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A Review on Transdermal Patches

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ABSTRACT

A Transdermal patch is a medicated adhesive patch that is placed on the skin to deliver a specific dose of medication through the skin and into the bloodstream. The transdermal drug delivery system is one of the novel drug delivery systems which overcome arise from the conventional dosage. Transdermal patches are pharmaceutical preparation of varying sizes, containing one or more active ingredients to the systemic circulations. The review gives valuable information about the transdermal patch like its advantage, disadvantage, mechanism of action, types of transdermal patch, factors basic components, methods and evaluation, application of a transdermal patch. A wide variety of pharmaceuticals are now available in transdermal patch form.

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INTRODUCTION

The transdermal drug delivery system has been in existence for a long time. In the past, the most commonly applied systems were topically applied creams and ointments for dermatological disorders. The occurrence of systemic side-effects with some of these formulations is indicative of absorption through the skin. A number of drugs have been applied to the skin for systemic treatment. In a broad sense, the term transdermal delivery system includes all topically administered drug formulations intended to deliver the active ingredient into the general circulation[1]. Transdermal therapeutic systems have been designed to provide controlled continuous delivery of drugs via the skin to the systemic circulation. Moreover, it overcomes various side effects like painful delivery of the drugs and the first-pass metabolism of the drug occurred by other means of drug delivery systems. Many drugs which can be injected directly into the bloodstream via skin have been formulated. The main advantages of this system are that there is controlled release of the drug and the medication is painless. The drug is mainly delivered to the skin with the help of a transdermal patch that adheres to the skin. A transdermal patch has several components including liners, adherents, drug reservoirs, drug release membranes which play a vital role in the release of the drug via skin. Various types of patches along with various methods of applications have been discovered to deliver the drug from the transdermal patch. Because of its great advantages, it has become one of the high research fields among the various drug delivery system[1].

Advantages

1. Hepatic first-pass metabolism, salivary metabolism, and intestinal metabolism are avoided.

2. The ease of usage makes it possible for patients to self-administer these systems.

3. In case of an emergency, removing the patch at any point of time during therapy can instantly stop drug input.

4. Since the composition of skin structurally and biologically is the same in almost all humans, it is minimal inter and intrapatient variation.

5. Drugs showing gastrointestinal irritation and absorption can be suitably administered through the skin.

Disadvantages

1. There is the possibility of skin irritation due to one or many of the formulation components.

2. Binding of the drug to the skin may result in dose dumping.

3. It can be used only for chronic conditions where drug therapy is desired for a long period of time including hypertension, angina, and diabetes.

4. Lag time is variable and can vary from several hours to days for different drug candidates.

5. Cutaneous metabolism will affect the therapeutic performance of the system[2].

Structure of skin:

The skin can be considered to have four distinct layers of tissues including non-viable epidermis, viable epidermis, viable dermis, and hypodermis. The epidermis is the relatively thin, tough, outer layer of the skin. The epidermis has keratinocytes. They originate from cells in the deepest layer of the epidermis called the basal layer. New keratinocytes slowly migrate up toward the surface of the epidermis. The stratum corneum is the outermost portion of the epidermis, relatively waterproof and, when undamaged, prevents most bacteria, viruses, and other foreign substances from entering the body. The epidermis also protects the internal organs, muscles, nerves, and blood vessels against trauma. The outer keratin layer of the epidermis is much thicker. The viable epidermis layer of the skin has a thickness ranging from 50-100 µm. The structure of the cells in the viable epidermis is physiochemically similar to other living tissues. Cells are held together by ton fibrils. The water content is about 90%. The dermis, the skin's next layer, is a thick layer of fibrous and elastic tissue that gives the skin its flexibility and strength. The dermis contains nerve endings, sweat glands, oil glands, hair follicles, and blood vessels. It is composed of loose textured, white, fibrous connective tissue containing blood and lymph vessels[3].

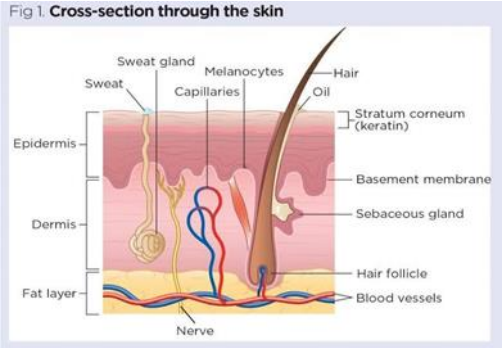

Figure no:01

Pathways of Skin Permeation:

Drug molecules permeate through the skin surface by the different potential pathways including through the sweat ducts, through the hair follicles and sebaceous glands, or directly across the stratum corneum Since the last few years there is a point of debate among scientists for the relative importance of the shunt or appendageal route of transport across the stratum corneum and is further complicated by the lack of a suitable experimental model to permit separation of these pathways. A recent review by Menon provides a valuable resource. The stratum corneum consists of 10 to15 layers of corneocytes[4].

TRANSDERMAL PATCH

A transdermal patch or skin patch is a medicated adhesive patch that is placed on the skin to deliver a specific dose of medication through the skin and into the bloodstream. The first commercially available prescription patch was approved by the U.S. Food and Drug Administration in December 1979 containing scopolamine for motion sickness The highest selling transdermal patch in the United States was the nicotine patch which releases nicotine to help with cessation of tobacco smoking. The first commercially available vapor patch to reduce smoking was approved in Europe in 2007.

In addition, various other patches are available in the market including fentanyl, an analgesic for severe pain, nitro-glycerine patches for angina, lidocaine patches, marketed as Lidoderm, relieve the peripheral pain of shingles Buprenorphine, marketed as Bu Trans, as analgesia for moderate to severe chronic pain. It is also now commonly used off-label, for pain from acute injuries and chronic pain. Flector (Diclofenac Epolamine) patch is an NSAID topical patch for the treatment of acute pain due to minor strains, sprains, and contusions. It is also being used in the treatment of pain and inflammation for chronic conditions benefiting from

NSAIDs including fibromyalgia and arthritis. Hyperactivity Disorder (ADHD). In 2005, the FDA announced that they are investigating reports of death and other serious adverse events related to narcotic overdose in patients using Duragesic, the fentanyl transdermal patch for pain control[5].

Components of the transdermal patch:

The basic components of transdermal patch consist of polymer matrix / Drug reservoir, active ingredient (drug), permeation enhancers, pressure-sensitive adhesive (PSA), backing laminates, release liner, and other excipients like plasticizers and solvents.

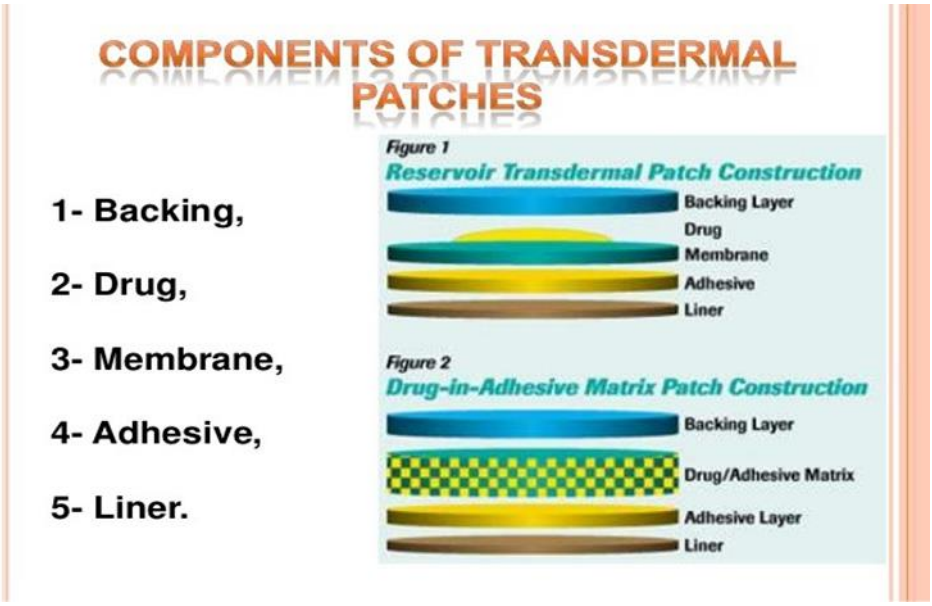

Figure no:02

1. Polymer matrix: Polymers are the backbone of a transdermal drug delivery system.

Systems for transdermal delivery are fabricated as multilayered polymeric laminates in which a drug reservoir or a drug-polymer matrix is sandwiched between two polymeric layers: an outer impervious backing layer that prevents the loss of drug through the backing surface and an inner polymeric layer that functions as an adhesive and/or rate-controlling membrane. Polymer selection and design must be considered when striving to meet the diverse criteria for the fabrication of effective transdermal delivery systems. The main challenge is in the design of a polymer matrix, followed by optimization of the drug-loaded matrix not only in terms of release properties but also with respect to its adhesion cohesion balance, physicochemical properties, compatibility, and stability with other components of the system as well as with skin. The polymers utilized for TDDS can be classified as

(1) Natural polymers: cellulose derivatives, zein, gelatin, shellac, waxes, gums, natural rubber, chitosan, etc,

(2) Synthetic elastomers: polybutadiene, hydrin rubber, polyisobutylene, silicon rubber, nitrile, acrylonitrile, neoprene, butyl rubber, etc,

(3) Synthetic polymers: polyvinyl alcohol,polyvinylchloride, polyethylene, polypropylene, polyacrylate, polyurea, polymethylmethacrylate etc.

2. Drug: The most important criteria for TDDS are that the drug should possess the right physicochemical and pharmacokinetic properties. Transdermal patches offer much to drugs that undergo extensive first-pass metabolism, drugs with narrow therapeutic window, or drugs with short half-life which causes non-compliance due to frequent dosing.

3. Permeation enhancers: To increase the permeability of stratum corneum so as to attain higher therapeutic levels of the drug permeation enhancers interact with structural components of stratum corneum i.e., proteins or lipids. The enhancement in the absorption of oil-soluble drugs is apparently due to the partial leaching of the epidermal lipids by the chemical enhancers, resulting in the improvement of the skin conditions for wetting and for trans-epidermal and trans-follicular permeation. The miscibility and solution properties of the enhancers used could be responsible for the enhanced transdermal permeation of water-soluble.

4. Pressure-sensitive adhesive (PSA): A PSA maintains intimate contact between the patch and the skin surface. It should adhere with not more than applied finger pressure, be aggressively and permanently tacky, and exert a strong holding force. These include polyacrylates, polyisobutylene, and silicon-based World Journal of Pharmacy and Pharmaceutical Sciences adhesives. The selection of an adhesive is based on numerous factors, including the patch design and drug formulation. PSA should be physicochemically and biologically compatible and should not alter drug release. The PSA can be positioned on the face of the device or in the back of the device and extending peripherally.

5. Backing laminate: The primary function of the backing laminate is to provide support. Backing layer should be chemically resistant and excipients compatible because the prolonged contact between the backing layer and the excipients may cause the additives to leach out or may lead to diffusion of excipients, drug, or permeation enhancer through the

layer. They should have a low moisture vapor transmission rate. They must have optimal elasticity, flexibility, and tensile strength.

6. Release liner: During storage, the release liner prevents the loss of the drug that has migrated into the adhesive layer and contamination. It is therefore regarded as a part of the primary packaging material rather than a part of the dosage form for delivering the drug. The release liner is composed of a base layer that may be non-occlusive or occlusive and a release coating layer made up of silicon or Teflon. Other materials used for TDDS release liner include polyester foil and metalized laminate.

7. Other excipients: Various solvents such as chloroform, methanol, acetone, isopropanol, and dichloromethane are used to prepare drug reservoirs. In addition plasticizers such as dibutyl phthalate, triethyl citrate, polyethylene glycol, and propylene glycol are added to provide plasticity to the transdermal patch[7].

TYPES OF TRANSDERMAL PATCHES

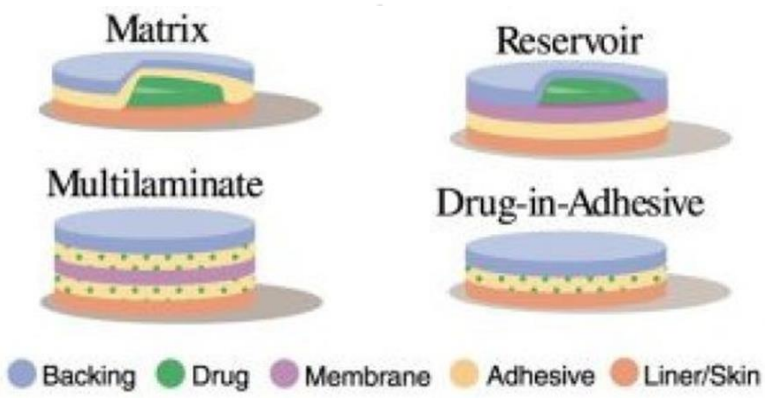

Figure no:03

SINGLE-LAYER DRUG IN ADHESIVE:

In this type, the adhesive layer contains the drug. The adhesive layer not only serves to adhere the various layers together and also responsible for releasing the drug to the skin. The adhesive layer is surrounded by a temporary liner and a backing.

a) Multi-layer drug in adhesive: This type is also similar to the single-layer but it contains an immediate drug-release-layer and the other layer will be a controlled release along with the adhesive layer. The adhesive layer is responsible for the release of the drug. This patch also has a temporary liner layer and a permanent backing.

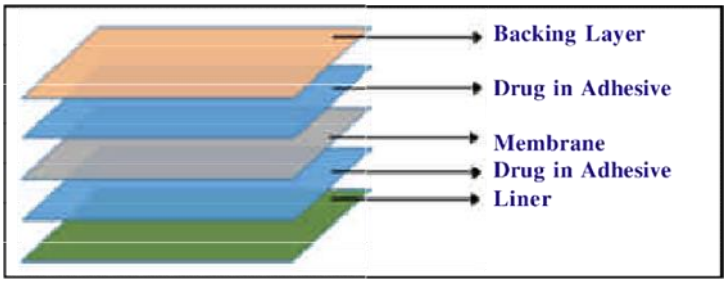

Figure no:04

b) Vapour patch: The patch containing the adhesive layer not only serves to adhere the various surfaces together but also serves to release the vapor. The vapor patches are new to the market, commonly used for releasing the essential oils in decongestion. Various other types of vapor patches are also available in the market which are used to improve the quality of sleep and reduce cigarette smoking conditions.

c) Reservoir system: In this system, the drug reservoir is embedded between an impervious backing layer and a rate controlling membrane. The drug releases only through the rate-controlling membrane, which can be microporous or nonporous. In the drug reservoir compartment, the drug can be in the form of a solution, suspension, gel, or dispersed in a solid polymer matrix. The hypoallergenic adhesive polymer can be applied as an outer surface polymeric membrane that is compatible with the drug.

d) Matrix system:

i. Drug-in-adhesive system: This type of patch is formulated by mixing the drug with adhesive polymer to form a drug reservoir. It is then followed by spreading on an impervious backing layer by solvent casting or melting method. The top of the reservoir is protected by unmediated adhesive polymer layers. It may further be categorized into single-layer and multi-layer drug-in-adhesive. The system is considered to be compatible with a wide variety of drugs. Moreover, the system is competent to deliver more than one drug in a single patch. It offers advantages in reduced size and thickness and improved conformability to the application site, helping drive patient preference.

ii. Matrix-dispersion system: The drug is dispersed homogeneously in a hydrophilic or lipophilic polymer matrix. It is then altered into a medicated disc with a definite shape and thickness. This drug-containing polymer disk is fixed onto an occlusive base plate in a compartment fabricated from a drug impermeable backing layer. Instead of applying the

adhesive on the face of the drug reservoir, it is spread along with the circumference to form a strip of the adhesive rim.

e) Micro reservoir system: The system consists of microscopic spheres of drug reservoirs that release drugs at a zero-order rate for maintaining constant drug levels. A micro reservoir system is a combination of the reservoir and matrix-dispersion system. The aqueous solution of the water-soluble polymer is mixed with the drug to form a reservoir. It is then followed by dispersing the solution homogeneously using high shear mechanical force in a lipophilic polymer to form thousands of microscopic drug reservoirs. Cross-linking agents are added to stabilize the thermodynamically unstable dispersion by in-situ cross-linking the polymer[8].

VARIOUS METHODS FOR PREPARATION OF TDDS

1. Circular Teflon mold method (Baker and Heller1989): Solutions containing polymers in various ratios are used in an organic solvent. The calculated amount of the drug is dissolved in half the quantity of the same organic solvent. Enhancers in different concentrations are dissolved in the other half of the organic solvent and then added. The plasticizer is added to the drug-polymer solution. The total contents are to be stirred for 12 hrs and then poured into a circular Teflon mold. The molds are to be placed on a leveled surface and covered with the inverted funnel to control solvent vaporization in a laminar flow hood model with an airspeed of 0.5 m/s. The solvent is allowed to evaporate for 24 h. The dried films are to be stored for another 24 h at 25±0.5°C in a desiccator containing silica gel before evaluation to eliminate aging effects. These types of films are to be evaluated within one week of their preparation have studied bioadhesive film containing ketorolac. Films were cast from organic and aqueous solvents using various bioadhesive polymers namely: sodium carboxymethyl cellulose (Na-CMC), hydroxypropyl cellulose (HPC), hydroxypropylmethylcellulose (HPMC), and Carbopol 934. The prepared films were subjected to investigations for their physical and mechanical properties, swelling behaviors, in-vitro bio adhesion, drug permeation via bovine buccal mucosa, and in-vitro drug release[9].

2. Asymmetric TPX membrane method (Berner and John 1994): A prototype patch can be fabricated for this a heat-sealable polyester film with a concave of 1cm diameter will be used as the backing membrane. Drug sample is dispensed into the concave membrane, covered by a TPX {poly (4-methyl-1-pentene)} asymmetric membrane, and sealed by an adhesive. These are fabricated by using the dry/wet inversion process. TPX is dissolved in a mixture of solvent (cyclohexane) and nonsolvent additives at 60°C to form a polymer

solution. The polymer solution is kept at 40°C for 24 hrs and cast on a glass plate to a predetermined thickness with a Gardner knife. After that the casting film is evaporated at 50°C for 30 sec, then the glass plate is to be immersed immediately in a coagulation bath. After 10 minutes of immersion, the membrane can be removed, air-dried in a circulation oven at 50°C for 12 h[10].

3. Mercury substrate method: The drug is dissolved in polymer solution along with plasticizer. It is followed by stirring for 10- 15 minutes to produce a homogenous dispersion and poured into a leveled mercury surface, covered with an inverted funnel to control solvent evaporation. Rathore et al have studied that transdermal matrix type patches of terbutaline sulfate were fabricated using ethylcellulose and cellulose acetate polymer. The transdermal patches of terbutaline sulfate were prepared by solvent casting technique employing a mercury substrate. In the present investigation, various polymeric transdermal patches of terbutaline sulfate were prepared. The effect of permeability enhancers on the permeability of drugs from cellulose acetate and ethylcellulose patches was studied. The polymeric combinations showed good film-forming properties and the method of casting on mercury substrate was found to give good films[11].

4. "IPM membranes" method: The drug is dispersed in a mixture of water and propylene glycol containing carbomer-940 polymers and stirred for 12 h in a magnetic stirrer. The dispersion is to be neutralized and made viscous by the addition of tri-ethanolamine. Buffer can be used in order to obtain solution gel if the drug solubility in an aqueous solution is very poor. The formed gel will be incorporated in the IPM membrane have studied the drug-in-adhesive transdermal patch and evaluated for the site-specific delivery of anastrozole. Different adhesive matrixes, permeation enhancers, and amounts of anastrozole were investigated for promoting the passage of anastrozole through the skin of rats in-vitro. The best skin permeation profile was obtained with the formulation containing DURO-TAK®, IPM 8%, and anastrozole 8%. For local tissue disposition studies, the anastrozole patch was applied to mouse abdominal skin, and blood, skin, and muscle samples were taken at different times after removing the residual adhesive from the skin. High accumulation of the drug in the skin and muscle tissue beneath the patch application site was observed in mice and compared with that after oral administration[12].

5. "EVAC membranes" method

APPROACHES USED IN THE DEVELOPMENT OF TRANSDERMAL PATCHES

A. Membrane moderated systems

B. Adhesive diffusion-controlled system

C. Matrix dispersion system:

D. Microreservoir systems[13]

Evaluation of Transdermal Patches

PHYSICOCHEMICAL EVALUATION

Thickness: The thickness of the transdermal film is determined by a traveling microscope, dial gauge, screw gauge, or micrometer at different points of the film.

Uniformity of weight: Weight variation is studied by individually weighing 10 randomly selected patches and calculating the average weight. The individual weight should not deviate significantly from the average weight.

Drug content determination: It can be determined by completely dissolving a small area of polymeric film in the suitable solvent of definite volume. The solvent is selected in which the drug is freely soluble. The selected area is weighed before dissolving in the solvent. The whole content is shaken continuously for 24 h in a shaker incubator followed by sonication and filtration. The drug in solution is assessed by the appropriate analytical method.

Content uniformity test: The test is applied as the gold standard to determine chemically the content of active constituent for each unit dose. The test is completed by performing an assay to find out the content of drug material contained in the polymeric film of the patch.

Moisture content: The prepared films are weighed individually and kept in a desiccator containing calcium chloride at room temperature for 24 h. The films are weighed again after a specified interval until they show a constant weight. The percent moisture content is calculated using the following formula.

Moisture Uptake: Weighed films are kept in a desiccator at room temperature for 24 h. These are then taken out and exposed to 84% relative humidity using a saturated solution of

Potassium chloride in a desiccator until a constant weight is achieved. % moisture uptake is calculated Flatness: A transdermal patch should possess a smooth surface and should not constrict with time. This can be demonstrated with the flatness study. For flatness determination, one strip is cut from the center and two from each side of the patches. The length of each strip is measured and variation in length is measured by determining percent constriction.

Folding Endurance: Evaluation of folding endurance involves determining the folding capacity of the films subjected to frequent extreme conditions of folding. Folding endurance is determined by repeatedly folding the film at the same place until it breaks. The number of times the films could be folded at the same place without breaking gives the folding endurance value.

Tensile Strength: To determine tensile strength, polymeric films are sandwiched separately by corked linear iron plates. One end of the film is kept fixed with the help of an iron screen and the other end is connected to a freely movable thread over a pulley. The weights are added gradually to the pan attached to the hanging end of the thread. A pointer on the thread is used to measure the elongation of the film.

Water vapor transmission studies (WVT): WVT is determined by taking one gram of calcium chloride in previously dried empty vials having equal diameters. The polymer films are pasted over the brim with the help of adhesive like silicon adhesive grease and then allowed to set for 5 minutes. The vials are accurately weighed and placed in a humidity chamber maintained at 68 % RH. The vials are then weighed repeatedly up to seven consecutive days and an increase in weight was considered as a quantitative measure of moisture transmitted through the patch.

Microscopic studies: The distribution of drugs and polymer in the film can be studied using a scanning electron microscope. For this study, the sections of each sample are cut and then mounted onto stubs using double-sided adhesive tape. The sections are then coated with gold, palladium alloy using fine coat ion sputter to render them electrically conductive. Then the sections are examined under a scanning electron microscope.

Adhesive studies: The therapeutic performance of TDDS can be affected by the quality of contact between the patch and the skin. The adhesion of a TDDS to the skin is obtained by using PSAs, which are defined as adhesives capable of bonding to surfaces with the

application of light pressure. The adhesive properties of a TDDS can be characterized by considering the following factors.

Peel Adhesion properties: It is the force required to remove the adhesive coating from the test substrate. It is tested by measuring the force required to pull a single coated tape, applied to the substrate at 180° angle. The test is passed if there is no residue on the substrate[14].

1. In-vitro studies

(A) In-vitro release studies:

The amount of drugs available for absorption to the systemic pool is greatly dependent on drugs released from the polymeric transdermal films. Drug release mechanisms and kinetics are two characteristics of the dosage forms which play an important role in describing the drug dissolution profile from controlled release dosage forms and hence their in-vivo performance. A number of mathematical models have been developed to describe the drug dissolution kinetics from controlled release drug delivery systems e.g., Higuchi, First order, Zero-order, and Peppas and Korsenmeyer models. The dissolution data is fitted to these models and the best fit is obtained to describe the release mechanism of the drug. Various methods are available for the determination of drug release from TDDS. The paddle over disc method is identical to the USP paddle dissolution apparatus, except that the transdermal system is attached to a disc or cell resting at the bottom of the vessel which contains medium at 32 ±5°C. The paddle over disk method in conjunction with a watch glass-patch-screen sandwich assembly is thought to be the preferable method. It is easier, more convenient, and exhibits experimentally almost the same release profile when compared with other more complicated methods. The cylinder-modified USP basket method is similar to the USP basket type dissolution apparatus, except that the system is attached to the surface of a hollow cylinder immersed in the medium at 32 ±5°C. The reciprocating disc method consists of attaching the patches to holders and oscillating in small volumes of the medium, allowing the apparatus to be useful for systems delivering low concentrations of the drug. The paddle over-extraction cell method may also be used. Diffusion cells include the Franz-diffusion cell and its modification Keshary-Chien Cell. In this method, the transdermal system is placed in between the receptor and donor compartment of the diffusion cell. The transdermal system faces the receptor compartment in which receptor fluid is placed. The agitation speed and temperature are kept constant. The whole assembly is kept on a magnetic stirrer and the solution in the receiver compartment is constantly and continuously stirred throughout the

experiment using magnetic beads. At predetermined time intervals, the receptor fluid is removed for analysis and is replaced with an equal volume of fresh receptor fluid. The concentration of a drug is determined by a suitable analytical method. The pH of the dissolution medium ideally should be adjusted to pH 5 to 6, reflecting physiological skin conditions[15].

(B) In-vitro permeation studies:

After release from the polymeric films, the drug reaches the skin surface is then passed to the dermal microcirculation by permeation through cells of the epidermis and/or between the cells of the epidermis through skin appendages. Usually, permeation studies are performed by placing the fabricated transdermal patch with rat skin or synthetic membrane in between receptor and donor compartment in a vertical diffusion cell such as Franz diffusion cell or Keshary-Chien diffusion cell. The transdermal system is applied to the hydrophilic side of the membrane and then mounted in the diffusion cell with the lipophilic side in contact with receptor fluid. The receiver compartment is maintained at a specific temperature and is continuously stirred at a constant rate. The samples are withdrawn at different time intervals and an equal amount of buffer is replaced each time. The samples are diluted appropriately and estimated by a suitable analytical method. The amount of drug permeated per square centimeter at each time interval is calculated[16].

2. In-vivo Studies: In-vivo evaluations are the true depiction of the drug performance. The variables which cannot be taken into account during in-vitro studies can be fully explored during Vivo studies. In-vivo evaluation of TDDS may be carried out using either animal models or human volunteers or both.

A.Animal models: Considerable time and resources are required to carry out human studies, so animal studies are preferred at a small scale. The most common animal species used for evaluating transdermal drug delivery systems are mouse, hairless rat, hairless dog, hairless rhesus monkey, rabbit, guinea pig, etc. Based on the experiments conducted so far it is concluded that hairless animals are preferred over hairy animals in both in-vitro and in-vivo experiments. Rhesus monkey is one of the most reliable models for in vivo evaluation of transdermal drug delivery[17].

B.Human models: The final stage of the development of a transdermal device involves the collection of pharmacokinetic and pharmacodynamic data following application of the patch

to human volunteers. Clinical trials are conducted to assess the transdermal systems including the efficacy, risk involved, side effects, and patient compliance. Phase-I clinical trials are conducted to determine mainly safety in volunteers and phase-II clinical trials determine short-term safety and mainly effectiveness in patients. Phase-III trials indicate the safety and effectiveness in a large number of the patient population and phase-IV trials at post-marketing surveillance are done for marketed patches to detect adverse drug reactions[18].

RECENT ADVANCES IN THE FIELD OF TRANSDERMAL PATCHES[19,20]:

1. Patch technology for protein delivery

2. Pain-free diabetic monitoring using transdermal patches

3. Testosterone transdermal patch system in young women with spontaneous premature ovarian failure

4. Transdermal Patch of Oxybutynin used in overactive bladder (OAB)

5. Pain relief

6. Molecular absorption enhancement technology.

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