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A Comparative Study of the Quality of OTC Transdermal Patches for Pain Relief

Tharunkumar J*[1], Padmapriya E[1],Selvamuthukumar R[2], Saminathan C[3]

1* B. Pharm, Mayor Radhakrishnan College of Pharmacy, Cuddalore, Tamilnadu-607001

2 Associate Professor, Mayor Radhakrishnan College of Pharmacy, Cuddalore, Tamilnadu-607001

3 Professor, Mayor Radhakrishnan College of Pharmacy, Cuddalore, Tamilnadu-607001

ABSTRACT

Transdermal drug delivery systems provide a convenient and non-invasive approach for delivering therapeutic agents through the skin and may offer advantages over conventional routes of administration. The present study was undertaken to comparatively evaluate the quality and physicochemical characteristics of commercially available over-the-counter (OTC) transdermal patches used for pain relief. Three commercially available patches containing different active pharmaceutical ingredients, namely diclofenac, lidocaine, and ketoprofen, were selected for evaluation. The patches were assessed for important physicochemical and mechanical parameters, including thickness, weight uniformity, folding endurance, moisture content, surface pH, and tensile strength. The results demonstrated that all three patches showed acceptable thickness and weight uniformity. The thickness values ranged from 0.22 to 0.28 mm, while percentage weight variation remained below 5%, indicating satisfactory formulation consistency. Ketoprofen patches exhibited the highest folding endurance (245 folds) and tensile strength (1.38), indicating superior flexibility and mechanical strength. Diclofenac patches demonstrated good uniformity and a surface pH of 6.2, while lidocaine patches showed a surface pH of 6.6 and comparatively lower folding endurance and tensile strength. Moisture content was below 5% for all tested patches, indicating acceptable moisture characteristics. Comparative evaluation indicated that ketoprofen patches demonstrated the most favorable mechanical properties, followed by diclofenac, whereas lidocaine patches showed comparatively lower mechanical strength and folding endurance. One-way ANOVA revealed statistically significant differences among the tested patches for tensile strength and folding endurance ($p < 0.05$), while differences in thickness and weight were not statistically significant. Overall, the study demonstrated that all three OTC transdermal patches possessed acceptable physicochemical characteristics; however, ketoprofen patches showed superior mechanical strength and flexibility, making them comparatively more robust for prolonged or active use. Diclofenac patches showed satisfactory uniformity and surface pH, whereas improvement in the mechanical properties of lidocaine patches may enhance their durability and user experience.

Keywords: Comparative study, Diclofenac, Ketoprofen, Lidocaine, Transdermal patches.

INTRODUCTION

Transdermal drug administration generally refers to topical application of agents to healthy intact skin either for localized treatment of tissues underlying the skin or for systemic therapy. For transdermal products the goal of dosage design is to maximize the flux through the skin into the systemic circulation and simultaneously minimize the retention and metabolism of the drug [1]. The idea of delivering drugs through skin is old, as the use is reported in 16th century in which the husk of castor oil plant in water was placed on an aching head. Today the transdermal drug delivery is well accepted for delivering drug to systemic circulation. Until recently, the use of transdermal patches for pharmaceuticals has been limited non-medicated patch markets include thermal and cold patches, nutrient patches, skin care patches (a category that consists of two major sub-categories: therapeutic and cosmetic), aroma patches, weight loss patches and patches that [2].

Now a day's transdermal drug delivery systems are a consistent source of interest because of the benefits that they afford in overcoming many drawbacks associated with other modes of antifungal drug delivery (i.e.oral,intravenous). Because of the Skin particularly the stratum corneum, provides a barrier for the penetration of the majority of the substances. Gels are semisolid formulations, which have an external solvent phase, may be hydrophilic or hydrophobic in nature, Recent studies have reported other types of gels for dermal drug application, such as niosomal gels, liposomal gel, erythrosomal gel, microsphere gel.[3] TDDS basically consists of adhesive drug-containing devices of defined surface area that delivers a predetermined amount of drug to the intact skin at a preprogrammed rate, which is able

to penetrate through different layers of skin to reach the systemic circulation.

Currently, the transdermal route, along with oral treatment, ranks as the most successful innovative research area in drug delivery. Backing layer, drug containing layer, rate controlling membrane, adhesive and release liner are the components of TDDS thoughall layers may not be available in all types of TDDS as there [4]. are several types of transdermal patches [5]. There is single layer drug in adhesive, multilayer drug in adhesive, vapour patch, reservoir system and matrix system. Similarly natural polymers, synthetic polymers, synthetic elastomers and biopolymers have been used in TDDS [6]. With the advent new era of pharmaceutical dosage forms (TDDS) established itself as an integral part novel drug delivery system. Transdermal drug delivery is the non-invasive delivery of medications from the surface of skin-the largest and most accessible organ of human body-through its layers, to the circulatory system. BASIC Components used for transdermal drug delivery system: Polymer matrix, Drug, Permeation enhancer, Adhesive and backing membrane Transdermal patches were developed in the1970s and the first was approved by the FDA in 1979 for the treatment of motion sickness. It was a three-day patch that delivered scopolamine. In 1981, patches for nitro-glycerine were approved, and today there exist a number of patches for drugs such as clonidine, fentanyl, lidocaine, nicotine, nitro-glycerine, oestradiol, oxybutynin, scopolamine, and testosterone. There are also combination patches for contraception, as well as hormone replacement. Depending on the drug, the patches generally last from one to seven days [6].

DRUG PROFILE.

Ketoprofen

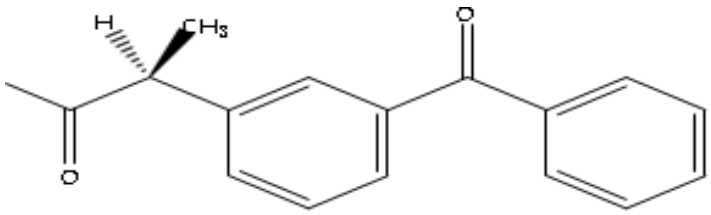

Figure no. 1 Structure of Ketoprofen.

Table no. 1 Drug profile of Ketoprofen

S. No.	Parameter	Details
1	**Generic Name**	Ketoprofen
2	**Drug Class**	Non-steroidal anti-inflammatory drug (NSAID)
3	**Chemical Class**	Propionic acid derivative
4	**Modality**	Small molecule
5	**Chemical Formula**	$C_{16}H_{14}O_3$
6	**Molecular Weight**	254.28 g/mol
7	**Mechanism of Action**	Non-selective inhibition of COX-1 and COX-2, resulting in reduced prostaglandin synthesis
8	**Pharmacological Effects**	Analgesic, anti-inflammatory and antipyretic
9	**Absorption**	Rapid and well absorbed orally; peak plasma concentration within approximately 0.5–2 hours
10	**Protein Binding**	Approximately 99%, primarily to albumin
11	**Metabolism**	Rapid and extensive hepatic metabolism, mainly by glucuronidation

S. No.	Parameter	Details
12	**Major Metabolite**	Ketoprofen glucuronide
13	**Route of Elimination**	Primarily renal; approximately 80% excreted in urine within 24 hours
14	**Half-life**	1.1–4 hours for immediate-release formulations; approximately 5.4 hours for extended-release formulations
15	**Clearance**	Approximately 6.9 ± 0.8 L/h for immediate-release and 6.8 ± 1.8 L/h for extended-release formulations
16	**Therapeutic Uses**	Management of pain and inflammatory conditions; reduction of fever
17	**Major Adverse Effects**	Gastrointestinal irritation, ulceration and bleeding
18	**Brand Name**	Kiprofen
19	**Synonyms**	2-(3-Benzoylphenyl)propionic acid; 3-Benzoylhydratropic acid; Ketoprofeno
20	**Drug Status**	Approved; investigational and veterinary applications reported

Figure no. 2 Structure of Diclofenac

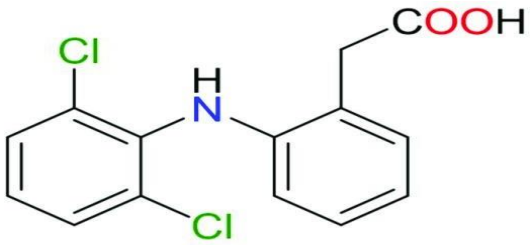

Table no. 2 Drug profile of Diclofenac

S. No.	Parameter	Details
1	**Generic Name**	Diclofenac
2	**Drug Class**	Non-steroidal anti-inflammatory drug (NSAID)
3	**Chemical Class**	Phenylacetic acid derivative
4	**Chemical Formula**	$C_{14}H_{11}Cl_2NO_2$
5	**Mechanism of Action**	Inhibits cyclooxygenase (COX) enzymes, reducing prostaglandin synthesis and producing analgesic and anti-inflammatory effects
6	**Brand Names**	Arthrotec, Cataflam, Flector, Licart, Lofena, Pennsaid, Solaraze, Voltaren, Voltaren Emulgel, Zipsor, Zorvolex
7	**Synonyms**	[2-(2,6-Dichloroanilino)phenyl]acetic acid; 2-((2,6-Dichlorophenyl)amino)benzeneacetic acid; Diclofenac acid; Diclofenaco; Diclofenacum
8	**Absorption**	Completely absorbed from the GI tract, with approximately 60% reaching systemic circulation unchanged due to first-pass metabolism. Topical formulations are absorbed percutaneously.
9	**Tmax**	Oral solution: approximately 10–40 min; enteric-coated tablet: 1.5–2 h; modified-release formulations have longer Tmax.
10	**Volume of Distribution**	Approximately 5–10 L or 0.1–0.2 L/kg

11	**Distribution**	Distributes into synovial fluid; peak synovial concentrations occur approximately 2–4 h after administration
12	**Protein Binding**	>99.7%, primarily to serum albumin
13	**Metabolism**	Extensively metabolized by oxidative hydroxylation and conjugation. CYP2C9 contributes to formation of 4′-hydroxy diclofenac.
14	**Major Metabolite**	4′-Hydroxy diclofenac
15	**Route of Elimination**	Mainly eliminated after metabolism; approximately 60–70% in urine and about 30% in feces
16	**Half-life**	Approximately 2 hours for diclofenac; metabolites have longer apparent half-lives
17	**Plasma Clearance**	Approximately 16 L/h
18	**Therapeutic Effects**	Analgesic and anti-inflammatory
19	**Therapeutic Uses**	Management of pain and inflammatory conditions
20	**Important Pharmacokinetic Feature**	Extensive first-pass metabolism and very high plasma protein binding

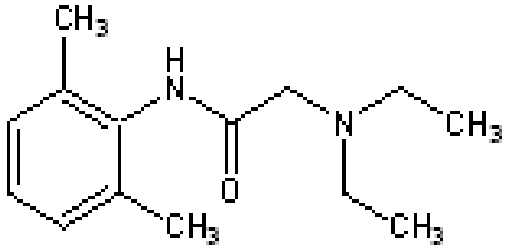

Figure no. 3 Structure of Lidocaine

Table no. 3 Drug profile of Lidocaine

S. No.	Parameter	Details
1	**Generic Name**	Lidocaine
2	**Drug Class**	Local anesthetic; Amide-type local anesthetic
3	**Chemical Formula**	$C_{14}H_{22}N_2O$
4	**Mechanism of Action**	Reversibly blocks voltage-gated sodium channels from the intracellular side, inhibiting initiation and conduction of nerve impulses and producing local anesthesia.
5	**Pharmacological Effects**	Local anesthetic; at systemic concentrations, it can also produce antiarrhythmic effects.
6	**Summary**	Lidocaine is an amide-type local anesthetic widely used for superficial and invasive procedures.
7	**Brand Names**	Dermalid, Lidoderm, ZTlido
8	**Synonyms**	2-(Diethylamino)-2′,6′-acetoxylidide; 2-(Diethylamino)-N-(2,6-dimethylphenyl)acetamide; α-Diethylamino-2,6-dimethylacetanilide
9	**Absorption**	Readily absorbed across mucous membranes and damaged skin but poorly through intact skin. Following injection, absorption depends on the injection site, vascularity, dose, tissue binding and presence of a vasoconstrictor.

10	**Bioavailability**	Oral bioavailability is approximately 35% because of extensive first-pass hepatic metabolism.
11	**Distribution**	Widely distributed throughout body tissues; crosses the blood-brain and placental barriers by passive diffusion.
12	**Volume of Distribution**	Approximately 0.7–1.5 L/kg
13	**Protein Binding**	Approximately 60–80%, mainly dependent on plasma concentrations of α1-acid glycoprotein.
14	**Metabolism**	Rapidly metabolized in the liver by oxidative N-dealkylation, hydroxylation, amide cleavage and conjugation.
15	**Major Metabolites**	Monoethylglycinexylidide (MEGX) and glycinexylidide (GX); other metabolites include conjugates of 4-hydroxy-2,6-dimethylaniline.
16	**Route of Elimination**	Predominantly renal. Less than 5% of the administered dose is excreted unchanged in urine.
17	**Half-life**	Approximately 1.5–2.0 hours following intravenous administration; may be prolonged two-fold or more in patients with hepatic dysfunction.
18	**Systemic Clearance**	Approximately 0.64 ± 0.18 L/min following intravenous administration.
19	**Therapeutic Uses**	Local or regional anesthesia for superficial and invasive procedures; also used intravenously as an antiarrhythmic agent in selected clinical settings.
20	**Important Pharmacokinetic Feature**	Rapid hepatic metabolism and relatively short elimination half-life; hepatic impairment can significantly prolong its elimination.

MATERIALS AND METHODS

MATERIALS

Sample collection

A total of three commercially available OTC transdermal patches for pain relief were selected based on market availability. These included patches containing **NSAIDs** (e.g., diclofenac, ketoprofen), **local anesthetics** (e.g., lidocaine). All products were within their expiry period.

Brands used:

1. Brand A – Diclofenac
2. Brand B – Lidocaine
3. Brand C – Ketoprofen

Each patch was stored at room temperature (25±2°C) in a dry place before testing.

Materials and Reagents used

Distilled water (for pH analysis), Phosphate buffer solution (pH7.4) – for some comparative studies, Ethanol (analytical grade)–if required for surface cleaning, Butter paper or non-stick backing sheets (for sample mounting), Razor blades or precision cutter, Digital Vernier caliper, Weighing balance (analytical), Glass plates, Texture analyzer

Instruments used

Table no. 4 Instruments used

Parameter	Instruments Used
Thickness	Digital Vernier Caliper (±0.01 mm)
Weight Uniformity	Analytical Balance (±0.1mg)
Folding Endurance	Manual Folding with Counting
Moisture Content	Desiccator, Hot Air Oven (±1°C)
Surface pH	Digital pH Meter (calibrated)
Tensile Strength	Texture Analyzer

METHODS

Thickness Measurement

Uniform thickness is essential for consistent drug release and mechanical integrity of transdermal patches. Thickness was measured using a **digital Vernier caliper** at **five distinct points** (four corners and centre) on each patch sample to account for heterogeneity. For each brand, **five replicates** were analysed, and the mean thickness ± standard deviation (SD) was calculated. Measurements were reported in millimeters (mm) [7].

Weight Uniformity

Weight uniformity testing provides insights into the homogeneity of the patch matrix and drug distribution. From each brand, **five patches** were cut into standardized dimensions of **1 cm × 1 cm** using a precision cutter. The individual weights of these patches were recorded using an **analytical balance** with ±0.1 mg sensitivity. Mean weight, SD, and percentage weight variation were calculated to assess consistency within each brand batch [8].

Folding Endurance

Folding endurance assesses the mechanical flexibility and durability of the patch material, which is crucial for maintaining integrity during handling and application. A patch strip measuring **1 cm×1cm** was repeatedly folded at the same spot until it exhibited visible cracks or broke. The number of folds sustained without damage was recorded as the folding endurance value. This test was performed on **three samples per brand**, and the average value was reported [9].

Moisture Content Determination

Moisture content influences the mechanical properties, drug release profile, and shelf life of transdermal patches. Initially, patch samples were weighed (initial weight, W1) and then placed in a **hot air oven maintained at 60±1 °C** for 4 hours to remove moisture. Post drying, patches were reweighed (final weight, W2). Moisture content (%) was calculated using the formula:

MoistureContent(%) = W1−W2W1×100 \ text {Moisture Content (\%)}=\ frac{W1-W2} {W1} \times100MoistureContent (%) =W1W1−W2×100

Tests were conducted in triplicate, and mean values were reported. Controlled moisture content helps in avoiding brittleness or excessive softness of the patches [10].

Surface pH Measurement

Surface pH testing is performed to evaluate the potential of patches to cause skin irritation or discomfort upon application. A patch sample (1 cm × 1 cm) was moistened with **10 mL of distilled water** and allowed to equilibrate at room temperature for **1 hour**. The pH of the resulting solution was measured using a calibrated **digital**

pH meter, which was standardized with standard buffer solutions of pH 4.0 and 7.0 prior to use [11].

Tensile Strength Testing

Tensile strength determines the mechanical resistance of patches to tension, which correlates with handling durability and application performance. Each patch was cut into strips of dimensions 10 mm × 50 mm. These strips were mounted onto a texture analyser or Universal Testing Machine (UTM), equipped with a load cell capable of detecting small force variations. The maximum force at break was recorded in Newtons (N). Tensile strength (TS) was calculated using the equation [12]:

$$\text{Tensile Strength (MPa)} = \text{Force at break (N)}/\text{Cross-sectional area of sample (mm}^2\text{)}$$

RESULTS AND DISCUSSION

Thickness Measurement

Table no. 5 Thickness Measurement

Patch Type	Mean Thickness (mm)	Standard Deviation (± mm)	Acceptable Range(mm
Diclofenac	0.22	±0.01	0.2 – 0.3
Lidocaine	0.28	±0.02	0.2 – 0.3
Ketoprofen	0.24	±0.01	0.2 – 0.3

From table 5 it shows the thickness values of all tested patches fall within the generally accepted range of 0.2 to 0.3 mm, reflecting good batch uniformity and manufacturing control. Lidocaine patches displayed a slightly greater thickness, which may influence their drug loading capacity and mechanical properties. Consistent thickness is critical for ensuring uniform drug release and mechanical stability of the patches.

Weight Uniformity

Table no. 6 Weight Uniformity

Patch Type	Mean Thickness (mm)	Standard Deviation (± mm)	Acceptable Range (mm)
Diclofenac	108.5	±2.1	1.94%
Lidocaine	115.3	±3.4	2.95%
Ketoprofen	112.8	±2.7	2.39%

From table 6 it shows All patches demonstrated acceptable weight uniformity, with percentage variations below 5%, indicating consistent formulation across samples. The Lidocaine patch again showed a slightly higher mean weight, correlating with its increased thickness. Consistency in weight ensures predictable drug content and uniformity in dosing across the patch matrix.

Folding Endurance

Table no. 7 Folding Endurance

Patch Type	Average Folding Endurance (Number of Folds)
Diclofenac	220
Lidocaine	175
Ketoprofen	245

From table 7 it shows that Ketoprofen patches exhibited the highest folding endurance, indicating excellent flexibility and mechanical integrity, followed by Diclofenac. Lidocaine patches, although adequate, showed the lowest folding endurance, suggesting a slightly more brittle formulation. High folding endurance is crucial for maintaining patch integrity during application, storage, and movement on the skin.

Moisture Content

Table no. 8 Moisture Content

Patch Type	Moisture Content (%)	Standard Deviation (±%)
Diclofenac	4.35	±0.12
Lidocaine	3.78	±0.15
Ketoprofen	4.91	±0.18

From table 8 it shows that the Moisture content was found to be within the acceptable range (<5%) for all formulations, which is essential for maintaining patch pliability without compromising stability. The Ketoprofen patch had the highest moisture content, potentially aiding in better skin adherence but possibly increasing susceptibility to microbial contamination or reduced shelf life if not properly packaged.

Surface PH

Table no. 9 Surface PH

Patch Type	Surface pH	Standard Deviation (%)
Diclofenac	6.2	±0.05
Lidocaine	6.6	±0.03
Ketoprofen	6.4	±0.06

From table 9 it shows that Surface pH values were close to the natural skin pH range (4.5–6.5), minimizing the like lihood of skin irritation. Lidocaine patches had as lightly higher pH (6.6), but still within a tolerable range. Maintaining appropriate surface pH is essential for user comfort and preventing dermal irritation during prolonged use.

Tensile Strength

Table no. 10 Tensile Strength

Patch Type	Tensile Strength	Standard Deviation(±%)
Diclofenac	1.25	±0.08
Lidocaine	0.92	±0.05
Ketoprofen	1.38	±0.07

From table 10 it shows that the Ketoprofen patch demonstrated the highest tensile strength, indicating superior mechanical resistance and durability. Diclofenac also showed good tensile characteristics. The Lidocaine patch had the lowest tensile strength, suggesting it may be more prone to tearing during handling. Strong tensile properties are critical for ensuring the patch remains intact during application and wear.

DISCUSSION

From the comparative analysis, Ketoprofen-based patches consistently outperformed others across key physicochemical properties such as tensile strength and folding endurance, indicating better structural integrity and flexibility. Diclofenac patches offered excellent uniformity and ideal surface pH, while Lidocaine patches, though generally acceptable, exhibited lower mechanical strength and folding endurance, which may impact their application in physically active users. Statistical analysis using one-way ANOVA showed significant differences ($p < 0.05$) among brands for tensile strength and folding endurance, while differences in thickness and weight were not statistically significant. This supports the interpretation that while manufacturing consistency is present, material composition and formulation choices significantly affect the mechanical properties and usability of patches.

CONCLUSION

Based on the physicochemical evaluations conducted, Ketoprofen patches emerged as the most robust in terms of mechanical strength and flexibility, making them more reliable for long-term or active use. Diclofenac patches also demonstrated acceptable quality, particularly in surface pH and uniformity, making them safe and comfortable for general use. Lidocaine patches, while effective in formulation, may require improvement in mechanical parameters to enhance durability and user experience.

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