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FORMULATION AND EVALUATION OF TRANSDERMAL PATCHES OF DICLOFENAC SODIUM: A REVIEW

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Abstract:

The development of transdermal patches containing diclofenac sodium has emerged as a promising approach for effective pain management. Diclofenac, a non-steroidal anti-inflammatory drug (NSAID), is commonly used to treat inflammatory conditions, arthritis, and musculoskeletal pain. These include enhanced bioavailability, avoidance of first-pass metabolism, maintenance of steady plasma drug concentrations, non-invasiveness, prolonged therapeutic effects, reduced adverse effects, and improved patient compliance. Transdermal patches are primarily made using NSAIDs (non-steroidal anti-inflammatory medications) to alleviate pain or inflammation. NSAID patches are more convenient and safe to use than the oral dosage type. TDDS provide a convenient, cost-effective, and self-administrable alternative, making them particularly beneficial for drugs that require frequent or long-term dosing. Diclofenac is a well-known nonsteroidal anti-inflammatory drug that is frequently used to treat pain and inflammation symptoms in musculoskeletal conditions, arthritis, toothaches, dysmenorrhea, and other conditions

Keywords: *TDDS, Anatomy of Skin , Transdermal Patches, Types, Function, Skin , Method, Evaluation.*

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INTRODUCTION:

Transdermal drug delivery devices [TDDS], often known as patches, offer a another way to administer drugs through the skin. In order to achieve effective concentrations for the treatment and prevention of disease, these systems are made to effectively transport therapeutic dosages of drug into the bloodstream There are various delivery methods available, including oral, transdermal, lung, mucosal, and intravenous injections. The transdermal drug delivery system (TDDS) is a promising technique. TDDS is a popular method of non-invasive medication delivery through the skin, as opposed to traditional needle-based injections. TDDS has had a considerable impact on the delivery of therapeutic drugs, particularly in pain management, hormonal therapy, and cardiovascular and nervous system illnesses.

Transdermal administration treats several different disorders in humans using a range of dose formulations. Recent years have seen the development of several extremely sophisticated drug delivery techniques, and these dosage forms allow for the medication's sudden release.

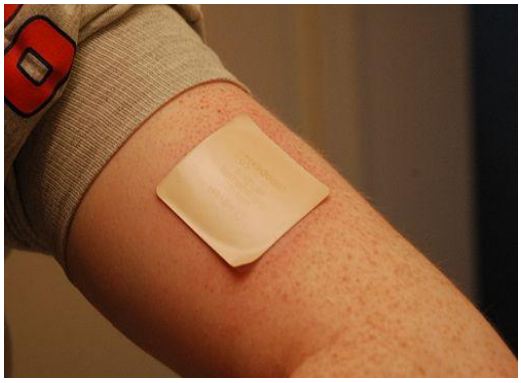

Fig 1: Transdermal patches

Transdermal patches are primarily made using NSAIDs (non-steroidal anti-inflammatory medications) to alleviate pain or inflammation. NSAID patches are more convenient and safe to use than the oral dosage type. The use of transdermal NSAID patches can prevent the negative effects of NSAID tablets for rheumatism, which include increased acidity, ulcers, and internal stomach bleeding [15].However, the NSAID analgesic patch can be applied to the sprain or strain region.

Diclofenac is a well-known nonsteroidal anti-inflammatory drug that is frequently used to treat pain and inflammation symptoms in musculoskeletal conditions, arthritis, toothaches, dysmenorrhea, and other conditions [17]. Within the NSAID family, diclofenac (2-[2-(2,6 dichlorophenyl amino)phenyl]acetic acid) is one of the most promising and commercially successful medications. The primary mode of action involves blocking the formation of prostaglandin (PG) in order to reduce the activity of cyclooxygenase (COX) Its molecular weight is 318.13 g/mol, and its formula is C14H10Cl2NNaO2 [18].

The medication undergoes significant hepatic first-pass metabolism, and only roughly half of the amount is absorbed by the body. Diclofenac sodium's main adverse effects include systemic toxicity, GIT irritation, nausea, vomiting, gastric erosion, and headaches, even though individuals with rheumatoid arthritis are encouraged to take NSAIDs for an extended period of time. Its frequent administration and brief biological half-life make it a good candidate to be formulated into a transdermal patch system of the sustained release matrix type.

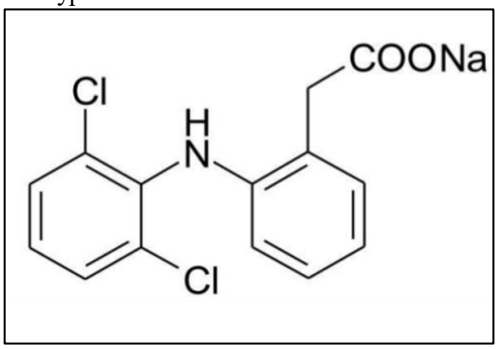

Fig. 2: Chemical structure of diclofenac sodium

Anatomy and Physiology of Skin

The skin, which makes up 16% of the average person's body mass and has a surface area of 1.7 m2, is the largest and easiest organ in the body to reach (Figure 1). The main job of the skin is to serve as a barrier of defence between the body and the environment, keeping out viruses, toxins, allergens, UV rays, and water loss.

1.Epidermis

most layer of skin, known as the epidermis, varies in thickness and is around 0.8 mm thick on the palms and soles of the hands and feet. The epidermal layers underneath the stratum corneum are commonly used to refer to the viable epidermis. It is made up of layers upon layers of epithelial cells.

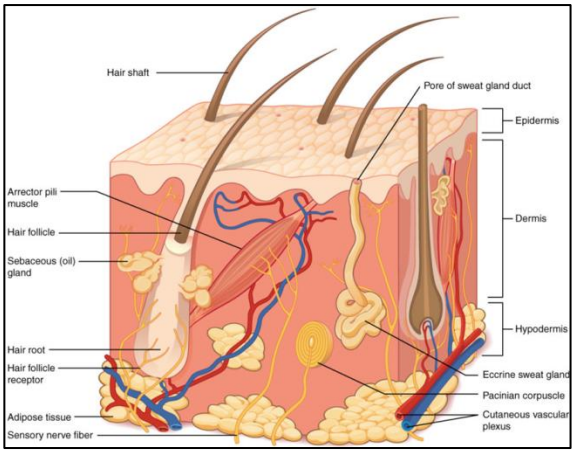

Fig. 3: Anatomy And Physiology of Skin

2. Dermis

The dermis, which gives the skin its strength and suppleness, is made up of 70% collagen and elastin fibres and is about 2-3 mm thick.

3. Hypodermis

The hypodermis contains fat cells, which are composed of two cell types: fibroblasts and macrophages, and account for around half of the body's total fat.

Pathway of skin permeation

The stratum corneum is the direct entry point for chemicals into the skin, whereas the sebaceous glands, hair follicles, and sweat ducts are the indirect entry points.

Function of skin

- Helps to keep skin hydrated by preventing moisture loss.
- serves as a sensory organ that enables humans to perceive temperature changes and touch.
- Sweating and cooling the body as needed help to regulate body temperature.

Types of transdermal patches

1. Single Layer Drug in Adhesive
2. Multi Layer in Adhesive
3. Reservoir
4. Matrix
5. Vapour patch

1. Single Layer Drug in Adhesive

Drugs are applied directly to the skin in a single layer using the Single Layer Drug-In-Adhesive technique, and this layer sticks to the skin's surface [Al Hanbali et al. 2019]. A backing membrane, an adhesive layer holding medication, and a liner layer make up the three primary layers of a conventional transdermal patch.

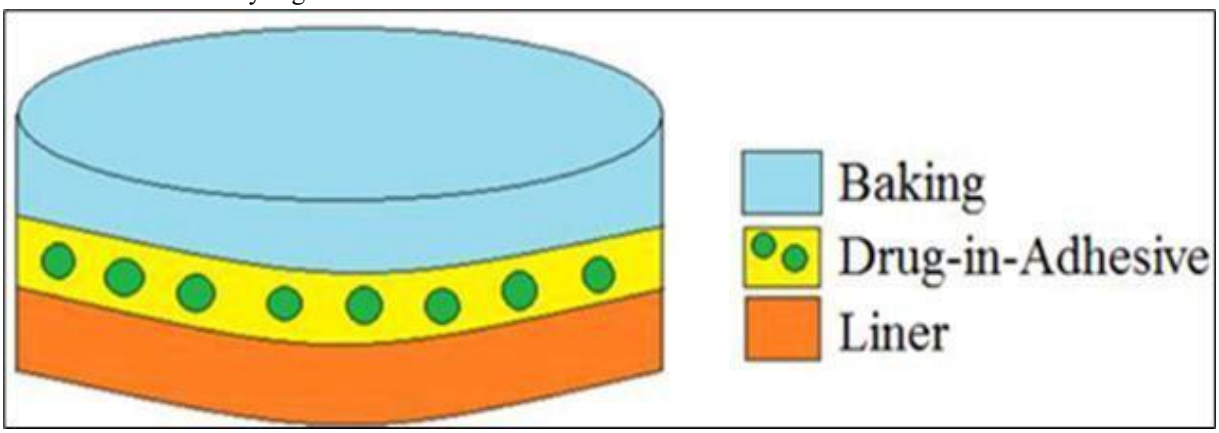

Figure 4: Single-layer drug Adhesive [31]

2. Multi Layer in Adhesive

The medication is released by both sticky layers in the multi-layer drug-in adhesive patch, which is comparable to the single-layer approach.

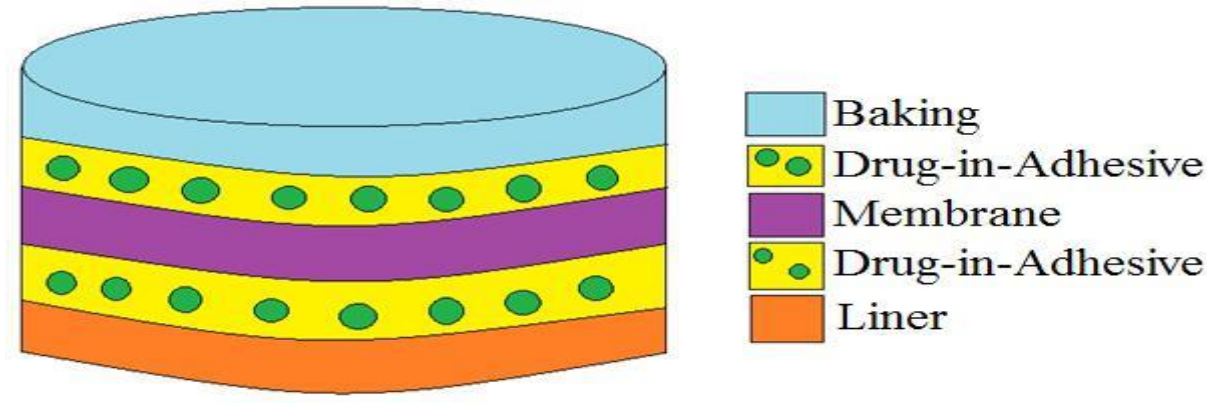

Figure 5: Multi -layer drug Adhesive [31]

3. Reservoir

The reservoir transdermal system features a distinct drug layer in contrast to the single-layer and multi-layer drug-in-adhesive systems.

4. Matrix

The drug layer of the Matrix system is a semisolid matrix that contains a drug suspension or solution. In this patch, the medication layer is partially covered by the adhesive layer.

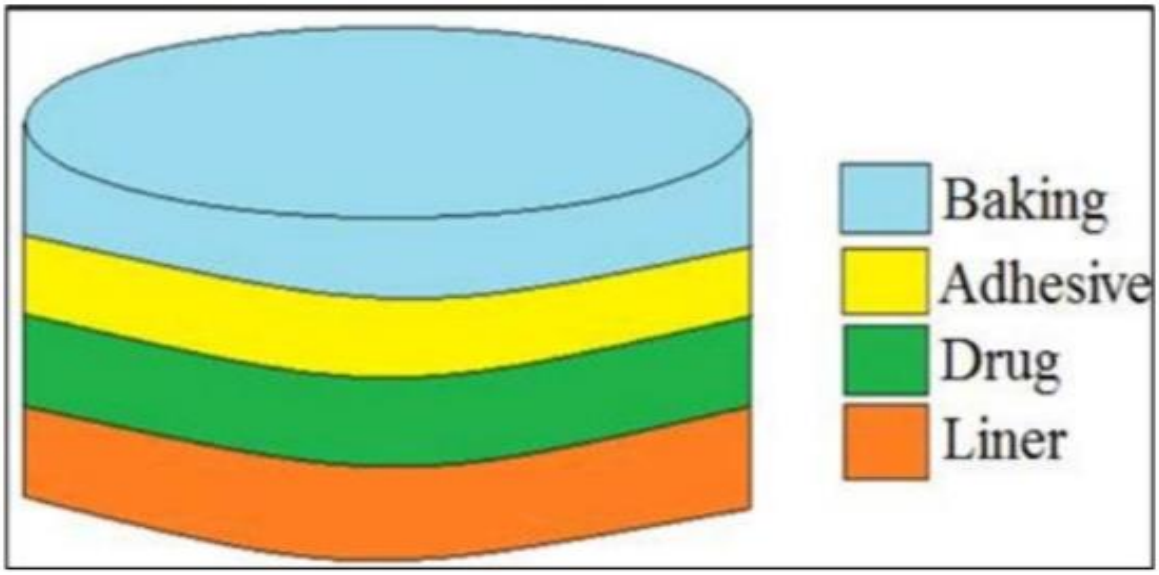

Fig 6: Matrix [31]

5. Vapour patch

In addition to keeping the various layers of this type of patch together, the adhesive layer also releases vapour.

Components of transdermal patches

1. Drug
2. Polymer matrix
3. Adhesives
4. Permeability enhancers
5. Backing membrane
6. Linear release [37]

1. Drug

Drugs must have particular physicochemical characteristics in order to facilitate drug absorption via the skin. These consist of low molecular weights (up to 1000 Daltons), short half-lives, low melting temperatures, non-irritating qualities, efficacy, and affinities for both hydrophilic and lipophilic substances. Direct contact between the drug solution and the release lining.

2. Polymer matrix

Transdermal Drug Delivery Systems [TDDS] rely heavily on polymers to regulate the system's controlled drug delivery.

4. Permeability enhancer

Polar, non-polar, and polar/non-polar routes are the three hypothesised routes for drug penetration through the skin. One of these routes is changed by the enhancers. The key to changing the polar route is to induce solvent swelling or a change in protein structure.

Factor affecting TDDS

- Skin Permeability: One important consideration is the skin's capacity to permit medication penetration. Skin integrity, moisture, and thickness are some of the variables that affect it.
- Medicine Properties: The size, solubility, molecular weight, and chemical characteristics of the medicine all matter. The skin tends to absorb smaller, lipophilic substances more easily.

Transdermal patch production methods

Solvent casting method : This technique involves casting a drug and polymer solution Onto a substrate, then evaporating the solvent to create the patch.

Hot melt extrusion : The drug and polymer mixture is melted, then extruded through a die to create a solid matrix that is then sliced into patches.

Compression moulding : To create the patch, the medication and polymer mixture is crushed into a mould at high temperatures and pressures.

Modern techniques of TDDS

- Microneedle Technology : Microneedles are little, painless needles utilised to form microchannels in the skin, facilitating enhanced medication penetration.
- Iontophoresis : This method improves drug absorption by driving charged drug molecules through the skin with a low-level electrical current.

MATERIAL AND METHOD:

Material:

All chemicals used in the studies discussed were of pharmaceutical or standard analytical grade. Diclofenac sodium, the active pharmaceutical ingredient, was obtained as a complimentary sample from a pharmaceutical company. Other essential components used in the formulation of the transdermal patch included a backing agent, plasticizer, penetration enhancer, and solvent. The commonly reported ingredients for diclofenac sodium transdermal patches are summarized in Table 1.

Table 1: Components Diclofenac Sodium Patch

Sr.No.	Ingredients	Function
1.	Diclofenac Sodium (mg)	Active Ingredient (Drug)
2.	Methyl cellulose (mg)	Backing Agent
3.	PG,PEG-400 (ml)	Plasticizer
4.	Dibutyl phthalate (ml)	Penetration Enhancer
5.	Distilled water : Ethanol (ml)	Solvent

Preparation of Patch by Solvent Casting Method

Table 2:Reported Compositions of Diclofenac Sodium Transdermal Patch[55–57].

Sr. No	Ingredients	Quantity
1.	Diclofenac Sodium	25 mg
2.	Methyl cellulose (mg)	300 mg
3.	PEG-400 (ml)	1.2 ml
4.	PG	-
5.	Dibutyl phthalate	1.2 ml
6.	Ethanol: Distilled Water	1.2 ml

Evaluation and Characterization of Transdermal Patches

The permeability, mechanical properties, and composition of transdermal films have been reported to significantly influence their performance.

Physical Appearance

1. Weight uniformity

In reported studies, weight uniformity is evaluated by weighing randomly selected patches individually and calculating the average weight to determine weight variation.

2. Patch Thickness

The thickness of transdermal patches is commonly measured at multiple points using a screw gauge or micrometre, and the mean value is calculated to ensure uniformity across the film.

3. Folding Endurance

Folding endurance evaluates the ability of transdermal films to withstand repeated folding without breaking.

4. Drug Content

The drug content of transdermal patches is generally determined by dissolving a specified area of the film in phosphate buffer solution with continuous stirring until complete dissolution.

5. Moisture Loss

Moisture uptake of transdermal films is typically evaluated by placing pre-weighed patches in a desiccator exposed to an environment of approximately 84% relative humidity at room temperature. After three days, the films are reweighed, and the percentage of moisture absorbed is calculated using the formula:

% Moisture Uptake = [(Final Weight – Initial Weight) / Initial Weight] × 100 [63].

6. Surface pH

The surface pH of transdermal films is generally determined by applying 0.5 mL of distilled water to the film surface and allowing it to swell for one hour at room temperature.

7. In vitro drug dissolution study

The assembly is immersed in 500 mL of phosphate buffer or dissolution medium (pH 7.4) maintained at 32.5 ± 2 °C. The paddle is positioned 2.5 cm above the glass plate and rotated at 50 rpm. Samples (5 mL aliquots) are withdrawn at predetermined intervals for up to 12 hours and analyzed using a UV spectrophotometer.

8. Stability Study

Stability studies of transdermal patches have been reported by storing the formulations for six months at 40 ± 0.5 °C and 75 ± 5% relative humidity in polyethylene-coated aluminium foils. Samples are withdrawn at predetermined intervals of 0, 30, 60, 90, and 180 days and evaluated for drug content as well as for any physical changes occurring during storage [66–68].

9. Content uniformity test

Content uniformity of transdermal patches has been evaluated in reported studies by randomly selecting individual patches for analysis. A formulation is considered to meet the content uniformity criteria if the drug content of nine out of ten patches falls within 85% to 115% of the specified value, and one patch is within 75% to 125%.

CONCLUSION:

Transdermal drug delivery systems (TDDS) offer several advantages over conventional routes of drug administration. These include enhanced bioavailability, avoidance of first-pass metabolism, maintenance of steady plasma drug concentrations, non-invasiveness, prolonged therapeutic effects, reduced adverse effects, and improved patient compliance. TDDS provide a convenient, cost-effective, and self-administrable alternative, making them particularly beneficial for drugs that

require frequent or long-term dosing.

A thorough understanding of the structure and physiology of the skin is fundamental to appreciating the mechanism of transdermal drug delivery. For systemic absorption, the drug must traverse multiple skin layers, including the epidermis, dermis, and hypodermis. The effectiveness of this process depends on the design and composition of the transdermal patch, which typically includes a drug reservoir or matrix, polymer base, adhesive layer, backing membrane, release liner, and permeation enhancers. Each of these components plays a vital role in ensuring optimal drug diffusion and controlled release through the skin barrier.

Diclofenac Sodium in Transdermal Patches

The development of transdermal patches containing diclofenac sodium has emerged as a promising approach for effective pain management. Diclofenac, a non-steroidal anti-inflammatory drug (NSAID), is commonly used to treat inflammatory conditions, arthritis, and musculoskeletal pain. Transdermal administration provides sustained drug delivery while minimizing gastrointestinal complications and hepatic first-pass metabolism associated with oral dosage forms. Moreover, it enables localized delivery to affected tissues, thereby reducing systemic exposure and potential side effects.

Several studies have successfully formulated diclofenac sodium patches using solvent casting and other fabrication techniques with various polymers, including methylcellulose, polyethylene Glycol (PEG), ethyl cellulose, and Eudragit. These studies collectively demonstrate that formulation parameters such as polymer concentration, plasticizer content, and the presence of penetration enhancers significantly influence drug release rates and skin permeation efficiency.

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