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Transdermal Patches: Design and Current Approaches Using Natural Polymers

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ABSTRACT

One method of controlled drug delivery is the transdermal drug delivery system (TDDS), which aims to distribute the drug through the skin at a predetermined and regulated rate. It provides a number of benefits, including a longer therapeutic impact, fewer side effects, increased bioavailability, better patient compliance, and simple medication therapy discontinuation. For most compounds, the stratum corneum is thought to be the rate limiting barrier in transdermal penetration. The appendageal, transcellular, and intercellular pathways are the three main ways that drugs can enter the body. When giving medication by this route, it is important to take into account the following aspects: skin age, condition, physicochemical characteristics, and environmental conditions. Polymer matrix, membrane, drug, penetration enhancers, pressure-sensitive adhesives, backing laminates, release liner, etc. are some of the fundamental parts of TDDS. Transdermal patches are used to deliver active chemicals to the circulatory system through the skin. These patches can be classified into a variety of systems, such as reservoir, matrix, and micro-reservoir systems. Consistent methodologies are used to assess the adhesion qualities, physicochemical properties, in vitro drug release studies, in vitro skin penetration studies, skin irritation studies, and stability studies once transdermal patches have been prepared. Different medications are marketed as transdermal patches, depending on the length of the therapy. Natural polymers can be used as the means of achieving predetermined rates of drug delivery. Natural polymers are basically polysaccharides so they are biocompatible and without any side effects. Gums, mucilages, resins and plant extracts are widely used natural materials for conventional and novel dosage forms. The present article highlights the available information on natural polymers and their versatile use.

Keywords- Natural polymer, Matrix system, micro-reservoir system, penetration enhancer, reservoir system, TDDS.

I. INTRODUCTION

The ideal drug delivery method to regulate and sustain drug release through the skin is transdermal. Control release drug systems, which contain the same medication and are generally quick release systems, restrict drug release and increase drug efficiency.[1] Many medications are administered orally these days, but the first pass metabolism makes the dose higher and the effects of the drug weaker. Transdermal medication delivery systems are therefore created to decrease the number of dosages while increasing the effectiveness and bioavailability of the medicament.[2] Drugs administered by transdermal drug delivery systems are directly injected into the bloodstream, maintaining ongoing efficacy. These methods provide the medication systemically at a consistent rate and sustain it for a long time, hence removing many issues with oral products such decreased bioavailability, improved first pass hepatic metabolism, relatively short residence duration, dose dumping, and

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inflexibility in dosing.[3] From a physicochemical point of view, an ideal transdermal drug candidate must satisfy a number of criteria, including being highly lipophilic by nature, having a melting point above 150, having a molecular weight above 500 Dalton, having log p values between 1 and 5, and not having any local toxicity or skin irritation.[4] The term "transdermal delivery," which refers to the administration of medications through the skin for a systemic impact, was first used in 1981 when Ciba-Geigy introduced TransdermV (now sold as Transdermal Scope) as a motion sickness treatment.[5]

Table 1: Advantages and disadvantages of TDDS [6,7-9]

Advantages	Disadvantages
Self-administration is conceivable, and the drug can be released continuously and steadily.	Currently, only tiny lipophilic medications may be administered through the skin.
Avoids longer and multiday dosage intervals, peak and trough medication levels.	Because patch size restricts the amount that may be administered, the drug molecule needs to be powerful.
Prevents gastrointestinal irritation, first-pass hepatic metabolism, and enzymatic breakdown by the digestive tract.	High medication doses are not recommended.
Patient compliance is improved with less frequent dosage.	The type of patch and the environment can affect how well a patch adheres.
Patients who are unable to take oral medication should consider an alternative method.	The type of patch and the environment can affect how well a patch adheres.
Vomiting or diarrhoea do not influence the delivery of doses.	It's possible to experience skin sensitivity and irritated skin.
When the patch is removed, the medication is stopped.	The skin's barrier functions vary depending on the site, the individual, and age.

II. TRANSDERMAL ROUTE AND DRUG DELIVERY BY SKIN

The largest organ:

The human body's largest organ, the skin, accounts for roughly 16% of total body weight. A healthy adult man's skin measures 1.5 to 2 m2 and weighs between 6 and 10 kg.[10] Cellular epidermis, underlying dermis, and subcutaneous layer are the three main cell layers that make up skin. The dermis layer is formed from the epidermis' rete ridges, as shown in Fig. 1.1. The dermal-epidermal junction serves as both a partial barrier against the exchange of cells and big molecules and a mechanical support for the epidermis. The fatty layer of panniculus adiposus tissues, often known as the subcutaneous layer, lies beneath the dermis.[11] Human skin comes in two varieties: glabrous skin, or skin without hair, and skin with hair. Thick epidermis and the presence of sensory organs in the dermis are characteristics of glabrous skin. Both sebaceous glands and hair follicles are absent. A distinctive personal configuration known as dermatoglyphics is formed by glabrous skin, which is primarily found on the palms and soles and has a continuous grooved surface with alternating ridges and sulci. While the skin that produces hair has both hair follicles and sebaceous glands, it does not have any sensory organs.[11]

Layers of the Skin:

1. Epidermis: It is the skin's outermost layer and is distinguished by the presence of stratified squamous epithelial tissues, mostly made up of keratinocytes that are differentiating in phases.[12] The epidermis's constructing cells are called keratinocytes. Because it lacks blood vessels, the epidermis depends on the dermis to transport nutrients and dispose of waste through the basement membrane.

2. Dermis: The layer below the epidermis is called the dermis, and it is far thicker than the epidermal layer (1-5mm thick).[15] The dermis is essential for maintaining and supporting the epidermis. The collagen and elastin fibres that make up the connective tissues in the dermis predominate. Numerous specialised cells, including mast cells and fibroblasts, as well as organs and tissues like blood arteries, lymphatics, sweat glands, and nerves are found there.[13]

3. Hypodermis: It is also referred to as the Panniculus layer or subcutaneous layer/fat. The layer that lies underneath the dermis is what attaches the skin to the fibrous tissue that makes up the bones and muscles. Adipose tissues and well-vascularized, loose, areolar connective tissues that make up the hypodermis work as a shock absorber by serving as a cushion to protect underlying structures from stress and as an energy reserve, insulation, and heat barrier for the body. It is the body's primary location for fat accumulation and is studded with blood arteries and neurons.[18]

Function of the Skin [19-22]

1. Protection: The human body's main physical defence against the outside world is its skin. Against bacteria, poisons, dehydration, UV light, and mechanical harm, skin offers defence.

2. Sensation: to deep pressure, temperature, touch, and pain.

3. Mobility: enabling fluid body movement.

4. Endocrine activity: Vitamin D production, which is necessary for calcium absorption and healthy bone metabolism, is triggered by biochemical reactions in the skin.

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5. Exocrine activity: Water, urea, and ammonia are released during exocrine action. Sebum, perspiration, and pheromones are among the compounds that the skin secretes. It also performs crucial immunologic tasks by releasing bioactive substances like cytokines.
6. Immunity: pathogen defense development.
7. Temperature Control: The skin contributes to thermal control by storing or releasing heat and aids in the preservation of the body's homeostatic and water balance.

III. BASIC COMPONENTS OF TRANSDERMAL DRUG DELIVERY SYSTEM

Polymer Matrix: *[23,24,25]*

An essential and crucial part of the transdermal drug delivery system is polymer. Rate controlled medication delivery has been made possible by the use of many kinds of polymeric materials. The physicochemical characteristics of the polymer and material utilised in the creation of the device determine how the medication is released. A polymer must meet the following requirements in order to be employed in a transdermal system.

1. The polymer's chemical functionality, molecular weight, and glass transition temperature must all permit the specific drug's release and diffusion.
2. A significant quantity of drug should be able to be incorporated into the polymer.
3. Neither the medicine nor the polymer should interact chemically or physically.
4. The polymer should be pricey and simple to build into the required product.
5. In the presence of the medicine and any other excipients used in the formulation, at high humidity levels, or at body temperature, the polymer must be stable and must not disintegrate.
6. Non-toxic polymers and their degradation products are required. No single substance can possess all of these qualities; various excipients may be added to change some characteristics, for instance, co-solvents such ethanol, propylene glycol, and PEG 400 may be added to boost drug solubility.

Natural polymers

These polymers are found in nature generally from plants and animals sources. Such as proteins, cellulose, starch, resins, etc.

Origin of Natural Polymer *[40]*

One reason why natural polymers have become an interest in undoubtedly because it can be obtained from natural sources that are abundant and renewable also ease to get. Polysaccharides are found in abundance in nature and are readily available from sources such as algae (e.g., alginates), plants (e.g., pectin, guar gum, mannan), microbes (e.g., dextran, xanthan gum) and animals (e.g., chitosan, chondroitin) and they can also be produced by means of recombinant DNA techniques. Monosaccharide polymers have many favourable properties such as high stability, nontoxicity, hydrophilicity, biodegradability, gel forming properties and ease of chemical modification. An enormous variety in plant polysaccharide structural composition exists, which is not only associated with different plants, but also with the part of the plant that they originate from, such as the leaves, seeds, roots and tubers. The complexity and variety of polysaccharides can be explained by two unique structural features: firstly, monosaccharides can be linked together in different ways and in an α- or β configuration and secondly, due to the presence of branched side-chains.

Physicochemical Properties of Natural Polymers *[40]*

Homogeneity/Polydispersity

Natural polymers such as proteins are rather uniform in size and there is no variation. Such polymers are said to be homogeneous or monodisperse. Most of natural polymers are naturally built by condensation polymerization. Natural polymers tend to be readily biodegradable and they show no adverse effects on the environment or human beings.

Importance Of Natural Polymers Over Synthetic Polymers *[41,42,43]*

- **Biodegradable**

Naturally occurring polymers produced by all living organisms. They show no adverse effects on the environment or human being. In contrary, synthetic polymers, being prepared by the help of chemicals have side effect on atmosphere as well as on the human being.

- **Biocompatible and non-toxic**

Chemically, nearly all of these plant materials are carbohydrates in nature and composed of repeating monosaccharide units. Hence, they are non-toxic as compared to synthetic polymers.

- **Economic**

Natural polymers are cheaper and their production cost is less than synthetic material.

- **Safe and devoid of side effects**

They are found in a natural form and hence, safe and having no side effects whereas synthetic polymers being prepared by using chemicals have side effects.

- **Easy availability**

Natural polymers are growing in the form of herbs in many counties being economical than synthetic polymers and having no side effect and keeping in view their huge application in many industries, they are produced in large quantity hence their availability is ensured than synthetic polymers.

Disadvantages Of Natural Polymers *[44,45]*

1. Microbial contamination – During production, they are exposed to external environment and hence, there are chances of microbial contamination.
2. Batch to batch variation – Synthetic manufacturing is controlled procedure with fixed quantities of ingredients while production of natural polymers is dependent on environment and various physical factors.
3. The uncontrolled rate of hydration - Due to differences in the collection of natural materials at

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different times, as well as differences in region, species, and climate conditions the percentage of chemical constituents present in a given material may vary.

Classification Of Natural Polymers [46]

Natural polymers are classified in three main categories, such as:

- Plants origin
- Animal's origin
- Microbes' origin

Table 3-Transdermal patch composition [48]

Polymer	Drug	Type of system
HPMC	Propranolol	Matrix
HPMC	Hydrocortisone	Gel
Silicone elastomers (MDX4-421)	L-Timolol maleate	Matrix
Carboxy vinyl	L-Dopa	Gel
Acrylic adhesives	Tacrine	Drug-in-adhesive
Ethyl cellulose T-50	Isosorbide dinitrate	Matrix
Cariflex TR-1107	Dihydroetorphine	Drug-in-adhesive
Acrylic PSA	Nicotine	Drug-in-adhesive
HPMC	Nicorandil	Reservoir
HPMC	Nimodipine	Membrane moderated
HPMC/ Eudragit RL100	Carvedilol	Reservoir
HPMC/ Chitosan	Etoricoxib	Matrix
Acrylic adhesives	Rivastigmine	Drug-in-adhesive
DURO-TAK® adhesives	Indapamide	Drug-in-adhesive
HPMC/ MC/ PVP	Celecoxib	Matrix
Acrylic adhesives	Meloxicam	Drug-in-adhesive
HPMC/ PVP/ CP	Glibenclamide/ Atenolol	Matrix
Acrylic / Silicone polymer	Diclofenac Diethylamide	Drug-in-adhesive

HPMC – hydroxypropyl methyl ether; MC – methyl cellulose; PVP – polyvinylpyrrolidone; CP – Carbopol

The three major classes polymers evaluated for potential medical applications in TDDS include: [25]

- Polyisobutylene-type pressure sensitive adhesives
- Acrylic type pressure sensitive adhesives
- Silicone type pressure sensitive adhesives

Transdermal Drug Delivery Device

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.

Rate controlling membranes: Transdermal devices' rate-controlling membranes control how much medication is released. For usage as rate-controlling membranes, natural polymeric materials like chitosan show considerable promise. Composite poly-2-hydroxyethyl methacrylate (PHEMA) membranes have recently been tested as transdermal rate-controlling barriers. [24,35]

Backing laminates: The backing laminate's main purpose is to provide support.

Ideal Characteristics:

- Must have a low moisture vapour transfer rate.
- Must be impermeable to medicines and permeation enhancers.
- Must have ideal tensile strength, elasticity, and flexibility.
- The medicine, enhancer, adhesive, and other excipients must all be chemically compatible with one other.
- Must allow printing and adhesive lamination

There are four major Transdermal System:

1. Single-layer Drug-in-Adhesive
2. Multi-layer Drug-in-Adhesive
3. Reservoir-drug in-adhesive
4. Matrix drug-in-adhesive

IV. EVALUATION PARAMETERS

The prepared transdermal patches were evaluated for various physiochemical parameters like physical examination, thickness, folding endurance, weight variation, tensile strength, moisture uptake, moisture loss and drug content.

1. Physical examination [37]

Transdermal patches were visually checked for their:

- Colour
- Clarity
- Flexibility
- Homogeneity
- Smoothness

2. Thickness: [37]

Three patches had their thickness measured using a micrometre at five separate locations, and the average was computed.

Folding endurance:

Manual folding endurance testing was done on the prepared patches. The number of times the film is folded at the same spot is expressed as the number of times the film must be broken or exposed cracks must appear. This is crucial to determine whether the sample can endure folding. Additionally, this suggests brittleness. A short, 2 cm × 2 cm (4 cm^2) piece of film was folded repeatedly at the same location until a crack was visible,

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at which point the film broke. This test was used to measure the film's folding endurance. The value of folding endurance is calculated by number of times the patch could be folded without breaking is note down.

3. Weight uniformity:

A study was conducted by weighing 5 patches in an electronic scale because weight variation between the formulations of patches can affect medication content and in-vitro behaviour. All of the patches were chosen at random and should be 1 cm × 1 cm in size. The following calculations were used to determine the standard deviation and average patch weight.

4. Tensile strength:

The tensile strength was measured using the apparatus, which was created in our lab. The tensile strength was determined by averaging the weight of three patches.

5. Moisture uptake:

The weighed films were removed from the desiccator after being held there for 24 hours at room temperature and exposed to 75% relative humidity (a saturated solution of sodium chloride) until a constant weight for the film was determined by dividing the final weight by the initial weight. The formula used to determine the

% moisture uptake is as follows: % Moisture uptake = [Final weight - Initial weight / Final weight] x 100

6. Moisture loss:[39]

4 cm^2 patches were weighed individually and maintained in desiccators with calcium chloride for 24 hours at room temperature (Fig. 5.10). After 3 days, the patches had regained their weight. The formula used to determine the percentage moisture content is as follows:

% Moisture content = [Initial weight – Final weight / Final weight] x 100

7. *Drug content:[39]*

The ATO content was evaluated using a 100 ml graduated flask containing phosphate buffer solution at a pH of 7.4. The flask was filled with a 1 cm^2 patch, which was then shaken for four hours in a mechanical shaker. The resulting solution was filtered, diluted with phosphate buffer pH 7.4, and then examined in a UV spectrophotometer at 246 nm for the presence of drug ATO. The patches used as a placebo served as a control. The amount of medication in one patch was determined by averaging the readings from three patches.

V. CONCLUSION

Natural polymers have received much more attention in the last decades due to their applications in the fields related to environmental protection and the maintenance of physical health. From the discussion, it can be concluded that by incorporating drugs in natural polymers, dosage forms that release the drug over a prolong length of time can be prepared in variety of shapes and sizes. Polymers play a vital role in the drug delivery so; the selection of polymer plays an important role in drug manufacturing. But while selecting polymers care has to be taken regarding its toxicity, drug compatibility and degradation pattern. By this review, we can say that for TDDS natural polymers can be good substitute for the synthetic polymers and many of the side effects of the synthetic polymers can be overcome by using natural polymers.

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