SJIF Impact Factor (2025): 8.688| ISI I.F. Value: 1.241| Journal DOI: 10.36713/epra2016 ISSN: 2455-7838(Online)
EPRA International Journal of Research and Development (IJRD)
Volume: 10 | Issue: 6 | June 2025 - Peer Reviewed Journal

TRANSDERMAL PATCH TECHNOLOGY IN PAIN MANAGEMENT

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ABSTRACT

A transdermal patch is a medicated adhesive patch that you place on your skin to deliver medication directly into your bloodstream. This method is part of a newer way to deliverdrugs, which offers benefits over traditional methods like pills. Transdermal patches come in different sizes and can contain one or more active ingredients. This review providesimportant information about transdermal patches, including their advantages and disadvantages, how they work, the different types available, their basic components, methods of making them, how they are evaluated, and their uses. Many types ofmedications are now available in patch form.Transdermal patch technology offers a promising alternative for pain management by delivering drugs directly through the skin into systemic circulation. This method bypasses the gastrointestinal tract, reducing potential side effects and improving patient compliance. Among various analgesics, drugs like diclofenac sodium are effectively administered via transdermal patches, providing sustained and controlled release over extended periods. The patches ensure steady plasma drug levels, minimize dosing frequency, and are especially useful in chronic pain conditions such as arthritis and musculoskeletal disorders.

KEYWORDS: *Diclofenac sodium, transdermal patch, pain management, NSAIDs, controlled drug release, skin permeation, topical drug delivery.*

INTRODUCTION

The transdermal drug delivery system has been around for a long time. In the past, people mostly used creams and ointments for skin issues, but these sometimes caused side effects because the medicine absorbed into the bloodstrem. Transdermal delivery includes any medication applied to the skin that aims to enter the bloodstream. These systems are designed for controlled, continuous release of drugs through the skin, avoiding painful injections and bypassing the liver's first-pass metabolism, which can reduce the drug's effectiveness.The main benefits of this system are the controlled release of medication and the fact that it's painless. A transdermal patch adheres to the skin and consists of several parts, such as liners, adhesives, drug reservoirs, and membranes, all of which help deliver the drug effectively. Different types of patches and application methods have been developed to enhance drug delivery. Because of these advantages, transdermal delivery has become an important area of research in drug delivery systems

FIGURE NO 1

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ADVANTAGES

Transdermal patches offer several advantages:

1. Steady Drug Delivery: They provide a controlled release of medication over time, maintaining stable drug levels in the bloodstream.
2. Convenience: Patches are easy to use and can be applied and removed without the need for injections or oral medications.
3. Reduced Side Effects: By bypassing the digestive system, transdermal patches can minimize gastrointestinal side effects and improve drug absorption.
4. Non-invasive: They offer a non-invasive alternative to injections, making them more acceptable for patients who fear needles.
5. Improved Adherence: The simplicity of use can enhance patient compliance with medication regimens.
6. Localized Treatment: Some patches can deliver medication directly to the site of action, reducing systemic exposure and potential side effects.
7. Long-lasting Effects: Many patches can provide extended relief for chronic conditions, reducing the need for frequent dosing.
8. Potential for Combination Therapies: Some patches can deliver multiple medications simultaneously, simplifying treatment for complex conditions.

DISADVANTAGES

Transdermal patches have several disadvantages, including:

1. Skin Reactions: Some users may experience irritation, redness, or allergic reactions at the application site.
2. Limited Drug Types: Not all medications can be effectively delivered through the skin due to molecular size or solubility issues.
3. Variable Absorption: Absorption rates can vary based on factors like skin thickness, temperature, and moisture levels, leading to inconsistent dosing.
4. Duration of Effect: Patches may not provide immediate relief, as they typically release medication slowly over time.
5. Cost: Transdermal patches can be more expensive than oral medications.
6. Displacement Issues: Patches may become dislodged or fall off, especially if exposed to moisture or friction.
7. Limited Dosing Flexibility: Once applied, it's challenging to adjust the dose quickly, unlike oral medications.
8. Potential for Systemic Side Effects: Medications delivered systemically can lead to side effects that may not occur with localized treatments.
9. Patient Compliance: Some patients may forget to change patches or may not follow the application guidelines properly.

DICLOFENAC SODIUM

Diclofenac sodium is a nonsteroidal anti-inflammatory drug (NSAID) used to relieve pain, inflammation, and swelling caused by various conditions such as arthritis, gout, and sprains. It works. by inhibiting the production of certain chemicals in the body that cause inflammation and pain. Diclofenac is available in various forms including tablets, capsules, gels, patches, and injections. It has some potential side effects such as stomach ulcers, bleeding, and kidney problems, especially with long-term use or at high dos-es. It's typically not recommended for use in the third trimester of pregnancy and caution should be exercised in individuals with a history of gastrointestinal issues or cardiovascular disease.

STRUCTURE OF SKIN

The skin is composed of three primary layers, each with distinct structures and functions:

1. **Epidermis**
   Outer Layer: The outermost layer, primarily made up of keratinized stratified squamous epithelium.
   Cell Types: Contains keratinocytes (produce keratin), melanocytes (produce melanin), Langerhans cells (immune response), and Merkel cells (touch sensation).
   Sub-Layers: Includes several sub-layers, such as the stratum corneum (outermost), stratum lucidum (found only in thick skin), stratum granulosum, stratum spinosum, and stratum basale (where new cells are generated).
2. **Dermis**
   Middle Layer: Beneath the epidermis, the dermis provides structural support and strength.Components: Contains connective tissue, blood vessels, nerves, hair follicles, and glands (sweat and sebaceous).
   Sub-Layers: Divided into the papillary dermis (upper layer with dermal papillae) and reticular dermis (deeper, thicker layer).
3. **Hypodermis (Subcutaneous Layer)**
   Deepest Layer: Not technically part of the skin but lies beneath the dermis.
   Function: Composed of loose connective tissue and fat, it provides insulation, cushioning, and energy storage, as well as anchors the skin to underlying structures.

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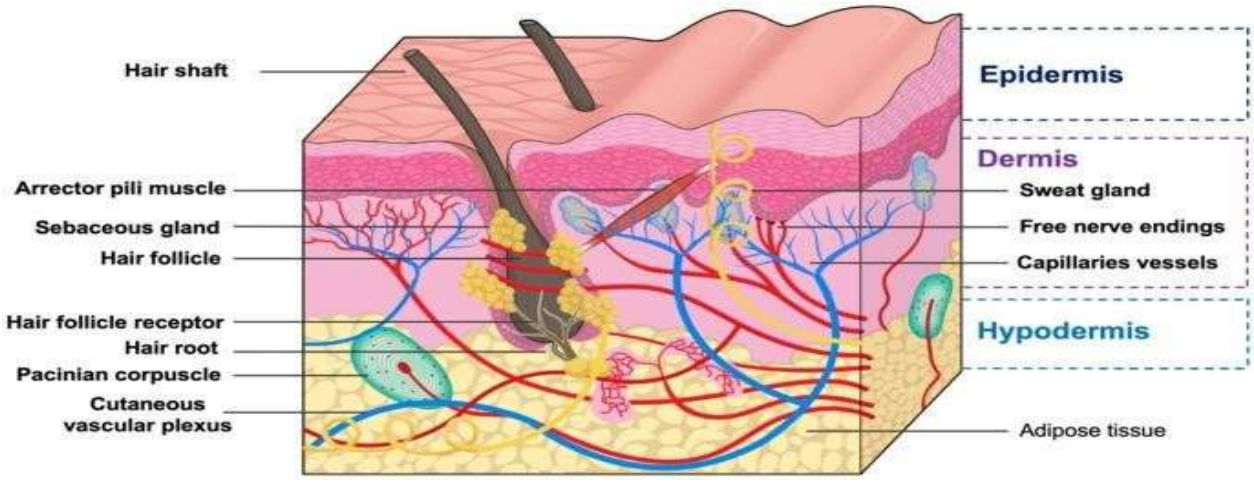

Figure no-02

PATHWAYS OF SKIN PERMEATION

Drug molecules can enter the skin through various pathways, including sweat ducts, hair follicles, and sebaceous glands, or directly across the outermost layer called the stratum corneum. Recently, scientists have debated the significance of these different routes, particularly the shunt (appendageal) pathway versus the direct pathway through the stratum corneum. This discussion is complicated by the absence of suitable experimental models to separate these pathways. A recent review by Menon offers useful insights into this topic. The stratum corneum is made up of 10 to 15 layers of cells called corneocytes

TRANSDERMAL PATCH

A transdermal patch is a medicated adhesive patch that you place on your skin to deliver medication directly into the bloodstream. The first prescription patch approved by the U.S. Food and Drug Administration (FDA) was for scopolamine to treat motion sickness, available since December 1979. The most popular transdermal patch in the U.S. is the nicotine patch, which helps people quit smoking. The first vapor patch for reducing smoking was approved in Europe in 2007.

Many other transdermal patches are available, including:

Diclofenac Sodium

Nonsteroidal anti-inflammatory drug (NSAID) patches for treating acute pain from minor injuries and for chronic conditions like fibromyalgia and arthritis.

In 2005, the FDA began investigating reports of serious side effects, including deaths related to narcotic overdoses, specifically concerning the Duragesic fentanyl patch.

COMPONENTS OF TRANSDERMAL PATCHS

Transdermal patches consist of several key components:

1. **Backing Layer**: This is the outer layer that protects the patch and provides structural support. It's usually made from a polymer material.
2. **Drug Reservoir or Matrix:** This contains the active pharmaceutical ingredient (API). It can be in a liquid reservoir or a solid matrix form.
3. **Rate-Control Membrane**: This regulates the release of the drug from the reservoir into the skin.
4. **Adhesive Layer:** This allows the patch to adhere to the skin. It must be biocompatible and often contains a specific type of adhesive that ensures effective contact.
5. **Release Liner**: This is a protective layer that covers the adhesive before application, preventing premature adhesion.
6. **Permeation Enhancers (optional):** These are added to increase the skin's permeability to the drug, facilitating better absorption.

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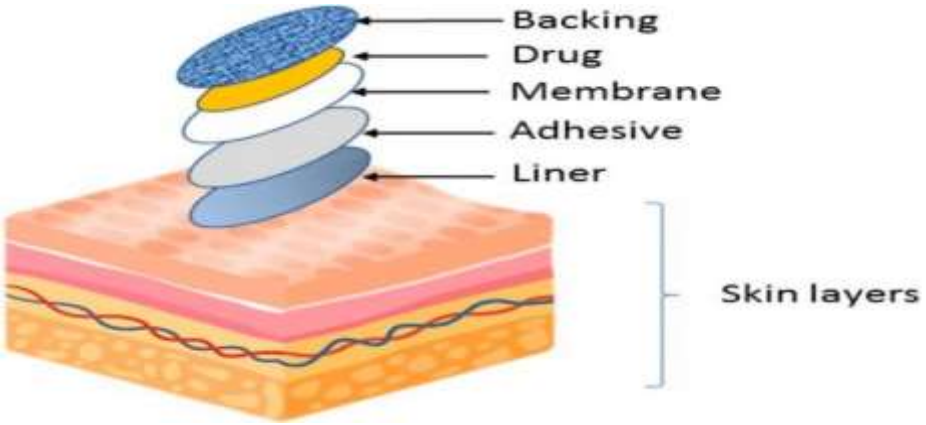

Figure no-03

1. Polymer Matrix

Polymers form the core of transdermal delivery systems. These systems typically consist of multilayer laminates with a drug reservoir sandwiched between two polymer layers:An outer layer that prevents drug loss.An inner adhesive layer that controls drug release and adheres to the skin.Choosing the right polymers is crucial for effectiveness, balancing release rates, adhesion, compatibility, and stability

Types of Polymers

Natural Polymers: Cellulose derivatives, zein, gelatin, waxes, chitosan.
Synthetic Elastomers: Polybutadiene, silicon rubber, butyl rubber.
Synthetic Polymers: Polyvinyl alcohol, polyethylene, polyacrylate.

2. Drug Properties

The drug must have suitable physicochemical and pharmacokinetic properties for TDDS. This method is ideal for drugs that:Undergo extensive first-pass metabolism.Have a narrow therapeutic window.Require frequent dosing due to short half-lives.

3. Permeation Enhancers

These substances increase skin permeability, allowing more drug absorption. They interact with skin components (like proteins and lipids) to improve drug delivery. Enhancers can help both oil-soluble and water-soluble drugs penetrate the skin better.

4. Pressure-Sensitive Adhesives (PSA)

PSAs ensure the patch stays in contact with the skin. They should adhere easily with light pressure and maintain a strong hold. Common PSAs include polyacrylates and silicon- based adhesives. The choice of adhesive depends on the patch design and drug formulation and should not interfere with drug release.

5. Backing Laminate

The backing layer provides structural support and must be chemically resistant to prevent interactions with the drug and other components. It should also ensure that no additives leach out during use.This simplified overview captures the key components and considerations for effective transdermal drug delivery systems.

6.Backing Layer

The backing layer should have low moisture vapor transmission to keep the drug stable. It needs to be elastic, flexible, and strong enough to support the patch.

7.Release Liner

The release liner protects the drug during storage, preventing it from migrating into the adhesive and avoiding contamination. It acts as primary packaging, not as part of the dosage form.The release liner consists of:A base layer (which can be either non-occlusive or occlusive).A release coating layer made of materials like silicone or Teflon.Other materials for release liners can include polyester foil and metalized laminates.

8.Other Excipients

Various solvents (like chloroform, methanol, and acetone) are used to create drug reservoirs.Plasticizers (such as dibutyl phthalate and polyethylene glycol) are added to make the transdermal patch more flexible.This summary highlights the key elements related to backing layers, release liners, and additional excipients in transdermal drug delivery systems.

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Types of Transdermal patches

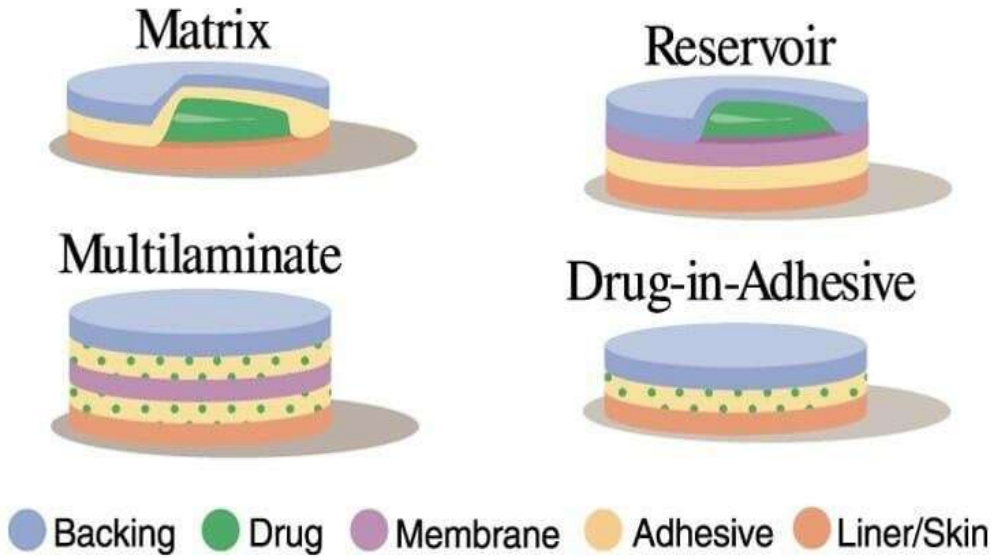

Figure no-04

1. **Single-Layer Drug-in-Adhesive Patch**

This patch has a layer of adhesive that contains the drug. The adhesive not only holds the patch together but also releases the drug onto the skin. It is covered by a temporary liner and a backing layer.

2. **Multi-Layer Drug-in-Adhesive Patch**

Similar to the single-layer patch, this type includes an immediate-release layer and a controlled-release layer, all within the adhesive. It also has a temporary liner and a permanent backing.

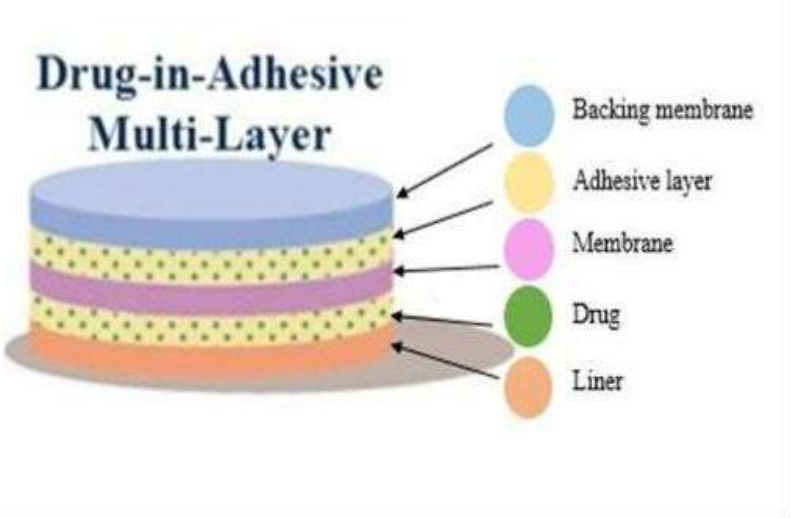

Figure no-05

3. **Vapor Patch**

These patches release vapor instead of a solid drug. They are used for various purposes, such as delivering essential oils for congestion relief or improving sleep quality.

4. **Reservoir System**

In this system, the drug is contained in a reservoir between a non-permeable backing and a rate-controlling membrane, which can be porous or non-porous. The drug can be in various forms (solution, suspension, gel) and is held with a hypoallergenic adhesive on the outer surface.

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5. Matrix System

Drug-in-Adhesive System: The drug is mixed with an adhesive to create a reservoir. This is then spread onto a non-permeable backing, protected by an additional adhesive layer. It can deliver multiple drugs and is known for its thin profile and good skin fit.

Matrix-Dispersion System: The drug is evenly mixed in a polymer matrix and formed into a medicated disc. This disc is then placed on an occlusive base, using a drug-impermeable backing layer.These systems are designed to enhance drug delivery through the skin, offering various benefits depending on their structure and formulation.

Micro Reservoir System: is a method for delivering drugs at a steady rate over time. It combines two types of drug delivery systems: the reservoir system and the matrix-
dispersion system. First, a water-soluble polymer is mixed with the drug to create a reservoir. Then, this mixture is dispersed using high shear mechanical force into a lipophilic (fat-loving) polymer to form tiny, microscopic drug reservoirs. To stabilize the mixture and prevent it from breaking down, cross-linking agents are added, which help form stable bonds and keep the system intact. This allows the drug to be released at a consistent rate, maintaining constant drug levels.

FACTORS AFFECTING TRANSDERMAL PATCH

There are various factors which affects the action of transdermal patches. These are given below: a.Physicochemical Properties

i. Partition coefficient
ii. Molecular size
iii. Solubility/melting point
iv. Ionization

b. Physiological C Pathological Conditions of Skin i.Reservoir effect of horny layer

ii. Lipid film
iii. Skin hydration

PHYSICOCHEMICAL PROPERTIES

- Partition coefficient
- Molecular size
- Solubility/melting point
- Ionization

PHYSIOLOGICAL s PATHOLOGICAL CONDITION OF SKIN

- Reservoir effect of horny layer
- Lipid film
- Skin hydration
- Skin temperature
- Regional variation
- Pathological injuries to the skin
- Cutaneous self-metabolism
- Skin barrier properties in the neonate and young infant
- Skin barrier properties in aged skin

APPROACHES IN DEVELOPING TRANSDERMAL PATCH

1. Membrane-Controlled System
   This type uses a membrane to control the release of the drug through the skin.
2. Adhesive Diffusion-Controlled System
   In this system, the drug is released through an adhesive layer that controls how the drug diffuses through the skin.
3. Matrix Dispersion System
   The drug is evenly dispersed within a matrix (a solid structure), and the drug is released as it diffuses through the matrix.

AIM& OBJECTIVES

To evaluate the effectiveness, safety, and clinical benefits of transdermal patch technology in the management of pain, as compared to conventional drug delivery methods.

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Objectives

1. To examine the mechanism and pharmacokinetics of transdermal drug delivery in pain management.
2. To assess the efficacy of transdermal patches in reducing pain across various types (e.g., chronic, acute, neuropathic, cancer-related pain).
3. To compare the patient compliance and convenience between transdermal patches and traditional oral or injectable pain medications.
4. To evaluate the incidence of side effects and adverse reactions associated with transdermal patch use.
5. To identify the limitations and challenges in the clinical application of transdermal patch technology.

LIMITATIONS TRANSDERMAL DRUG DELIVERY SYSTEM (TDDS)

1. Not all drugs are suitable: The drug must have specific physical and chemical properties to be effective for transdermal delivery.
2. Drugs needing high plasma levels: TDDS is not suitable for drugs that require high concentrations in the bloodstream.
3. Skin irritation: Drugs that cause skin irritation or contact dermatitis cannot be used in transdermal patches.
4. High molecular weight drugs: Drugs with large molecules are not suitable for transdermal delivery.
5. Metabolism through the skin: Drugs that are metabolized by the skin cannot be delivered effectively through this route
6. Limited drug penetration: The skin is a strong barrier, so only drugs with low doses can be delivered transdermally.In summary, the transdermal route has limitations and is not suitable for all drugs, particularly those that require high doses or are prone to causing skin irritation.

PLAN OF WORK

1. Selection and approval of research topic
2. Comprehensive literature review
3. Formulation of research problem, aim, objectives, and hypothesis
4. Design of research methodology and tools
5. Collection of data (clinical, experimental, or literature-based)
6. Analysis and interpretation of data
7. Discussion of findings in comparison with existing studies
8. Conclusion and formulation of recommendations
9. Preparation of final report or thesis
10. Submission and presentation of research work

RECENT ADVANCES IN TRANSDERMAL PATCH

1. Protein Delivery via Patch Technology
   New patches are being developed to deliver proteins through the skin, providing a non-invasive alternative to injections.
2. Pain-Free Monitoring for Diabetes
   Transdermal patches are now being used to monitor blood glucose levels in diabetics without the need for painful finger pricks.
3. Testosterone Patches for Women with Premature Ovarian Failure
   A transdermal patch system is being used to deliver testosterone to young women with spontaneous premature ovarian failure to help manage symptoms.
4. Oxybutynin Patch for Overactive Bladder (OAB)
   Transdermal patches delivering oxybutynin are being used to treat overactive bladder, offering a more convenient treatment option.
5. Pain Relief through Transdermal Patches
   Transdermal patches are being developed to provide localized pain relief, offering an alternative to oral pain medications.
6. Molecular Absorption Enhancement
   New technologies are improving the skin's ability to absorb medications, making transdermal patches more effective in delivering various drugs.
   This arrangement provides a clearer overview of current developments in transdermal patch technology.

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Formulation of Diclofenec Sodium Transdermal Patch

SR NO	Ingredient	Quantity	Activity
1	Diclofenac sodium	10 mg	Active ingredient
2	HPMC	200 mg	Film-forming agent
3	Dibutyl phthalate	1.2 ml	Penetration enhancer ,humectants
4	Glycerin	1ml	Plasticizer ,moisture retention
5	Ethanol	20 ml	Solvent+skin permeation

Table no – 1

Procedure

1. Take 20 ml ethanol
2. Add Diclofenac sodium (salt) 10 mg
3. After add Hydroxypropyl methyl cellulose (HPMC) 200 mg & Dibutyl phthalate 1.2 ml
4. Add ghycerin 1 ml
5. Add HPMC & add dibutyl phthalate
6. Add glycerine
7. Transfer the solution into petri plate
8. Now cover the petri plate by inverted funnel for 24 hours
9. Put aside for 24 hrs. After 24 hrs the solution will become solidify and form patches. After that obtain the diclofenac sodium patch from petri plate and will be cut into desired size and shape for use

Sr.no	Ingredients	F1	F2	F3
1	Diclofenac sodium	10 mg	10 mg	10 mg
2	HPMC	200 mg	300 mg	400 mg
3	Dibutyl phthalate	1.2 mi	1.2 ml	1.2 ml
4	Glycerin	1ml	1ml	1ml
5	Ethanol	20 ml	20 ml	20 ml

Table no- 2

Evaluation and characterization

The efficacy of diclofenac patches depends on factors such as patch design, skin permeability, and the individual patient's response to the medication.

Physical appearance

All the patches were visually observed, inspected for colour, flexibility, smoothness, etc. They often have a semi-transparent or opaque backing to protect the medication and an adhesive side that sticks to the skin.

Thickness of patch

The thickness of each patch was measured by using digital mi-crometer at three different points. Micrometer. a tool that mea-sures the size of a target by enclosing it. Some models are even able to perform measurements in Unlike hand callipers, micrometers adhere to Abbes' principle, which enables them to perform more accurate measurements.

Weight Uniformity

The uniformity of weight was calculated by weighing3 differ-ence patches and the average was taken.
Weigh 5–10 individual patches (5 × 5 cm) and calculate average weight and standard deviation.

Folding Endurance

A part of patch is to be cut evenly and repeatedly folded at same place until it breaks. The result indicates that the patches wouldn't break and can withstand the normal handling and application.

Moisture Content

Place the patch in the analyzer or desiccator for 24 hrs and measure the change in weight before and after drying. The percentage moisture absorbed was calculated by the below mentioned formula:

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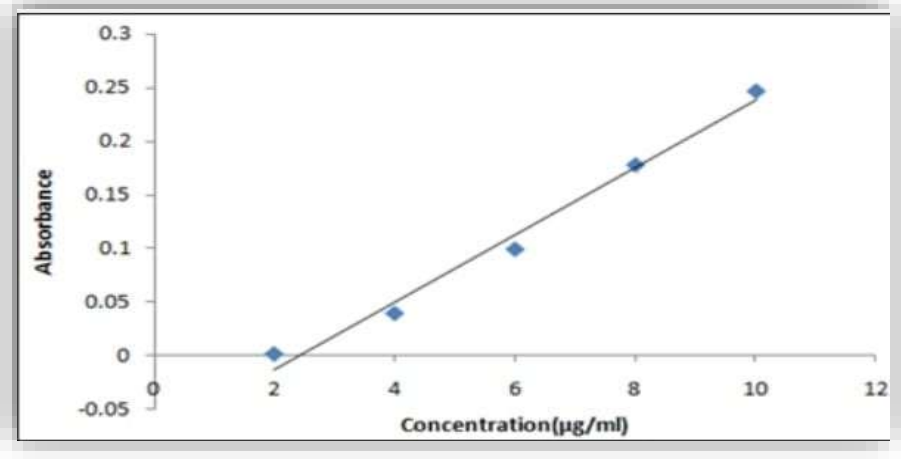
Moisture content = Final weight - Initial weight x 100 / Initial weigh

Preparad diclofenac of patch



Standard curve of diclofenac sodium

RESULTS AND DISCUSSION

The study shows the physical appearance of Diclofenac Sodium Transdermal Patch is off-white in colour, smooth in texture and round in shape. On comparison of prepared patch and marketed patch of Diclofenac sodium, the thickness and folding endurance of prepared patch is found to be similar to the marketed patch. The study seemed that as the concentration of polymer increases the thickness of patch, weight uniformity, folding endurance increases. The evaluation studies show that the patch formulation F1 having less thickness, high folding endurance, less moisture content, and have optimum uniformity of weight characteristics as compared to other formulations (F1-F3). The present work can further be pro-ceeding with in-vivo study on healthy animals to evaluate the pharmacokinetic profile The results support the growing evidence that transdermal patch technology is a highly effective alternative to conventional pain management approaches. Unlike oral medications that can lead to fluctuations in plasma drug concentrations and gastrointestinal issues, transdermal patches provide a controlled and sustained release of medication directly into the bloodstream.

These findings align with previous studies. For example, Gourlay et al. (2001) demonstrated the effectiveness of fentanyl patches in chronic cancer pain, while Galer et al. (2000) showed that lidocaine patches are beneficial for localized neuropathic pain. The improved patient compliance in this study also mirrors research by Allen et al. (2005), who found transdermal systems reduce dosing frequency, a common barrier to adherence in pain therapy.

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However, the limitations of this study include the small sample size and short observation period. Additionally, drug selection remains limited to compounds suitable for transdermal absorption. Continued innovation is needed to expand the range of applicable drugs and reduce minor skin-related side effects In conclusion, transdermal patch technology represents a valuable tool in modern pain management strategies, offering effective analgesia, fewer systemic side effects, and greater patient satisfaction.

CONCLUSION

The development of transdermal patches containing diclofenac sodium offers a promising alternative for effective pain management. This delivery system provides sustained drug release, reduces gastrointestinal side effects commonly associated with oral NSAIDs, and enhances patient compliance through non-invasive administration. The transdermal route ensures localized drug delivery, minimizing systemic exposure and associated risks. Overall, diclofenac sodium transdermal patches represent a valuable advancement in the treatment of chronic and acute pain conditions, with potential for further optimization through formulation improvements and permeation enhancers.

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SJIF Impact Factor (2025): 8.688| ISI I.F. Value: 1.241| Journal DOI: 10.36713/epra2016 ISSN: 2455-7838(Online)
EPRA International Journal of Research and Development (IJRD)
Volume: 10 | Issue: 6 | June 2025 - Peer Reviewed Journal

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