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Transdermal Patches: A Detailed Review

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ABSTRACT :

The skin is the body's largest and most accessible organ, making it a great pathway for delivering certain medications. Transdermal drug delivery systems, like medicated patches placed on the skin, have become popular because they offer several benefits over taking medicine by mouth or injection. With these patches, medicine is absorbed through the skin and into the bloodstream at a steady rate, helping to maintain consistent drug levels in the body. This means people may not need to take medicine as often, and it can help avoid problems like stomach irritation or the drug being broken down by the liver before it works. Unlike traditional topical medicines that work only where they are applied, transdermal systems are designed to provide both local and whole-body effects.

Overall, transdermal patches make medication easier to use, can reduce side effects, and improve how well treatments work by keeping drug levels steady and bypassing the digestive system.

Key words: Permeation, skin, components, method, evaluation.

INTRODUCTION

Taking medicine by mouth is the most common and convenient way to deliver drugs, especially when the drug dissolves easily in water and is absorbed well through the gut lining. However, this method doesn't work as well for drugs that aren't water-soluble. The body's natural processes—like liver metabolism, stomach acid, digestive enzymes, and gut movement—can reduce how much of the drug actually reaches the bloodstream. As a result, patients often need to take higher or more frequent doses, which can lower effectiveness and make it harder to stick to treatment.

To overcome these problems, scientists have explored other ways to deliver medicine. One method that stands out is transdermal drug delivery—where the drug is absorbed through the skin. While our skin, particularly the outermost layer (the stratum corneum), is a tough barrier to cross, modern transdermal systems have made great progress.

These systems can release drugs steadily over time, reducing how often doses are needed and minimizing side effects. Since the FDA approved the first skin patch for motion sickness in 1979, researchers have developed new techniques to help drugs pass through the skin more easily—using structural designs, electrical methods, and pressure-based approaches. These innovations have made it possible to deliver medications for serious chronic illnesses like cancer, diabetes, heart disease, and neurological disorders in a more effective and patient-friendly way.

STRUCTURE OF SKIN:

Our skin is made up of four key layers that play important roles in how drugs can be absorbed: the stratum corneum, viable epidermis, dermis, and hypodermis.

At the very surface is the stratum corneum—a tough, protective layer made of dead, flattened skin cells filled with keratin. Though it may not be alive, it acts like a strong shield, keeping out harmful substances and locking in moisture. Its dense, waterproof nature makes it the biggest obstacle for any drug trying to pass through the skin.

Just beneath that is the viable epidermis, a layer of living cells roughly 50 to 100 micrometers thick. These cells, called keratinocytes, start their life at the bottom and slowly move upward. Packed closely together and full of water, they're similar in makeup to other tissues in the body.

Next comes the dermis, a thicker, deeper layer rich in connective tissue. It contains important structural proteins like collagen and elastin, which give the skin its strength and flexibility. It's also where many vital structures live—like nerves, sweat glands, oil glands, hair follicles, and blood vessels.

Finally, at the bottom is the hypodermis (or subcutaneous layer). This isn't always considered a true part of the skin, but it plays a major role. Made of loose tissue and fat, it stores lipophilic (fat-loving) drugs temporarily before they make their way into the bloodstream.

Together, these layers form a complex barrier that affects how well a drug can be absorbed through the skin—something researchers must carefully consider when designing transdermal delivery systems.

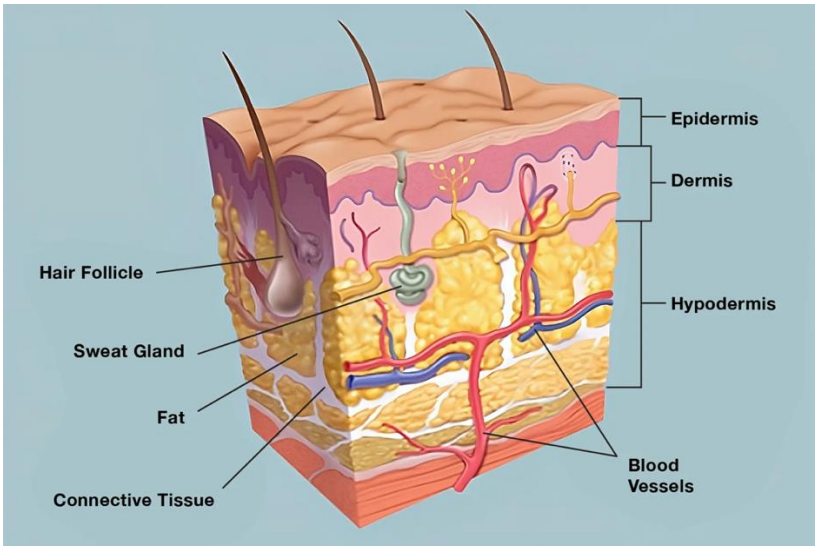

Fig.1:-Diagramatic view of skin

Permeation Process in Transdermal Drug Delivery

Drug molecules can penetrate the skin and reach systemic circulation through three primary pathways: the trans-appendageal, transcellular, and intercellular routes.

- **Trans-appendageal Route (Shunt Route):**
  This route utilizes skin appendages such as hair follicles, sweat glands, and sebaceous glands as channels for drug transport. Although these structures cover a small surface area, they offer low-resistance pathways bypassing the dense stratum corneum. The efficiency of this route is influenced by the number of follicles, glandular volume, and diameter of openings. This pathway is particularly useful for large, ionized, or hydrophilic molecules that would otherwise struggle to diffuse through the lipid-rich layers of the skin.

- **Transcellular Route:**
  In this pathway, drug molecules travel directly through the cells of the stratum corneum. To do so, they must pass through alternating hydrophilic and lipophilic domains, requiring repeated partitioning. Due to this complexity, only small molecules or those using carrier-mediated transport are typically able to utilize this route effectively. Despite being a direct path, the varied polarity makes it a challenging route for consistent drug delivery.

- **Intercellular Route (Paracellular Pathway):**
  Here, the drug diffuses between the cells of the stratum corneum, navigating the extracellular lipid matrix. It is considered the primary route for lipophilic drugs. Hydrophilic drugs can also use this path but only if they are sufficiently small, as tight junctions restrict larger molecules. This route presents a balance between permeability and resistance, often offering the most practical route for transdermal delivery.

TRANSDERMAL PATCHES

A transdermal patch is a small, medicated adhesive patch placed on the skin that delivers a steady dose of medication directly into the bloodstream. It works through a process called *transdermal absorption* and is a popular, non-invasive method for treating both systemic conditions and localized pain. The very first transdermal patch approved by the FDA came out in December 1979 and was designed to help with motion sickness, using a drug called *scopolamine*. Since then, patches have become widely used in medicine. One of the most well-known examples is the nicotine patch, which has helped millions of people quit smoking. Europe even introduced a vapor-based nicotine patch in 2007 to support smoking reduction.

Other common examples include:

- Fentanyl patches for managing severe pain
- Nitroglycerin patches for heart-related chest pain (angina)
- Lidocaine patches (Lidoderm) for nerve pain caused by shingles
- Buprenorphine patches (Bu Trans) for chronic pain
- Diclofenac epolamine patches (Flector) for minor injuries or chronic inflammation like arthritis or fibromyalgia
  More recently, patches have been developed to deliver hormonal birth control, antidepressants, and medications for ADHD.

Despite their benefits, transdermal patches are not without risks. In 2005, the FDA updated safety labels on Duragesic (fentanyl**)** patches after reports of overdose deaths. In 2009, a public health warning was issued about the risk of burns during MRI scans caused by patches that contain metal in their backing.

These incidents highlight the need for proper design, usage, and regulation. Still, transdermal patches remain a major advancement in drug delivery—offering a convenient, needle-free option, especially useful for chronic conditions that need long-term medication.

TYPES OF TRANSDERMAL PATCHES

1) **A single-layer drug-in-adhesive patch** is a simple yet effective type of transdermal patch. In this design, the medication is mixed directly into a sticky adhesive layer—the same layer that helps the patch stick to the skin. This adhesive not only holds the patch in place but also acts as the reservoir that slowly releases the drug.
   Behind this layer is a protective backing, which prevents the drug from leaking out the other side and keeps the patch structurally stable.
   A real-world example of this kind of patch is Daytrana®, which delivers methylphenidate to help manage symptoms of ADHD. It's easy to use, discreet, and provides controlled drug release through the skin over time**.**

2) **Multilayer drug-in-adhesive patches** are a more advanced type of transdermal patch. Unlike the simpler single-layer design, these patches contain two key layers: one that holds the medication (the drug reservoir) and another adhesive layer that controls how the drug is released into the skin over time.
   In addition to these layers, the patch includes a protective peel-off layer that's removed before use, and a backing layer that stays in place to protect the patch and keep the drug moving in the right direction—toward the skin.
   These patches are especially useful for delivering pain relief medications, hormone treatments, or drugs that help people quit smoking. Some can even provide a steady dose of medication for up to seven days, offering convenience and better treatment consistency.

3) **Vapour transdermal patches** are a special kind of patch designed to release active ingredients in the form of vapor through the skin. These patches have a single adhesive layer that not only helps them stick to the skin but also allows the controlled release of vapours, such as essential oils or medications.
   Several types of vapor patches are available on the market for different purposes. For instance, NicoDerm CQ® patches, introduced in Europe in 2007, contain nicotine and essential oils that are gradually released to help people quit smoking.
   Another example is Al-tacura®, a vapor patch that releases essential oils to help relieve nasal congestion. There are also vapor patches being used as natural sedatives or to support mood improvement—such as in antidepressant therapies.
   These patches offer a non-invasive, user-friendly alternative for delivering therapeutic vapours throughout the day.

4) **Membrane-moderated transdermal patches** are designed to release medication slowly and steadily over time. These patches contain a drug reservoir—a space that holds the medication—enclosed between two important layers.
   On one side, there's a backing layer made from metallic plastic laminate, which is impermeable, meaning it prevents anything from escaping through the back of the patch. On the other side, there's a special membrane made from porous polymers—like hypoallergenic adhesives or ethylene vinyl acetate—that controls how quickly the drug moves from the reservoir into the skin.
   This membrane acts like a gate, regulating the flow of the drug so it's delivered at a consistent rate, providing long-lasting effects without the need for multiple doses.
   Several well-known products use this technology:
   - Transderm-Nitro® delivers nitroglycerin for chest pain and is used for one day.
   - Transderm-Scop® contains scopolamine to prevent motion sickness and works for up to three days.
   - Catapres® releases clonidine, used to treat high blood pressure, and lasts for a full week.

   These patches make it easier for patients to get sustained, effective treatment without having to remember frequent doses.

5) **Microreservoir transdermal patches** are a more advanced type of patch that blend two methods: matrix dispersion (where the drug is spread evenly through a material) and a reservoir system (where the drug is stored in a concentrated form).
   To create this type of patch, the drug is first mixed into a water-based gel made with hydrophilic (water-loving) polymers. This mixture is then evenly spread onto a lipophilic (fat-loving) polymer layer. Using strong mechanical mixing, the process forms thousands of tiny, stable micro-spheres, each holding a small amount of the drug.
   These microspheres don't leak, and they're designed to release the drug slowly and steadily, following what's called zero-order kinetics—meaning the drug is released at a constant rate over time. This helps maintain a stable level of medication in the bloodstream, which is ideal for long-term treatment.
   To keep the whole system stable, crosslinking agents are added to hold the structure together and ensure the drug doesn't separate or degrade over time.

Advantages :-

1. Avoids First-Pass Metabolism: When medicines are taken orally, they often get broken down by the liver or intestines before reaching the bloodstream. Patches placed on the skin bypass this process, allowing more of the medicine to enter the body and work effectively.
2. Painless and Non-Invasive: Using a patch means no needles or injections are needed, which is more comfortable and lowers the risk of infections.
3. Simple to Use: Patients can easily apply and remove these patches themselves, making it convenient and promoting independence in managing their treatment.
4. Quick Stop if Needed: If any side effects or problems occur, simply taking off the patch stops the medicine delivery right away, which is not possible with oral or injected forms.
5. Skin Uniformity Helps: Since skin structure is fairly consistent from person to person, transdermal medicine absorption tends to be reliable and predictable.
6. Better Compliance: Because patches often need to be changed less frequently and cause fewer side effects, patients are more likely to follow their treatment plans.
7. Steady and Long-Lasting: These systems release drugs slowly over time, keeping medicine levels in the body steady and avoiding the peaks and valleys sometimes caused by pills.

DISADVANTAGES:

1. Local Skin Irritation: The application site may experience irritation due to prolonged contact.
2. Adverse Skin Reactions: Erythema (redness), itching, and local oedema may result from the drug, adhesive, or other excipients in the patch.
3. 3.Allergic Reactions: Some patients may develop allergic responses to components in the formulation.
4. 4.Molecular Weight Restrictions: Effective transdermal delivery typically requires drugs with a molecular weight under 500 Daltons.
5. 5.Solubility Requirements: Drugs must possess both aqueous and lipid solubility, with an ideal log P (octanol/water) between 1 and 3, to effectively penetrate the stratum corneum (SC) and reach systemic circulation.

Components of transdermal drug delivery systems – especially transdermal patches:

A transdermal patch usually consists of the following components

- Liner
- Drug
- Adhesive (pressure-sensitive adhesive)
- Membrane (polymer matrix/drug reservoir)
- Backing laminates
- And Other excipients.

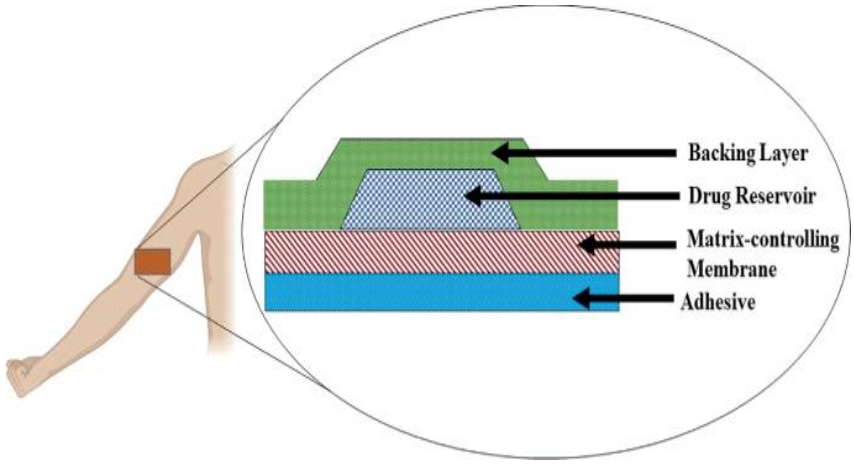

FIG.2:-Components of Transdermal patches

1. **Liner:-**

The liner is the part of the patch that you peel off and throw away right before sticking the patch onto your skin. Think of it like the protective backing on a sticker.

Its main job is to keep the medication and adhesive layer safe during storage, making sure the patch stays clean, stable, and effective until it's ready to use.

Because it's in direct contact with the drug before use, the liner is made from chemically stable materials—meaning it won't react with the medicine or affect how the patch works. Common materials include paper, plastic films like polyethylene or PVC, or high-tech materials like Teflon or silicone-coated polyester that allow easy removal.

2. Drug

Transdermal patches are a great option for certain types of medications—especially those that don't work well when taken by mouth. For example, drugs that are *broken down in the stomach or liver*, or those that have a *very short half-life (less than 2 hours)* and require frequent dosing, can benefit from patch delivery. By delivering the drug through the skin, patches help maintain steady levels of the medication and improve patient compliance.
But not every drug is a good fit for a patch. There are specific characteristics that make a drug more suitable for transdermal delivery:

- *Small Molecular Size*
  The drug should be *less than 500 daltons* in molecular weight so it can pass through the skin effectively.
- *Balance Between Water & Fat Solubility*
  It needs to dissolve in both *water (hydrophilic)* and *fat (lipophilic)* environments to move through skin layers properly.
- *Low Melting Point*
  A *lower melting point* generally means the drug can be released more easily from the patch.
- *Low Daily Dose*
  Ideally, the patch should deliver *less than 20 mg per day*. The drug should also be *non-irritating and non-allergic* to avoid skin reactions.
- *Short Half-Life*
  Drugs with a short half-life (quickly leave the body) are good candidates because the patch can provide a *steady, continuous dose***.**
- *Log P Value Between 1 and 4*
  This value tells us how well the drug can move between oily and watery environments—*a balance is key* for crossing the skin barrier.
- *Solubility*
  The drug should dissolve at a level of *at least 1 mg/mL*, ideally in a *pH range of 5 to 9*.

3. Adhesives:

In transdermal drug delivery systems, pressure-sensitive adhesives play a vital role — they're the "glue" that keeps the patch firmly attached to the skin, ensuring the medication can be delivered effectively over time.
The performance of these adhesives depends on a variety of factors — not just the type and amount of ingredients used (known as excipients), but also the overall design of the patch. Things like how thick the adhesive layer is, the backing material, any leftover solvents, and how concentrated the drug is in the system all influence how well the adhesive works.

For an adhesive to do its job properly, it needs to meet a few important requirements:

- Safe and gentle application – It should stick to the skin without causing any damage when applied.
- Clean removal – It must peel off easily and completely, without leaving any sticky residue behind.
- Skin-friendly – It should not cause irritation, allergies, or sensitivity reactions.
- Compatible with ingredients – It needs to work well with the drugs and other components in the patch, both physically and chemically.
- No interference – It should allow the drug to pass through the skin just as intended, without blocking or slowing down the delivery

4. Membrane (Polymer Matrix) – The Core Structure of a Transdermal Patch

At the heart of every transdermal drug delivery system is the polymer matrix — the structure that controls how the medication is released over time. Think of it as the "engine" that drives the patch's performance.
In these systems, the drug is blended into a synthetic polymer, either as a liquid or solid. This forms the matrix through which the drug gradually diffuses and enters the skin. But not just any polymer will do — the materials used must meet several key requirements.
To work effectively, the polymer must:

- Be safe and skin-friendly
- Release the drug steadily and predictably
- Stay stable with the drug and other patch ingredients
- Be easy and affordable to manufacture
- Remain strong, even with high drug content

Polymers can be natural (like gelatin or rubber), synthetic elastomers (like silicone rubber), or synthetic plastics (like polyvinyl alcohol)**.**

5. Backing Laminates – The Protective Shield of a Patch

The backing film is the outermost layer of a transdermal patch — and it plays a key role. It protects the patch from the outside environment, keeps the drug layer stable, and helps control how the skin reacts by managing airflow and moisture (breathability or occlusion).
A good backing laminate should**:**

- Be chemically resistant and not break down easily
- Be compatible with the drug and other ingredients (no unwanted reactions or leaching)
- Be flexible so it sticks comfortably to the skin
- Be impermeable, providing a barrier to protect the patch
- Allow moisture and oxygen to pass through at the right levels, depending on the formulation

Common materials include vinyl, polyethylene, polyester, aluminium, and polyolefin films.

6. **6.Other Key Components in Transdermal Patches**

Transdermal patches aren't just about the drug — several other ingredients work behind the scenes to make sure the medication is absorbed effectively and safely.

1. Permeation Enhancers

These help the drug pass through the skin by temporarily loosening the skin's outer barrier (the stratum corneum). They work by:

- Altering skin proteins or lipids
- Increasing drug solubility or mobility
- Enhancing both polar and non-polar drug absorption

Ideal enhancers should be:

- Non-toxic and skin-safe
- Compatible with the drug
- Cost-effective and easy to use
- Reversible — restoring skin function after removal

2. Plasticizers

Plasticizers add flexibility and strength to the patch film. They also help:

- Control drug release
- Improve patch wearability
- Prevent cracking or drying out

Examples**:** Phthalate esters, glycol derivatives, fatty acid esters

3. Solvents

Solvents enhance skin permeability, often by softening skin layers or helping the drug dissolve better.

Common ones include**:** Ethanol, methanol, DMSO, glycerol, propylene glycol

4. Surfactants

Surfactants help drugs (especially water-loving ones) move through the skin by changing how they interact with the skin barrier.

Types:

- Anionic (e.g., sodium lauryl sulphate) – strong but may irritate
- Nonionic (e.g., Pluronic F68/F127) – gentler, commonly used
- Binary systems – combine agents to open up skin layers more effectively.

Method of preparation:

1.Circular Teflon mould method-

The Circular Teflon Mould Method, developed by Baker and Heller (1989), involves dissolving polymers and the drug in an organic solvent, with the drug and enhancers mixed separately in two halves of the solvent. A plasticizer like di-n-butyl phthalate is added, and the mixture is stirred for 12 hours before being poured into a circular Teflon mould. The mould is placed on a leveled surface, covered with an inverted funnel, and kept in a laminar airflow hood to allow controlled solvent evaporation for 24 hours. The dried films are then stored in a desiccator at $25 \pm 0.5°C$ for another 24 hours to prevent aging effects and are evaluated within a week. Alanazi et al. (2007) used this method to prepare ketorolac bioadhesive films using various polymers (e.g., Na-CMC, HPMC, Carbopol 934) and found that film properties varied with polymer type and plasticizer concentration. The films maintained therapeutic ketorolac levels in the oral cavity for up to 6 hours, showing promise for buccal drug delivery.

2.Mercury Substrate Method

The Mercury Substrate Method, described by Wiechers (1992), involves dissolving the drug in a polymer solution along with a plasticizer, followed by stirring for 10–15 minutes to obtain a uniform mixture. This solution is then poured onto a flat mercury surface, which acts as a casting base. To ensure controlled solvent evaporation, the setup is covered with an inverted funnel. This method helps in forming smooth and uniform films. Rathore et al. (2006) used this technique to prepare transdermal patches of terbutaline sulphate using ethyl cellulose and cellulose acetate. They found that the combination of polymers provided good film-forming properties and that permeability enhancers effectively influenced drug release. Similarly, Patel et al. (2009) formulated glibenclamide transdermal patches using Eudragit RL 100, Eudragit RS 100, and PVP, with glycerol and propylene glycol as plasticizers, and Span 80 as a permeation enhancer. Their best-performing formulation, containing Eudragit RL 100 and propylene glycol, achieved a sustained drug release of 98.02% over 24 hours, demonstrating the method's effectiveness for prolonged drug delivery.

3.Solvent Casting Method-

The solvent casting method is a simple and widely used technique for preparing transdermal patches. In this method, the drug is first dissolved or dispersed in a suitable solvent along with one or more film-forming polymers (like HPMC, PVP, or Eudragit). To improve the flexibility and handling of the patch, a plasticizer (such as glycerol or PEG) is added to the mixture. Sometimes, permeation enhancers are also included to help the drug pass through the skin more effectively.

Once all ingredients are thoroughly mixed—usually by stirring—the uniform solution is poured onto a flat surface, such as a Petri dish or glass plate, and then spread evenly using a film applicator or similar tool. The solvent is allowed to evaporate slowly at room temperature or under controlled conditions,

leaving behind a thin drug-loaded film. After drying, the film is cut into patches of the desired size and shape and stored in airtight containers or desiccators to prevent moisture absorption before use.
This method is favoured because it is cost-effective, easy to perform, and produces uniform and flexible patches suitable for drug delivery through the skin.

4. EVAC membrane method-
The EVAC membrane method is used to create transdermal drug delivery systems where a gel-based drug reservoir is combined with a rate-controlling membrane to manage drug release. In this method, a 1% Carbopol gel is prepared, and if the drug is not water-soluble, propylene glycol is used as the solvent. The drug is first dissolved in propylene glycol, and then Carbopol resin is added to form the gel. This mixture is neutralized with a 5% sodium hydroxide solution to stabilize the gel. The resulting drug gel is then applied to a backing layer, and a rate-controlling membrane, such as ethylene vinyl acetate copolymer (EVAC) or polyethylene, is placed over it. The edges are sealed with heat to form a leak-proof transdermal patch.
Friend et al. (1991**)** studied this system for delivering levonorgestrel, using ethyl acetate with or without ethanol as permeation enhancers. They tested the skin irritation caused by these patches in rabbits and observed mild to moderate irritation, primarily as erythema (redness). No significant difference in irritation was found between devices using pure ethyl acetate, ethyl acetate-ethanol mixtures, or pure ethanol, suggesting that the type of enhancer used had little impact on skin irritation levels.

5.Hot Melt Extrusion:
The hot-melt extrusion method is commonly used to prepare transdermal patches when both the drug and polymers can tolerate heat. In this process, the drug, polymer, and other solid ingredients (like plasticizers or release enhancers) are first mixed together in their dry form until they form a uniform blend.
This mixture is then heated and melted, and the molten mass is passed through an extruder, a machine that shapes the material into a thin, even sheet. Once the sheet is formed, it is cooled down, allowing it to solidify and retain its shape. The final solid sheet is then cut into patches of the desired size for use.
This method is solvent-free, making it environmentally friendly and ideal for heat-stable drugs. It also produces uniform patches with consistent drug distribution and good mechanical strength.

EVALUATION:-

- **Physicochemical evaluation:-**

A. Physical Appearance:-***We start by checking the patch visually. It should have a smooth and uniform surface, without any cracks, bubbles, or visible crystals. The colour and texture should also be consistent across all patches.***

B. Patch Thickness:-***The thickness of the patch is measured using a micrometre to ensure uniformity. Even thickness is important because it affects how much drug is delivered to the skin.***

C. Weight Uniformity:-***Each patch should have roughly the same weight. This helps confirm that each one contains the same amount of ingredients and will perform similarly.***

D. Moisture Content:-***We measure how much water is inside the patch. Too much moisture can cause microbial growth, while too little may make the patch brittle.***

$$\% \text{ moisture content} = \frac{(\text{initial weight} - \text{final weight}) \times 100}{\text{Final weight}}$$

E. Moisture Uptake:-***We also test how much moisture the patch absorbs from the environment. This helps predict how it will behave under different storage or usage conditions.***

F. Tensile Strength:-***This measures how much force the patch can handle before breaking. It ensures the patch will not tear easily during application or use.***

G. Folding Endurance :-***Folding endurance tells us*** how strong and flexible a patch is***. It's checked by*** bending the patch over and over at the same spot ***until it breaks.***

- **In Vitro Permeation Studies**

In vitro permeation studies are lab tests we do to see *how well the drug from a patch passes through the skin* **—** without testing on actual people (in vitro simply means testing done outside the body, usually in a lab dish or test tube — not in a living person or animal. It's like studying something in a controlled lab environment).
We usually use *animal skin, synthetic membranes*, or *donated human skin* to mimic real skin. The patch is placed on the skin sample, and we measure *how much of the drug travels through the skin over time*.

- ***In Vivo Studies***

After a patch is tested in the lab (in vitro), it needs to be tested *on living beings* to see how it actually behaves *in real-life conditions*. That's where in vivo studies come in — this just means the testing is done inside a living body, like in a person or animal, rather than in a lab dish.
These studies are usually done in *animals first*, and then in *humans* (clinical trials), under strict ethical guidelines. The goal is to understand how the drug from the patch performs *inside a living body***.**

CONCLUSION:-

Transdermal patches have changed the way we think about taking medicine. Instead of pills or injections, these patches offer a simple, painless way to deliver medication through the skin and into the bloodstream. They're especially helpful for people who have trouble swallowing pills or need steady, long-term treatment. While they aren't perfect — not all drugs can be delivered this way, and some people may have skin reactions — the benefits are clear. As science continues to advance, transdermal patches are likely to become even more effective and widely used, making treatment easier and more comfortable for many patients**.**

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