick and 34.0–46.0 µm in diameter. They are encased in a lipid matrix that consists of crystalline or gel lipid bilayers and lamellar structures. Importantly, mortar is not just a homogenous matrix; rather, lipids are fairly connected with the lamellar part (corresponding layers of lipid bilayers and water), together with other lipid bilayers found to be in the crystalline or gel form.

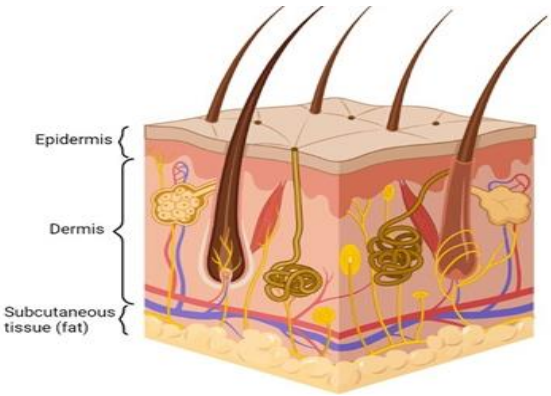

Figure 1: Structure of skin.

SKIN AND PERMEATION

The skin is the body's largest organ, with a surface area of approximately 2 square meters, and obtains approximately one-third of the overall blood supply.

Its functions are as follows:

- It protects from physical, chemical, and biological attacks and environmental conditions.
- It works as a permeability barrier, enabling biological and chemical substances to be absorbed transdermally.

There are three main regions of the skin, i.e., epidermis, dermis, and hypodermis. The epidermis is the outermost layer of the skin, which covers the whole body's surface. It is a self-regenerating and stratified squamous epithelium that comprises a nonviable epidermis called the SC and a viable epidermis separated into four layers, i.e., the stratum lucidum, stratum granulosum, stratum spinosum, and stratum germinativum. The SC, which is composed of 15-20 layers of keratinocytes bound to a lipophilic matrix, is the rate-limiting barrier in the transdermal permeability process.13 The dermis is the skin's middle layer, approximately 2-3 mm thick. It comprises 70% collagenous tissues and elastic fibres, giving the skin strength and elasticity. It also comprises different blood vessels, nerves, and lymph vessels. It possesses a negligible hurdle to the transdermal entry of polar drugs. The subcutaneous layer is the innermost layer of the skin and consists of fat cells. It helps to maintain body temperature and provides nutritional support and mechanical strength to withstand physical shock. A transdermal drug delivery system must penetrate all three layers of the skin for medication delivery to the systemic circulation.

Permeation process

The transdermal drug can be delivered through the skin into circulation by three different routes:

1. Trans-appendageal route

This is also referred to as the SHUNT route. Permeation occurs across the hair follicles through the sweat glands and sebaceous glands. The presence of these appendages provides a clear path across the SC. The follicular number, volume, and opening width are all significant factors in the transport of drugs via appendages.

2. Transcellular route

Although it is thought to be the quickest pathway, drug molecules face significant obstacles since they must go beyond both the hydrophilic and hydrophobic structures. A candidate to cross via this route must partition into and diffuse through the corneocytes. Small lipophilic molecules after partitioning in cell membranes can penetrate via this route.

Hydrophilic molecule partitioning is limited in the cell membrane; however, such types of molecules can penetrate via this pathway if their size is small and/or receptor-mediated transporters are used.

3. Intercellular route

This route is also known as the paracellular route. Hydrophilic drugs can diffuse via this route; however, a smaller particle size is preferred for this pathway. The diffusion of drugs is limited owing to the occurrence of tight junctions.

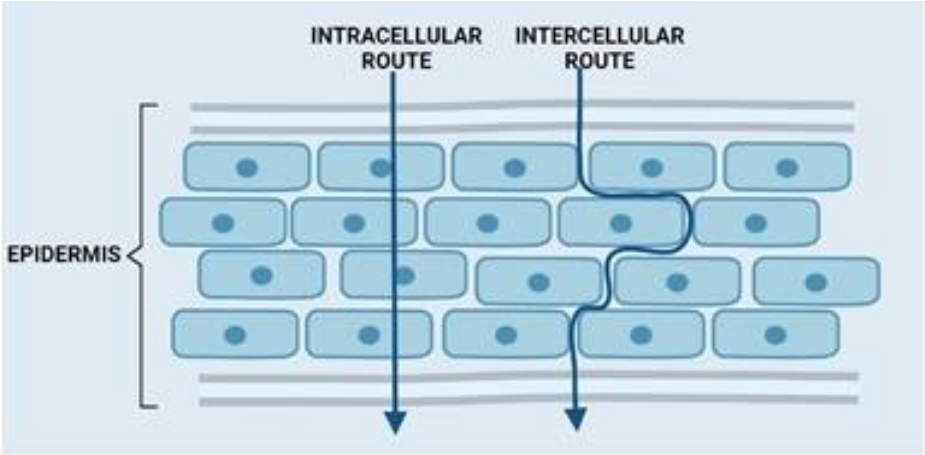

Figure 2: Routes of transdermal permeation.

TRANSFEROSOME

In 1991, Gregor Cevc came up with the term "Transferosome" and the underpinning concept. A Transferosome is a complex agglomeration that is very adaptable and responsive to stress. An ultra-deformable vesicle with a highly complex lipid bilayer entrapping an aqueous core in its preferred form. Because the local composition and form of the bilayer are dependent on one another, the vesicle is self-regulating and self-optimizing. This enables the Transferosome to easily navigate a range of transportation challenges and function as a drug carrier for non-invasive targeted medicine administration and sustained release of therapeutic substances. The transferosome carriers are applied on the skin topically and are designed to attain high medication concentration at the point of delivery or nearby, increasing drug potency and reducing side effects. Transferosomes were developed in order to utilize phospholipid vesicle as transdermal drug transporters. With their ultra-flexible membrane, these self-optimized aggregates can distribute medication into or through the skin in a reproducible manner, regardless of the method of administration or application. These vesicular transferosomes are more flexible than conventional liposomes, making them excellent for skin penetration.

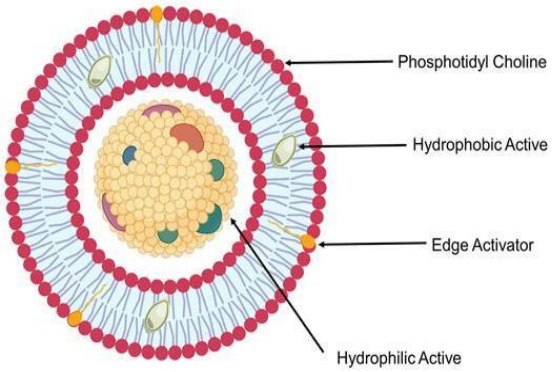

Figure 3: Structure of transferosome.

Transferosomes squeeze along the stratum corneum's intracellular barrier lipid to circumvent the skin's physical barriers to penetration. Due to the high degree of vesicle deformability, which permits entrance due to environmental physical stress in a self-adapting way. The membrane of transferosomes is made flexible by combining the proper surface-active substances in the right amounts. As transferosomes may preserve the naturally occurring water gradient all across epidermis when employed under nonocclusive settings, there is less possibility of a full vesicles rupture in the skin.

Transferosomes can enter the intact skin barrier by themselves through one of the two intra - cellular channels with unique bilayer characteristics. Two intracellular lipid routes with different bilayer properties can both spontaneously allow transferosomes to penetrate the intact stratum corneum.

MATERIALS FOR TRANSFEROSOMES

INGREDIENTS	EXAMPLE	USES
Phospholipids	Soya phosphatidylcholine, egg phosphatidylcholine	Vesicles forming component
Surfactant	Sodium cholate, Sodium deoxycholate, span-80, Tween-80	Providing flexibility
Alcohol	Ethanol, methanol	Solvent
Buffering agent	Saline phosphate buffer (pH 7.4)	Hydrating medium

ADVANTAGES

- Transferosomal carriers are made up of both hydrophilic and hydrophobic units, making them the only drug delivery system capable of delivering therapeutic compounds in a wide range of solubility.
- Because of their ultra-deformability and elastic qualities, transferosomes can squeeze through skin barrier constrictions that are thin, such as 5-10 times smaller than vesicle size.
- High vesicle deformability allows medications to flow through the skin without causing significant vesicle loss, and can be employed for both topical and systemic therapy.
- Regardless of size, shape, molecular weight, or polarity, these carriers are highly adaptable and efficient in accommodating a range of agents.
- As these units are prepared with natural phospholipids and edge activators. These are biodegradable and biocompatible.
- Transferosomes are used to transfer proteins and peptides, insulin, corticosteroids, interferons, anaesthetics, NSAIDS, anti-tumor medications, and herbal remedies, among other active chemicals.
- Transferosomes are prime choice for obtaining a sustained drug release, as well as expectable and extended period of activity.

DISADVANTAGES

- Because of their proclivity for oxidative stress, transferosome formulations are chemically unstable. When aqueous media is degassed and purged with inert gases such as nitrogen and argon, the oxidation of transferosomes is dramatically reduced.
- Another challenge of using transferosomes as drug delivery vehicles is obtaining the 117 purity of natural phospholipids, which is difficult to produce. As a result, synthetic phospholipids could be used as a substitute.

CHARACTERIZATION OF TRANSFEROSOMES

1. The zeta potential and particle size determination

The particle size and zeta potential will be assessed at 250°C using a dynamic light scattering instrument and particle size analysis. The produced sample is diluted with filtered water before being measured using a Malvern zeta sizer made in the United Kingdom. Zeta sizer made in the United Kingdom.

2. Vesicle morphology

Transmission electron microscopy and phase contrast microscopy were used to visualize transferosome vesicles. The size and structure of vesicles can be used to determine the stability of vesicles throughout time.

3. Entrapment efficiency

It is expressed in terms of percent drug entrapment, and the unentrapped drug can be separated first using the micro column centrifugation method. 0.1 percent Triton x-100 or 50 percent n-propanol are used to disrupt vesicles.

Entrapment efficiency = (Amount entrapped/Total amount absorbed) x 100

4. Drug content

The drug content can be calculated by using HPLC with UV detectors or Spectrophotometric methods.

5. In-vitro drug release

Mini column centrifugation is used to measure the penetration rate, in which the suspension is incubated at 32°C and samples are obtained at different time intervals, with the free drug being extracted. Secondarily, the volume of drug entrapped at Zero times is used to compute the quantity of drug released.

6. In-vitro skin permeation study

The skin of a goat is utilised in a phosphate buffer with a pH of 7.4. The hair on the skin is removed, and the skin is moisturised with regular saline. The cotton swab should be used to remove fat tissues. A modified franz diffusion cell with a 50 mL column and a receiver compartment effective area of 2.50 cm2. Skin can be kept at a low temperature in IPA. with a 100rpm stirring speed and the stratum corneum towards the donor compartment A 1mL aliquot is drawn and replenished with fresh phosphate buffer on a regular basis.

7. Penetration ability

Assessment of penetration capability of transferosomes can be performed by using Fluorescence Microscopy.

MECHANISIM OF ACTION OF TRANSFEROSOME:

Transferosomes have a better penetration efficiency (through small skin pores) than traditional liposomes, but they have a similar bilayer structure that allows for the encapsulation of hydrophobic, hydrophilic, and amphiphilic medicines. Transferosomes differ from liposomes in that their non-natural membranes are softer, more flexible, and ultra-deformable.

Transferosomes are supramolecular units made up bilayer of amphipathic agent (phospholipid), and adding a bilayer unstiffening agent improves the elasticity and penetrability of the bilayer (edge activator). Alcohol is present in high or low concentrations in the formulations of several transferosomes as penetration enhancers and as solvating cosolvents. Vesicles are self-regulating and self- optimizing due to the shape of the lipid bilayer and the interdependency of local composition. Transferosomes can effectively and easily bypass many transport barriers in the body due to the existence of this feature.

Ethanol has been suggested as a way to modify the polar head area of the lipid bilayer. Following penetration, ethanol increases the fluidity of the intercellular lipid matrix and, as a result, the density of the lipid lamellae decreases.

Transferosomes can pass through the stratum corneum and reach the dermis and blood flow, among other places. The deformability of the transferosomal membrane, which can be linked to the vesicle compositions, determines their ability to penetrate. As a result, the best vesicle compositions must be found by executing specially tailored experimental procedures for each medicinal drug in order to acquire the best carriers.

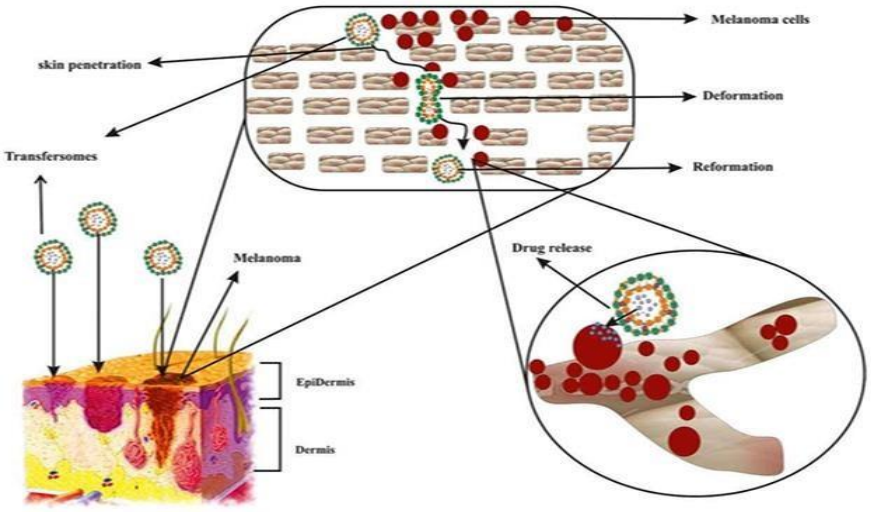

Figure 4: Mechanism of action of transferosomes.

METHODS OF PREPARATIONS

1. Thin film hydration technique

A thin film is formed by dissolving the lipids, such as phospholipids and surfactant in organic solvent, such as chloroform or methanol. The solvent is then evaporated using a rotary evaporator or a vacuum pump to obtain a thin lipid on the walls of the flask. The lipid film is then hydrated with an aqueous solution containing the drug or active compound of interest, along with additives such as stabilizers, permeation enhancers or preservatives. The hydration process leads to the formation of multilamellar vesicles, which are subjected to size reduction step, either by sonication or extrusion to obtain smaller vesicles.

2. Modified hand shaking method

The modified handshaking method has the same basic principle as the rotary evaporation-sonication method. In the modified handshaking process, a lipid mixture is prepared by dissolving the lipids, such as phospholipids and surfactants, in a suitable organic solvent, such as chloroform or methanol. A solution of the drug or active compound of interest is prepared separately in an aqueous solvent, such as distilled water or phosphate buffered saline. The lipid mixture is then added to the drug solution drop wise and the mixture is shaken vigorously by hand to form milky suspension. The shaking process is repeated for a few minutes to ensure uniform mixing and entrapment of the drug in the lipid bilayer. The milky suspension is then subjected to sonication to obtain smaller vesicles.

3. Reverse -phase evaporation Method

The phospholipids and edge activator are added to a round-bottom flask containing organic solvent mixture such as diethyl ether and chloroform. The lipophilic drug can be incorporated in this step. Then, the solvent is evaporated using rotary evaporator to form concentrated lipid films. The lipid films are rehydrated by dissolving in the organic phase mostly composed of isopropyl ether and or diethyl ether the aqueous phase is added to the organic phase, which leads to formation of two-phase system. The hydrophilic drug incorporation can be done in this stage. This system is then subjected to sonication using a bath sonicator until a homogeneous w/o (water oil) emulsion is formed. The organic solvent is slowly evaporated using rotary evaporator to form a viscous gel, which then becomes a vesicular suspension.

4. High-pressure homogenization Technique

The phospholipids, edge activator and the drug are uniformly dispersed in phosphate-bufered saline or distilled water containing alcohol and followed by ultrasonic shaking and stirred simultaneously. The mixture is then subjected to intermittent ultrasonic shaking. The resulting mixture is then homogenized using a high-pressure homogenizer. The homogenizer applies high pressure to the suspension to break down the lipid bilayers and form smaller vesicles.

5. Ethanol injection method

The organic phase is prepared by dissolving the phospholipid, edge activator and the lipophilic drug in ethanol with magnetic stirring for the respective time, until a clear solution is obtained. The aqueous phase is produced by dissolving the water-soluble substances in the phosphate buffer. The hydrophilic drug incorporation can be done in this stage. Both solutions are heated up to 45-50°C. Afterwards, the ethanolic phospholipid solution is injected drop wise into the aqueous solution with continuous stirring for the respective time. The addition of ethanol causes the formation of smaller lipid aggregates which fuse to form larger vesicles. The mixture is then stirred for a sufficient period of time to allow for the complete removal of the ethanol and then subjected to sonication for particle size reduction.

6. Vortexing-sonication method

The phospholipids, surfactants and the drug are mixed in a phosphate buffer. The mixture is then vortexed until a milky transferosomal suspension is obtained. The milky suspension is subjected to sonication, either by using a probe sonicator, bath sonicator, smaller vesicles.

APPLICATION OF TRANSFEROSOME

- **Delivery of proteins and peptides**

Transferosomes are frequently used to deliver proteins and peptides because these large molecules are typically hard to transport into the body when taken orally, as they can be degraded in the gastrointestinal tract. This is why they are usually introduced into the body through injections.

- **Delivery of insulin**

Transferosomes are a successful way to deliver large drugs non- invasively through the skin. Insulin is usually given through inconvenient subcutaneous injections.

- **Delivery of corticosteroids**

Transferosomes can be used to deliver corticosteriods to the skin. By optimizing the dose of the drug given through the skin, transferosomes can improve the specificity and safety of corticosteriod delivery.

- **Delivery of anti-inflammatory drugs**

Transferosomes have been studied as a means of delivering anti - inflammatory drugs such as diclofenac sodium, celecoxib, mefenamic acid, and curcumin through topical administration.

- **Delivery of anticancer drugs**

Researchers have studied the use of transferosomes to deliver anti-cancer drugs such as methotrexate, through the skin.

- **Delivery of herbal drugs**

Transferosomes can be used to deliver herbal drugs through the skin and provided nutrients to support the function of the stratum corneum. Curcumin and capsium are examples of herbal drugs that have been delivered topically using transferosomal formulations.

TRANSFEROSOMAL GEL

A gel consists of a natural or synthetic polymer forming a three dimensional matrix throughout a dispersion medium or hydrophilic liquid after application the liquid evaporates leaving the drug entrapped in a thin film of the gel forming matrix physically covering the skin. The presence of a network formed by the interlocking of particles of the gelling agent gives rise to the rigidity of a gel. The nature of the particles and the type of form that is responsible for the linkage determines the structure of the network and property of the gel. The forces of attraction responsible for the linkage between gelling agent particles may range from strong primary valencies, as in silica acid gels, to weaker hydrogen bond and wander wall forces. The weaker nature of these latter forces is indicated by the fact that a slight increase in temperature often causes liquefaction of gel.

CLASSIFICATION

Gels can be classified based on colloidal phases, nature of solvent used, physical nature and rheological properties.

1. **Based on Colloidal phase**

a) **Inorganic (Two phase system)-** If the partition size of dispersed phase is relatively large and form the three-dimension structure throughout gel such a system consists of floccules of small particles rather than larger molecules and gel structure, in this system is not always stable. They must be thixotropic forming semisolid on standing and become liquid on agitation.

b) **Organic (single phase system) –** These consist of large molecules existing on the twisted strands dissolved in a continuous phase. This larger organic molecule either natural or synthetic polymers are referred as gel formers they tend to entangle with each other their random motion or bound together by Vander walls forces.

2. **Based on nature of solvent**

a) **Hydro gels (water based) -** they contain water as their continuous liquid phase. E.g. - Gelatin, cellulose derivatives.

b) **Organic gels (non-aqueous solvent)-**they contain non- aqueous solvent on their continuous phase. E.g. - Olag gel and dispersion of metallic stearate in oils.

c) **Xerogels -** solid gels with low solvent concentration. E.g. - Tragacanth ribbons.

3. **Based on rheological properties**

Usually gels exhibit non- Newtonian properties

a) **Plastic gels -** E.g. - Bingham Bodies, flocculated suspensions of Aluminium hydroxide exhibit a plastic flow and the plot of rheogram gives the yield value of the gels above which the elastic gel distorts and begins to flow.

b) **Pseudo plastic gels-** The viscosity of these gels decreases with increasing rate of shear, with no yield value. As the shearing stress is increased the disarranged molecules begin to align their long axis in the direction of flow with the release of solvent matrix E.g. - Liquid dispersion of tragacanth, Na CMC.

c) **Thixotropic gels**- The bonds between particles in these gels are very weak and can be broken down by shaking. The resulting solution will revert back to gel due to the particle colliding and linking together again (the reversible isothermal gel-sol-gel transformation). E.g. - Kaolin, bentonite, agar.

4. Based on physical nature

a) **Elastic gels-** the fibrous molecules in these gels are being linked at the point of junction by comparatively weak bonds like hydrogen bonds and dipole attraction. If the molecule possesses free COOH group then additional bonding takes place by a salt bridge of type COO-X-COO between two adjacent strand networks. E.g. - Alginate and Carbopol

b) **Rigid gels-** This can be formed from macromolecules in which the framework linked by primary valence bonds. E.g. - Silica gel

Preparation of Transferosomal Gel

Taking a one-unit equivalent dose of transferosomes and integrating them into a suitable gel basis or vehicle can produce the gel. If the amount of unentrapped medication is greater than 10%, it can be removed before turning in the gel by centrifuging the transferosomes at 6000 rpm for 15-30 minutes and discarding the supernatant. Mechanical stirring at 25 rpm for five minutes is used to incorporate transferosomes into gel.

Evaluation of Transferosomal Gel

1. Determination of pH

The pH of the topical applications is evaluated by using a digital pH meter by immersing the glass electrode in formulation totally so as to cover the electrodes.

2. Spreadability

The spreadability of a gel can be determined using the gel's slip and drag characteristics. Spreadability is determined using modified equipment. The modified apparatus is made up of two glass slides, one of which is fastened to a wooden plate and the other of which is controlled by a hook.

$$S=m\ xl/t$$

3. Drug content

For a gel formulation, the drug content must be processed by converting equivalent weight to one-unit dose and estimating the drug using appropriate analytical techniques. Because the gel is viscous, at least 6 samples should be calculated to assure consistent medication distribution inside the gel.

4. In –vitro diffusion study

An in-vitro drug release studies can be carried out using the Franz diffusion cell. The dialysis membrane is positioned between the receptor and donor compartments. The donor compartment is filled with transferosomes gel equivalent to one-unit dose, while the Phosphate buffer pH 7.4 is filled in receptor compartment. Throughout the trial, the diffusion cells should be stirred at 50 rpm at 320± 0.5o C. Then required sample should be retrieved from the receiver compartment via the side tube at various time intervals and analysed for drug content using an appropriate analytical method.

5. Skin irritation study

Guinea pigs (400-500g) of either sex were used for testing of skin irritation. The animals were maintained on standard animal feed and had free access to water. The animals were kept under standard conditions. Hair was shaved from back of guinea pigs and area of 4c 2 was mark done both the sides, one side served as control while the other side was test. Gel was applied (500mg/ guinea pig0 twice a day for7 days and the site was observed for any sensitivity and the reaction, slight patchy erythema, slight but confluent or moderate but patchy erythema and severe erythema with or without edema, respectively.

6. In vitro Diffusion studies

The diffusion studies of the prepared gels can be carrying out in Franz diffusion cell for studying the dissolution release of gels through a cellophane membrane. Gel sample (0.5g) was taken in cellophane membrane and the diffusion studies were carried out at 37±1˚ using 250 ml of phosphate buffer (pH 7.4) as the dissolution medium. Five millilitres of each sample was withdrawn periodically at 1,2,3,4,5,6,7 and 8h and each sample was replaced with equal volume of fresh dissolution medium. Then the sample were analysed for the drug content by using phosphate buffer as blank.

CONCLUSION

Transferosomes have several advantages over other vesicular systems, including greater deformability, greater penetration power across skin, the ability to deliver systemic drugs, and higher stability. Transferosomes are made up of hydrophilic and hydrophobic moieties and have a wide range of solubility. The developed transferosomal gel could be used to improve medicine delivery through the skin.Gels are getting considerable amount of popularity because of it easy application controlled release of drug and are more stable. Conventional formulations for topical and dermatological administration of drugs have certain limitation like poor adherence to skin, poor permeability and compromised patient compliance. Gels overcome this problem and provide better site of disorder by allowing the accumulation of drug concentration within the tissue. The clinical evidence indicates the topical gel is a safe and effective treatment option for use in the management of skin related disease and used for local action to reduce the side effects associated with other conventional dosage form.

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