



Research Article

Formulation And Evaluation Of Curcuma Longa Transdermal Films

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ABSTRACT

Transdermal films are new formulations which are widely used nowadays and taking the new development in the current treatments in wound healing. In Ayurvedic medicine, which combines the therapeutic benefits of food and herbs, turmeric has been utilized for ages as an antibacterial, antifungal, and antioxidant and has very excellent wound healing properties. In this research transdermal films were prepared with the help of turmeric extract and semisynthetic polymer which is very easily available and less cost and is used in bakery jelly preparations and polyethylene glycol, propylene glycol, glycerin and distilled water. The ethanol-based extraction of the turmeric and the extract utilized in the formulation. Transdermal films are useful for easy application and termination of the therapy. It is a quick and long-lasting means to deliver the medications.

INTRODUCTION

In Ayurvedic medicine, which combines the therapeutic benefits of food and herbs, turmeric has been utilized for ages. Due to its numerous medical advantages, this amazing herb has gained attention in the west and throughout the rest of the world. In India's Vedic culture, turmeric has been used for around 4,000 years. It is a popular home cure for several illnesses in Ayurveda, Unani, and Siddha medicine. The perennial plant *Curcuma longa* (family: Zingiberaceae), from which turmeric is derived, has huge oblong leaves has

short stems and bears ovate, pyriform, or oblong rhizomes, that are frequently branching and brownish-yellow in colour.



Fig 1: Turmeric rhizomes with turmeric powder

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The biological effects of turmeric are extremely diverse. These include anti-inflammatory, anti-carcinogenic, anti-coagulant, anti-fertility, anti-mutagenic, anti-diabetic, anti-protozoal, anti-fungal, anti-viral, anti-bacterial, antioxidant, anti-venom, anti-ulcer, hypotensive, and hypercholesteremia properties.[1] The patches know as transdermal drug delivery systems when applied topically releases the pharmaceuticals at a predetermined and regulated rate for systemic effects. An apparatus known as a transdermal therapeutic system releases drugs into the skin at a controlled pace that is significantly lower than the maximum rate that the tissue can tolerate. Thus, the apparatus regulates how quickly a drug diffuses through the epidermis rather than the stratum corneum.[2]

TRANSDERMAL FILMS TYPES:

1. Multi-layer drug in adhesive
2. Single layer drug in adhesive
3. Reservoir system
4. Vapour patch
5. Matrix system
6. Micro-reservoir system [3]

The Benefits of Medication Delivery Through the Skin Include:

- Avoiding intestinal, salivary, and hepatic first pass metabolisms.
- These systems enable patients to self-administer due to their simplicity of use.
- During the period of emergency, the patch removal in the course of therapy can stop the input of the drug immediately.
- There is very little variation between patients because the structure and biology of skin are nearly identical in all persons.[4]

Transdermal Medication Delivery Technologies
Negative Aspects

- When large doses of drugs must be delivered through the skin, it is inappropriate to use transdermal delivery.

- Drugs requiring high blood pressure cannot be provided.
- A medicine of drug formulation may irritate or sensitize people.
- Not feasible if the medicine is significantly metabolised in the skin and if the molecules are too large to diffuse through the skin.
- Not suitable for a medication with an unfavourable o/w partition coefficient
- The barrier of skin functions varies from one region to another on the same person from one to another person and with aging.[5]

Components Of Transdermal Films:

1. Polymer Matrix:

The release of drugs from the device is managed by the polymer.

A polymer must meet the following requirements in order to get utilized in transdermal films.

- a. The polymer's molecular weight and chemical activity should be chosen such that the particular medicine may diffuse and be released through it effectively
- b. The polymer needs to be reliable. The polymer must not be harmful.
- c. The production of the polymer should have simple procedure. Polymer should be reasonably priced.
- d. Both polymer and the result of its breakdown must not be harmful or hostile to the host.
- e. It incorporates a significant amount of the active agent.

Polymer types:

Natural polymers:

Shellac, Gum, Waxes, Gelatine, Protein, derivatives of starch and cellulose

Synthetic Elastomers:

Hydrin rubber, silicone rubber, Nitrile, Acrylonitrile, Neoprene.

Synthetic polymers:

Polyvinyl alcohol, polyvinyl chloride, polyethylene, polypropylene, polyamide, polyurea, epoxy.[6]



2. Drugs:

Drugs having a lengthy first pass metabolism, a limited therapeutic window, or a short half-life that exhibits noncompliance owing to repeated dosage all benefit greatly from transdermal patches. The primary criterion of TDDS is that the medication has sufficient physical, chemical, and biological qualities to administer transdermal drugs.[7],[8] The medicine should be carefully chosen for the development of a transdermal drug delivery system. The ideal properties have mentioned in the table 1.

Table 1: Ideal Properties of Drug For TDDS

Parameters	Properties
Dose	Should be low (less than 20mg/day)
Half life	>10h
Molecular weight	<400 Da
Partition co-efficient	Log P (octanol-water) between 1.0-4.0
Skin permeability co-efficient	>0.5x10 ⁻³ cm/h
Skin reaction	Non irritating and non-sensitizing
Oral bioavailability, Therapeutic index	Low
Melting point	<2000F
pH	5.0-9.0

The following are some characteristics of medicine that are ideal for transdermal distribution.

3. Permeation enhancers:

These are chemical substances that increase the stratum corneum's permeability in order to reach higher therapeutic levels of the drug candidate.[9] Penetration enhancers interact with the proteins and lipids that make up the stratum corneum's structural elements. They change the stratum corneum's protein and lipid packing, chemically altering the barrier's activities and increasing permeability.[10] Some of the individual compounds or chemical combinations also serve as penetration enhancers.

a. Solvents:

These substances improve penetration, perhaps by liquefying lipids. Examples include the following: alcohols, such as methanol and ethanol; alkyl methyl sulfoxides, such as dimethyl sulfoxide; alkyl homologs of methyl sulfoxide, such as dimethyl acetamide and dimethyl formamide; 2 pyrrolidone, N-methyl, 2-pyrrolidone; laurocapram (Azone); and various solvents, such as propylene glycol, glycerol

b. Surfactant:

These substances are recommended to improve the transport of hydrophilic medicines along polar pathways. The polar head group and the length of the hydrocarbon chain affect a surfactant's capacity to change penetration.[11],[12]

Anionic surfactants, Nonionic surfactants, Bile salts, Binary system

c. Chemicals in general:

These include the keratolytic and hydrating substance urea, the anticholinergic drugs N-N dimethyl-m-tolamide calcium thio glycolate, and others. Recent research has described a few putative permeation enhancers, although there is little information on their efficacy. Eucalptol, di-o-methyl-cyclodextrin, and soyabean are a few of these. [13]

4. Adhesive:

Holds the patch to the skin so that the medicine can be delivered throughout the body. Ex: Polyisobutylene with silicones.

Adhesives need to have the following characteristics

- Not irritable
- Simple removal
- Firm skin contact
- Biocompatible
- Don't interfere with drug permeation
- Remove everything without leaving any trace.

5. The backing layer shields the patch from the outside environment. Illustration:

Rubber made of polypropylene and cellulose derivatives.[7],[9] adhesives that are pressure-



sensitive.[10],[14] It keeps the transdermal system and skin surface in close touch. By applying finger pressure, it clings to the skin's surface.

The following adhesives are frequently used in creation of transdermal films:

1. Polyacrylates
2. Poly isobutylene
3. Adhesives made of silicone: It may be positioned on the patch's back or front.

6. Backing laminates:

When designing the backing layers, take into account chemical resistance, excipient compatibility, flexibility, and higher tensile strength. It must permit the transfer of water vapour and oxygen. Currently, the backing layer itself serves as a drug reservoir rather than the usual dosing form.

The following materials are typically used to prepare backing laminates:

- Polyesters
- Polyolefin
- Aluminium plastic lamination
- Low density polyethylene
- Resin.[6]

7. Release liner:

The protective liner that covers the patch while it is being stored is taken off and discharged just before the film is applied to the skin. As a result, it is viewed as a component of the principal package rather than a component of the dosage form for dispensing the medication. The liner which is in intimate contact to the delivery system should adhere to certain specifications for resistance to chemicals and permeability to the drug, penetration enhancer, and water. Typically, the release liner is formed of a base layer that may be non-occlusive (e.g. Paper fabric) or occlusive (e.g. polyethylene, polyvinylchloride) and a release coating layer made up of silicon or teflon. Metalized laminates and polyester foils are other materials utilized to make TDDS release liners.[15]

8. Other excipients:

The transdermal patch is made more malleable by the addition of glycerine and propylene glycol, as well as plasticizers such as di-n-butyl phthalate, triethyl citrate, and polyethylene glycol [9]. Additionally, it contains solvents that are used to manufacture drug reservoirs, including chloroform, methanol, acetone, isopropanol, and dichloromethane.[14]

Technologies in the development of TDDS.[12],[16],[17]

1. Membrane moderated systems:

In these, the reservoir of the drug is completely enclosed in a chamber made of a metallic plastic laminate that is impermeable to drugs and a polymeric membrane that regulates flow rate. The drug solids are either suspended in a viscous, unbleachable liquid media, such as silicon fluid, or dispersed in a solid polymer matrix in the drug reservoir compartment. A layer of skin of the drug and a compatible, hypoallergenic adhesive polymer may be applied to achieve an intimate contact of transdermal drug delivery with the surface of the skin. The microporous or nonporous polymeric membrane can be accepted as a rate-controlling membrane, for example, an external surface of the polymeric membrane contains the ethylene vinyl acetate copolymer.

2. Adhesive diffusion-controlled system:

The membrane-moderated drug delivery system is the simplest type of adhesive diffusion-controlled system. This type of approach, the reservoir of drug is created by directly dispersing the drug in an adhesive polymer, followed by solvent casting the medicated adhesive onto a flat sheet of metallic plastic backing that is drug impermeable to create a thin drug reservoir layer. The upper layer of the reservoir consists of layers of non-medicated rate-controlling adhesive polymer with constant thickness.

3. Matrix dispersion:

Here, a lipophilic or hydrophilic polymer matrix is used to uniformly disperse the drug particles, and the resulting drug reservoir is subsequently moulded into a disc with a specific dimension and thickness. This is adhered to an occlusive base plate on the disc's surface, and an adhesive rim is created around the disc by spreading adhesive polymer around the edge.

4. Micro-reservoir system:

The system is a mixture of the matrix and reservoir dispersion types. Above technique involves first drug particles suspending in an aqueous solution of a water-soluble polymer, which is followed by uniformly dispersing the drug suspension in a lipophilic polymer under high shear mechanical stress to produce unleachable microscopic spheres of the drug reservoir. Cross-linking the polymer chains stabilizes this dispersion right away, creating a medicated disc with a consistent surface dimension and thickness.

5. Membrane matrix hybrid type patches:

These patches are prepared by the modification of reservoir-type transdermal patches. The drug reservoir's liquid formulation is swapped out for a solid polymer matrix (such as polyisobutylene), which is inserted between a backing laminate and a rate-regulating membrane.[18] Catapress® and TransdermScop® are two examples of commercialized preparations.

Transappendegeal penetration:

The shunt pathway is another name for this. The drug molecule may travel along this channel via passing through hair follicles, the pilosebaceous apparatus' sebaceous pathway, or the salty sweat glands aqueous pathway. Due to its very tiny area (less than 0.1% of the total surface), the transappendegeal pathway is regarded as being of minor value. However, for big polar molecules, this method might be significant. The relative ability of the penetrant to partition into each skin phase, which is particularly essential, determines the route by which permeation occurs. The

transdermal penetration can be seen as a mixed set of events that occur in this order:

- a. A penetrant molecule adhering to the stratum corneum's surface layers.
- b. Diffusion through the viable epidermis and stratum corneum.
- c. Finally, into the microcirculation through the papillary dermis. The capillaries and viable tissue layer are both fairly permeable, and the peripheral circulation is adequately quick. So, the rate-limiting stage is diffusion via the stratum corneum. It functions as a passive diffusion medium, the stratum corneum.[19]

SKIN PHYSIOLOGY:

Earlier research revealed the skin's value as the main way to systemic administration. Previously, the skin was thought to be an impermeable protective barrier. Given that only a few hundredths of a millimeter of tissue separate the surface of the skin from the basic capillary network, the body's most active and accessible organ is the skin.²⁰ Despite the fact that skin is a formidable barrier to the entry of medications and other molecules, there are several benefits that make it a viable alternative for systemic drug delivery.[16] Since the skin is the bulkiest and most prominent organ in the human body, it plays a unique role in expressing a person's emotional condition. Traditionally, the skin is split into three sections. The stratum corneum, viable epidermis, and dermis are listed.

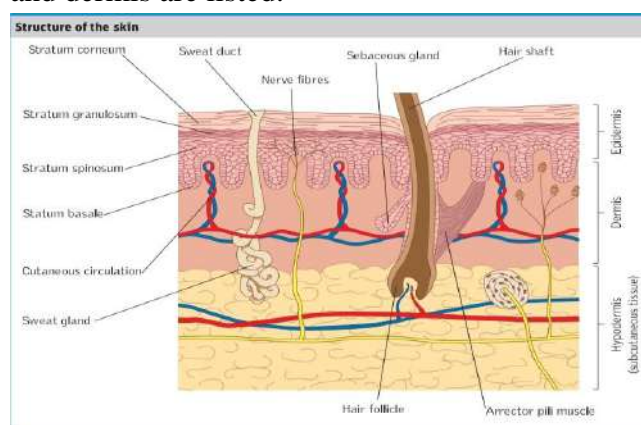


Fig 2: Structure of skin

The stratum corneum, the outermost of these layers, serves as a barrier to prevent most cells (squamous), which are roughly pentagonal plates of 0.5 thick and 30–40 m across, from penetrating. Bilayer structured lipids fill the intercellular space between these cells. The stratified keratinizing epithelial cells that make up the viable epidermis, which is located underneath the stratum corneum, are ultimately responsible for producing the stratum corneum. This layer lacks blood arteries and is nourished by the dermis layer's cell fluid. Dermis, the layer of skin that is the deepest, is nourished directly by blood vessels and is made up of dense connective tissue that is structured erratically. These layers of the skin, which are joined to the subcutaneous tissue by collagen fibre bundles, are combined. Eccrine, subcutaneous, apocrine, and hair follicle glands are also found in the skin. Interestingly, studies have shown that the stratum corneum, the skin's thinnest layer, offers the strongest resistance to drug absorption despite having a composite structure and many different parts.[21]

MATERIALS AND METHODOLOGY

Drug profile

Curcuma longa

Synonym:

Turmeric, Haldi, Harishina, Pasupu

Chemical formula:

$C_{21}H_{20}O_6$

Appearance:

Bright yellow-orange powder

Therapeutic Uses: Anti-inflammatory, anti-carcinogenic, anti-oxidant, anti-mutagenic, anti-fertility, anti-coagulant, anti-diabetic, anti-fungal, anti-bacterial, anti-protozoal, anti-venom, anti-viral, anti-ulcer, anti-hypotensive, and hypocholesterolaemia actions are the main uses for it.

Polymer profile

Carboxy Methylcellulose

Synonym:

Cellulose Carboxymethyl Ether, Cellulose Gum and CMC Powder

Molecular formula:

$C_8H_{15}NaO_8$

Chemical name:

sodium 2,3,4,5,6-pentahydroxyhexanal; acetate

Solubility:

CMC is a substance that is soluble in water and is dissolvable in both hot and cold water. It won't dissolve in organic solvents, but it will in miscible ones like acetone or ethanol. The viscosity won't get thicker as the temperature rises.

Storage:

CMC powder should be kept in an airtight container. For a longer shelf life, you could also put it in the fridge.

Polyethylene glycol

Synonym:

Polyethylene oxide (PEO) or polyoxyethylene (POE), Carbowax, Golytely, GlycoLax, Fortrans, TriLyte

Chemical name:

poly(oxyethylene) {structure-based}, poly(ethylene oxide)

Molecular formula:

$C_{2n}H_{4n+2}O_{n+1}$

Description:

It is a polyether substance made from petroleum that has numerous uses in both industrial manufacture and medicine.

Solubility:

Soluble in toluene, water, methylene chloride, and many more organic solvents. Insoluble in ethyl ether, ethylene glycol and hexane, and in water at elevated temperatures. Making derivatives allows you to manage solubility and partitioning.

Category:

Laxative

Storage:

Store in a cool place and well-ventilated place

Propylene glycol

Synonym:

α -Propylene glycol, 1,2-Dihydroxypropane, 1,2-Propanediol, Methyl ethyl glycol, Methyl ethylene glycol

Chemical name:



Propane-1,2-diol

Molecular formula:

CH₃CH(OH)CH₂OH.

Description:

Colourless and transparent liquid with no odour

Solubility:

Water, ethanol, acetone, diethyl ether, and chloroform-soluble

Storage:

Keep things dry, cold, and well-ventilated when storing. When not in use, keep the container closed. Avoid hot temperatures and sunlight.

Glycerine

Synonym:

Glycerol, glycerine, glycerolum.

Chemical name:

propane-1,2,3, -triol

Molecular formula:

C₃H₈O₃

Description:

Glycerine is a transparent, colourless, syrup-like liquid that is extremely hygroscopic and odourless.

Solubility:

It is almost completely insoluble in ether, fixed oils, and volatile oils. It is miscible with water and ethanol (95%) and just slightly soluble in acetone.

Density:

1.258 to 1.263 g/m³

Category:

Lubricant, laxative, plasticizer and pharmaceutical aid (humectants)

Storage:

It should be kept in a container that is properly sealed.

METHODOLOGY

Extraction of Turmeric

The Soxhlet apparatus is used for the extraction. The turmeric rhizomes were dried and then grinded into slight coarse powder by mechanical methods. The timple was prepared with 25g of turmeric powder and 250 ml of ethanol is kept in round bottom flask and 100ml of ethanol is poured into timple. The soxhlet apparatus is run upto 6hours for complete extraction of components. Then the extract is evaporated to half and then treated with the toulene for defatting and the toluene layer is removed. The ethanolic layer is collected and evaporated to get crude powder. The powder obtained is used in the preparation of transdermal films.

The steps involved in formation of the transdermal films contain Curcuma longa

In order to prepare the transdermal film, excipients like plasticizers, polymers are used.

The primary component for its effect is the powdered ethanolic extract of Curcuma longa.

The materials used in the formulation is given in the table 2

Sr. No	INGREDIENTS	Quantity	Suppliers
1	Carboxy methyl cellulose	400mg	Thomas BR chemicals limited Bombay
2	Polyethylene glycol	0.5ml	Antares Chem Private Ltd Mumbai
3	Propylene glycol	0.1ml	Techno Lab Kraft Bangalore
4	Glycerine	0.1ml	Central drug house ltd New Delhi
5	Water	10ml	Distilled water
6	Turmeric extract	20 mg	Collected from local area and extracted in St. Johns pharmacy college

Take 5 ml of distilled water and 400 mg of carboxymethyl cellulose, and soak the mixture for up to 24 hours. After soaking it, keep it on a magnetic stirrer and stir it for 5 to 10 minutes. Then, add 1 ml of turmeric ethanolic extract and 0.5 ml each of polyethylene glycol, propylene

glycol, and glycerine to it. For 15 to 30 minutes, mix it continually with the magnetic stirrer. Pour it into the glycerine-coated Petri plate to make it simple to remove the film. For drying, leave it in the microwave for roughly 24 to 48 hours. The transdermal patch is then gathered. The prepared

blank film and active ingredient films are given in fig 3 and fig 4.



Fig 3: Blank film without active ingredient



Fig 4: Transdermal film with active ingredien

EVALUATION PARAMETERS

1. Weight uniformity:

The produced patches are tested after 4 hours of drying at 60 °C. A predetermined patch area must be divided into various patches and weighed using a weighing balance. From each weights, the standard deviation and average weight values should computed.

2. Thickness of the patch:

The thickness of the drug-loaded patch is measured at several sites using a digital vernier caliper, and average thickness and standard deviation are calculated to guarantee the created patch's thickness. At various spots along the transdermal film, a traveling microscope dial gauge, screw gauge, and micrometer can be used to measure the thickness of the film.

3. Percentage Moisture content:

Weigh each manufactured film separately, place it in a desiccator with calcium chloride fused for 1 day at room temperature. The patch must be reweighed after 1 day to ascertain their moisture content percentage.

4. Moisture Uptake:

The films weighed are maintained in desiccators for 24 hours at normal room temperature to absorb moisture. These are then removed and dried in desiccators using potassium chloride solution

saturated and 84% relative humidity is maintained until a consistent weight is reached.

5. Folding endurance:

A strip of a particular size must be folded at the same spot continuously until it breaks. Value of folding endurance is determined by how many times film could be folded in same position without breaking.

6. Studies on stability:

The formulation underwent accelerated stability tests for 60 days at 40°F and 75°RH; research on in vitro permeation was conducted for 30 days and revealed little change in the permeation profile. The stability experiments on the membrane revealed that it was smooth and flexible, and no physical changes to the membrane were noticed.^[19]

7. Percentage flatness:

Longitudinal strips from each film were cut out, one from the centre and two from either side. Without applying additional pressure, every strip was measured for length, and the discrepancy in length resulting from uneven flatness was identified. by determining the percent constitution equivalent to 100%.

8. Transmission of water vapour:

Using an adhesive containing 1 g of calcium chloride fused as a desiccant, the film was attached

to the glass vial. The vial was then placed in desiccators with a potassium chloride solution saturated (relative humidity: 84%). Periodically, the vial was removed and weighed.^[22]

9. Physical characteristics:

The colour, clarity, flexibility, and smoothness of each created patch were visually examined.

10. Drug content determination:

Drug content was determined by cutting pieces of each type of formulation into 2 x 2 sizes and placing them in a 100 ml phosphate buffered saline pH 7.4 solution. The mixture was swirled magnetically for two hours. The solution was then diluted appropriately using phosphate buffer saline pH 7.4 before being filtered by Whatman filter paper (0.45). Solution's absorbance at 289 nm was then measured using a placebo patch as a control. It was possible to calculate the drug content using the absorbance readings.

11. Surface pH:

Patches were placed in glass tubes and allowed to contact for 1 hour with 0.5 ml of de-ionized water while being given time to swell. After giving the patch an equilibration period of 1 minute, a combination glass electrode was brought close to the surface, and pH values were taken.^[23]

RESULTS:

1. Weight consistency:

Prepared patches were divided into 1cm² squares and weighed with a digital balance. 18 films were determined to have an average weight of 0.0259g.

2. Patch thickness:

Vernier callipers were used to measure the prepared patches' thickness. It was discovered that the film had an average thickness of 0.1mm.

3. Percentage moisture content:

Prepared patches were weighed separately, cut into 1 cm² squares, and stored for 24 hours in desiccators. The films are reweighed 24 hours later. Six movies were averaged, and the result was 34.275%.

4. Moisture Uptake:

Cut into 1 cm² pieces, prepared patches were placed on weighed films, which were then placed in desiccators for 24 hours and exposed to 84%

relative humidity to achieve a consistent weight. Six patches were averaged, and the result was 40.605%.

5. Folding endurance:

The 1 cm² square patches were cut and prepared and folded repeatedly in the same spot. Following folding, there are no discernible cracks.

6. Water vapour transmission:

Prepared patches were cut into 1 cm² squares, and adhesive-fixed films were placed over the glass vial. The vials were inserted within the desiccators. The vial is weighed periodically until the required weight is reached. The 4 films' combined average weight was determined to be 5.510-3 gm/cm².

7. Physical characteristics:

Films were tested for colour, flexibility, smoothness, and clarity. Due to the addition of turmeric, the patches were given a yellow colour. They are smooth, flexible, and clear.

8. Surface pH:

Prepared patches were cut into 1 cm² squares, and films were allowed to expand for 1 hour while it is in intimate contact with the 0.5 ml of deionized water present in the test tubes. The pH is determined, pH was found to be 6.

DISCUSSION AND SUMMARY

Since a huge variety of formulations have been shown to be absorbed through the skin, transdermal delivery of drug is growing in popularity. The transdermal administration of the drug method operates as a continuous intravenous infusion and approaches zero-order input. The development of TDDS for this purpose necessitates the use of appropriate matrix systems, rate-controlling membranes, and drug reservoirs. Turmeric is used to treat wounds because it has anti-inflammatory, anti-carcinogenic, antioxidant, anti-mutagenic, anti-diabetic, anti-coagulant and anti-fungal properties. It is selected for the study as it possesses the ideal qualities and characteristics which should be there during the

generation of transdermal delivery of drug system. Carboxymethyl cellulose, is a semi-synthetic polymer which have low adverse effects and is readily available due its widespread use in food products and it is the polymer used in the current investigation. The membranes were assessed based on a number of factors, including thickness, weight uniformity, folding durability, moisture content, moisture uptake, water vapour transmission research, and in vitro permeation tests. Transdermal films were created using a reproducible procedure, ensured high quality and homogeneity in patch features, and had minimal variability, according to observations of the formulation for physical and mechanical characterization.

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