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"Advanced Permeation Strategies for Transdermal NSAID Delivery"

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Abstract
Nonsteroidal anti-inflammatory drugs (NSAIDs) are commonly used for pain relief and inflammation management. However, their oral and injectable forms often cause gastrointestinal irritation, undergo first-pass metabolism, and lead to systemic side effects. Transdermal patches provide an innovative alternative by offering controlled drug release, enhanced patient compliance, and reduced side effects. This review highlights recent advancements in NSAID transdermal patch formulations, focusing on penetration enhancers, novel polymers, and nanotechnology-based approaches. It also discusses key challenges such as skin permeability, drug stability, and regulatory concerns. With their non-invasive nature and promising therapeutic potential, NSAID transdermal patches are emerging as a valuable option in modern drug delivery systems.

Keywords : NSAIDs, transdermal patches, pain relief, inflammation management, controlled drug release, patient compliance, side effects, penetration enhancers, novel polymers, nanotechnology, skin permeability, drug stability, regulatory concerns, non-invasive, drug delivery systems.

Introduction:-

Common Routes of NSAID

NSAIDs are primarily administered through oral and injectable routes. The oral route is the most widely used due to its convenience, with formulations like tablets, capsules, and suspensions. However, oral NSAIDs often cause gastrointestinal (GI) irritation, ulcers, and bleeding with prolonged use. They also undergo first-pass metabolism, reducing bioavailability and sometimes requiring higher doses, which increases the risk of kidney damage. On the other hand, injectable NSAIDs, such as intramuscular (IM) and intravenous (IV) formulations, provide rapid pain relief and bypass the GI tract. However, they come with drawbacks like pain at the injection site, systemic side effects (renal and cardiovascular risks), and the need for trained personnel to administer them.

Need of Transdermal NSAID Patches

Due to these limitations, transdermal NSAID patches have emerged as an effective alternative. These patches deliver the drug directly through the skin into systemic circulation, bypassing first-pass metabolism and reducing GI-related side effects. They provide sustained drug release, ensuring long-lasting pain relief with fewer systemic complications. Additionally, transdermal patches are non-invasive, easy to use, and improve patient compliance, making them an ideal choice for chronic pain management. Due to the limitations of traditional NSAID

administration routes (oral and injectable), transdermal patches have emerged as a promising alternative.

1. Avoidance of Gastrointestinal (GI) Side Effects

Oral NSAIDs often cause gastric irritation, ulcers, and bleeding, particularly with long-term use. Transdermal patches bypass the digestive system, significantly reducing the risk of GI complications and making them safer for patients with a history of gastric issues.

2. Bypassing First-Pass Metabolism

Oral NSAIDs undergo hepatic first-pass metabolism, which reduces their bioavailability and may require higher doses to achieve therapeutic effects. Transdermal patches deliver the drug directly into the bloodstream, improving bioavailability and enhancing effectiveness at lower doses.

3. Sustained and Controlled Drug Release

Unlike oral or injectable forms that can cause fluctuations in drug levels, transdermal patches provide a steady, prolonged release of the drug. This ensures consistent pain relief over an extended period, reducing the need for frequent dosing and enhancing therapeutic outcomes.

4. Reduced Systemic Side Effects

Injectable NSAIDs, while effective, may lead to renal toxicity, cardiovascular complications, and hypersensitivity reactions. Transdermal delivery minimizes systemic drug exposure, lowering the risk of these adverse effects while maintaining therapeutic benefits.

Mechanism of Transdermal Drug Delivery (TDD)

Transdermal drug delivery (TDD) involves the transport of drugs through the skin to reach systemic circulation. It is a non-invasive method that offers advantages such as avoiding first-pass metabolism and providing sustained drug release. However, the biggest challenge of TDD is overcoming the natural barrier properties of the skin, primarily the stratum corneum.

1) Role of the Skin Barrier

The skin is composed of three main layers: the epidermis, dermis, and hypodermis. The outermost layer, the stratum corneum, is the principal barrier for drug permeation. It consists of dead, flattened keratinized cells (corneocytes) embedded in a lipid matrix, forming a "brick-and-mortar" structure. The corneocytes act as bricks, while the lipid bilayers form the mortar. This layer prevents excessive water loss and blocks the entry of foreign substances, making drug penetration difficult.

2) Pathways for Transdermal Drug Penetration

Drug molecules can cross the skin through three primary pathways:

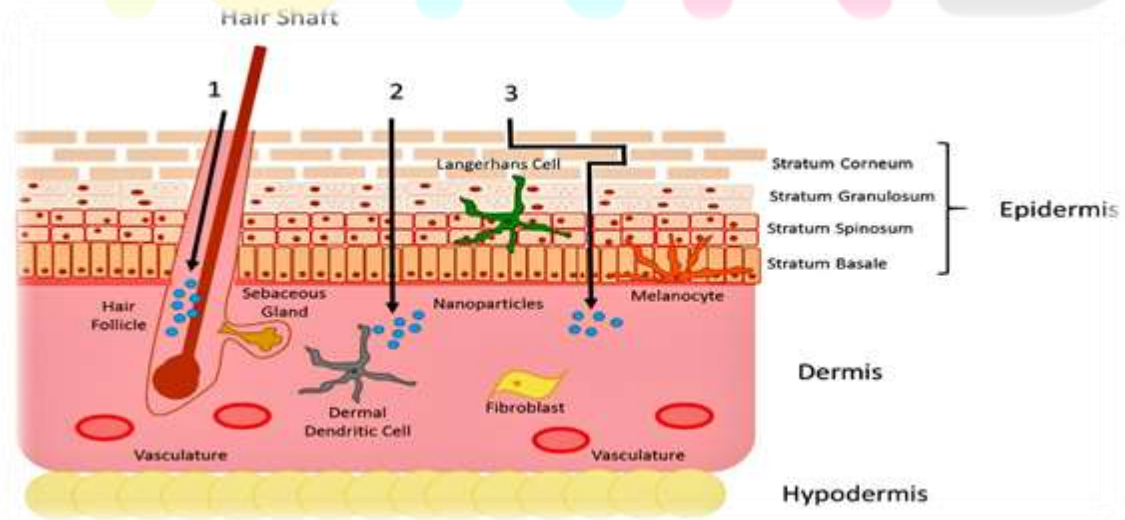

FIG. **Pathways of Transdermal Drug Penetration**

1. **Transcellular Pathway (Intracellular Route) –** In this pathway, the drug molecules pass directly through the keratinocytes, which are the main cells of the epidermis. The drug must cross multiple lipid bilayers and aqueous intracellular regions, making this route challenging for hydrophilic drugs. However, lipophilic drugs with small molecular weight can easily diffuse through this pathway. Since the transcellular route involves crossing both hydrophilic and lipophilic domains, the penetration rate depends on the drug's solubility in both environments
2. **Paracellular Pathway (Intercellular Route) –** Instead of passing through the cells, the drug moves between adjacent cells by diffusing through the lipid-rich intercellular spaces of the stratum corneum. This pathway is more suitable for lipophilic drugs because they can dissolve in the intercellular lipids. However, large molecules and highly hydrophilic drugs struggle to penetrate through this route due to the tightly packed lipid layers, which act as a major diffusion barrier. The rate of penetration depends on the lipid composition and the presence of penetration enhancers.
3. **Transappendageal Pathway (Shunt Route) –** This pathway allows drugs to bypass the stratum corneum by diffusing through skin appendages such as sweat glands, sebaceous glands, and hair follicles. It is particularly useful for large, hydrophilic, or charged molecules that face resistance from the lipid-rich stratum corneum. Although this route offers faster penetration, its contribution to overall drug delivery is limited because skin appendages occupy only a small fraction (~0.1%) of the total skin surface.

3) Factors Affecting Transdermal Permeation

Physicochemical properties of the penetrant molecules

Molecular Properties: Drugs with low molecular weight (<500 Da) and balanced lipophilicity (log P between 1-3) permeate more easily.

Partition coefficient :A lipid/water partition coefficient of 1 or greater is generally required for optimal transdermal permeability.It may be altered by chemical modification without affecting the pharmacological activity of the drug.

pH conditions: Applications of solutions whose pH values are very high or very low can be destructive to the skin. With moderate pH values, the flux of ionizable drugs can be affected by changes in pH that alter the ratio of charged and uncharged species and their transdermal permeability

Penetrant concentration: Assuming membrane related transport, increasing concentration of dissolved drug causes a proportional increase in flux. At concentration higher than the solubility, excess solid drug functions as a reservoir and helps maintain a constant drug constitution for a prolonged period of time.

Physicochemical properties of the drug delivery system

Release characteristics Solubility of the drug in the vehicle determines the release rate. The mechanism of drug release depends on the following factors: Whether the drug molecules are dissolved or suspended in the delivery systems.The interfacial partition coefficient of the drug from the delivery system to the skin tissue.pH of the vehicle

Composition of the drug delivery systems The composition of the drug delivery systemse.g., boundary layers, thickness, polymers, vehicles not only affects the rate of drug release, but also the permeability of the stratum corneum by means of hydration, making with skin ipids, or other sorption promoting effects e.g., benzocaine permeation decreases with PEG of low molecular weightMajority of drugs will not penetrate skin at rates sufficiently high for therapeutic efficacy. In order to allow clinically useful transdermal permeation of most drugs, the penetration can be improved by the addition of a permeation promoter into the drug delivery systems.

4) Components used to Inhance skin penetration of NSAIDs

Chemical Enhancers:

1. Lipid Disruption – Many chemical enhancers work by disrupting the lipid bilayers in the stratum corneum, which serve as a major barrier to drug penetration. Solvents like ethanol, isopropanol, and dimethyl sulfoxide (DMSO) fluidize these lipids, allowing drugs to pass through more easily. Terpenes such as menthol and limonene also interact with the lipid structure, increasing permeability. This method is widely used in transdermal patches and topical formulations.

2. Protein Modification – Some enhancers target the keratin proteins present within corneocytes, altering their structure and making the skin more permeable. Surfactants like sodium lauryl sulfate (SLS) and cetyltrimethylammonium bromide (CTAB) modify protein conformation, allowing drugs to penetrate deeper. However, excessive protein modification can cause skin irritation and damage, so these enhancers must be used carefully.

3. Partitioning Promotion – This method enhances the solubility and diffusion of drugs within the skin. Certain enhancers, such as Azone (Laurocapram) and Transcutol (Diethylene glycol monoethyl ether), alter the drug's affinity for the stratum corneum, increasing its ability to partition from the formulation into the skin layers. Fatty acids like oleic acid and lauric acid also improve drug partitioning by modifying the lipophilic environment of the skin**.**

Physical Methods:

1. **Microneedles** – Microneedles are tiny, minimally invasive needles that create microscopic pores in the skin, allowing drugs to penetrate deeper layers without significant pain or damage. They can be solid (to create temporary pathways) or coated with drugs for direct delivery. This method is commonly used for transdermal vaccines, insulin, and peptide-based drugs.

2. Iontophoresis – This technique uses a mild electrical current to push charged drug molecules through the skin. The electric field enhances the transport of drugs, making it useful for delivering local anesthetics (e.g., lidocaine), peptides, and proteins. It is a painless, non-invasive method that ensures controlled drug release over time.

3. Sonophoresis (Ultrasound Drug Delivery) – High-frequency sound waves disrupt the lipid structure of the stratum corneum, temporarily increasing skin permeability. This method is used in cosmetic applications (e.g., anti-aging treatments) and pharmaceutical formulations, improving drug absorption without damaging skin tissues.

4. Electroporation – Short bursts of high-voltage electrical pulses create temporary pores in cell membranes, enabling the passage of large molecules such as DNA, RNA, and peptides. It is widely used in gene therapy, vaccine delivery, and experimental drug formulations.

5. Thermal Ablation – Controlled heat removes or disrupts the outer skin layer, enhancing drug penetration. It is commonly used in laser-assisted transdermal drug delivery, improving the absorption of large or hydrophilic drugs.

6. Microdermabrasion – This mechanical exfoliation technique removes the stratum corneum, making the skin more permeable. It is often used in dermatology for improving drug absorption in acne, scars, and pigmentation treatments.

Novel formulation approaches for improving skin delivery of NSAIDs

1. Liposomes – These are spherical vesicles composed of one or more phospholipid bilayers, capable of encapsulating both hydrophilic and lipophilic NSAIDs. They enhance drug solubility, stability, and bioavailability by merging with skin lipids, improving penetration through the stratum corneum. Liposomes also

provide sustained drug release, reducing systemic toxicity and irritation, making them ideal for prolonged NSAID therapy. Their flexibility allows them to accumulate in the deeper layers of the skin, offering localized and prolonged anti-inflammatory effects.

2. Ethosomes – Ethosomes are advanced lipid vesicles containing high ethanol concentrations, which disrupt the rigid structure of the stratum corneum, allowing deeper drug penetration. Ethanol also enhances the fluidity of ethosomal membranes, making them more permeable. These vesicles can deliver NSAIDs to both superficial and deeper skin layers, providing sustained and localized effects. Ethosomal formulations have shown improved therapeutic outcomes compared to conventional topical NSAIDs, especially in managing chronic inflammatory conditions like arthritis.

3. Transfersomes – Transfersomes are ultra-deformable vesicles that can squeeze through narrow intercellular spaces in the skin due to their flexible structure. They use osmotic pressure to penetrate deeper tissues without disrupting skin integrity. Transfersomes are highly effective in enhancing transdermal NSAID delivery, ensuring deep tissue targeting, prolonged action, and improved bioavailability. These vesicles allow for better drug retention at the target site, reducing the need for frequent applications.

4. Niosomes – These are non-ionic surfactant-based vesicles that enhance NSAID stability and permeation through the skin. Compared to liposomes, niosomes are more stable, cost-effective, and resistant to oxidative degradation. They help in controlled drug release, leading to prolonged therapeutic effects with reduced systemic absorption. The surfactants in niosomes can also act as penetration enhancers, improving drug diffusion through the stratum corneum and increasing the efficiency of NSAID therapy.

5. Nanoemulsions – These are fine oil-in-water or water-in-oil dispersions with droplet sizes in the nanometer range, offering excellent solubilization for poorly water-soluble NSAIDs. Nanoemulsions improve drug permeability by reducing interfacial tension and increasing drug solubility in the skin's lipid environment. They provide enhanced skin hydration, longer drug retention, and controlled release. Due to their thermodynamic stability, nanoemulsions are ideal for NSAID formulations, preventing drug degradation while improving efficacy.

6. Solid Lipid Nanoparticles (SLNs) – SLNs are colloidal carriers composed of biodegradable lipids in solid form at body temperature. They encapsulate NSAIDs, protecting them from oxidation and degradation while enabling controlled release. SLNs enhance penetration by increasing drug deposition in the stratum corneum and epidermis. They also improve skin hydration and provide an occlusive effect, which can further enhance NSAID absorption and efficacy. This makes SLNs particularly useful for long-term anti-inflammatory therapy.

Mechanism of NSAID delivery through Transdermal patches

1. Drug Release from the Patch

NSAIDs in transdermal patches are formulated using different delivery systems such as matrix-type, reservoir-type, or adhesive-type patches, each influencing the drug release mechanism. In matrix-type patches, the NSAID is dispersed in a polymer matrix that gradually releases the drug upon contact with the skin. Reservoir-type patches contain a liquid NSAID formulation stored behind a rate-controlling membrane, ensuring a steady and controlled release. Adhesive-type patches incorporate NSAIDs within the adhesive layer, allowing direct drug release when applied. The release of NSAIDs from the patch follows Fick's law of diffusion, where the concentration gradient between the patch and the skin acts as the driving force for drug movement.

2. Penetration Through the Stratum Corneum

The stratum corneum (SC), the outermost layer of the epidermis, is the primary barrier that regulates drug penetration. NSAIDs pass through the SC using three different pathways: the intercellular lipid pathway, the transcellular route, and the appendageal route (shunt pathway). The intercellular lipid pathway is the most

common, where NSAIDs diffuse between lipid bilayers in the SC. Lipophilic NSAIDs, such as diclofenac, easily dissolve in these lipid domains, facilitating penetration. The transcellular route involves the drug passing directly through corneocytes (keratinized cells), but due to the high protein density, this route is less effective. The appendageal route involves penetration through sweat glands and hair follicles, providing an alternative low-resistance pathway, particularly for hydrophilic NSAIDs. To enhance penetration, transdermal patches often contain chemical penetration enhancers such as ethanol, menthol, and terpenes, which temporarily disrupt skin lipids and proteins to increase permeability. Physical enhancement techniques such as iontophoresis, microneedles, and ultrasound can further improve NSAID delivery.

3. Diffusion Through Deeper Skin Layers (Viable Epidermis and Dermis)

After crossing the stratum corneum, NSAIDs enter the viable epidermis and dermis, where they diffuse through both aqueous and lipid-rich environments. The ability of NSAIDs to penetrate these layers is determined by their partition coefficient (log P), which defines their solubility in skin lipids. Lipophilic NSAIDs, such as ibuprofen and diclofenac, diffuse efficiently through lipid-rich domains in the epidermis, while hydrophilic NSAIDs require penetration enhancers or specialized nanoformulations like liposomes, ethosomes, and nanostructured lipid carriers (NLCs) to improve transport. Once in the dermis, NSAIDs may bind to skin proteins such as albumin, forming a drug depot that allows for sustained release, prolonging the therapeutic effect.

4. Absorption into Systemic Circulation

The final step involves the absorption of NSAIDs into the dermal capillaries, where they enter systemic circulation. Several factors influence this process, including local blood flow rate, NSAID molecular weight, and drug binding to skin components. Increased blood circulation enhances NSAID absorption, while strong binding to skin proteins can delay systemic uptake, leading to prolonged therapeutic effects. The advantage of transdermal NSAID delivery is that it avoids first-pass metabolism, ensuring higher bioavailability and reducing systemic side effects compared to oral NSAIDs.

Methods of preperation of NSAIDS Patches

1. Solvent Casting Method – This is the most commonly used method for preparing transdermal patches. In this approach, the NSAID and polymer are dissolved in a volatile solvent such as ethanol, chloroform, or methanol. A plasticizer is added to improve the flexibility of the patch. The solution is then poured onto a flat surface, such as a glass plate or Teflon mold, and spread evenly to form a uniform layer. The solvent is allowed to evaporate under controlled temperature and humidity conditions, leaving behind a thin polymeric film containing the drug. Once dried, the film is carefully peeled off and cut into patches of the desired size. A backing membrane is then laminated onto the film to prevent drug loss. This method ensures uniform drug distribution and allows for the incorporation of different excipients to modify drug release. However, solvent residue and proper film thickness control can be challenging.

Reference: Patel, H.; Panchal, D.R.; Patel, U.; Brahmbhatt, T.; Suthar, M. "Matrix Type Transdermal Drug Delivery System: A Review." J. Pharm. Sci. Bioscientific Res., 2011, 1(1), 25-34.

2. Melt Extrusion Method – This is a solvent-free technique used for transdermal patch preparation. In this method, the NSAID and polymer are physically mixed and heated until they melt, forming a homogeneous mixture. The molten mass is then passed through an extruder, which shapes it into a thin film. This film is rapidly cooled and solidified, followed by cutting into patches of the required size. The melt extrusion method eliminates issues related to solvent toxicity and residual solvent traces. It also enhances drug stability, as the absence of solvents prevents chemical degradation. This technique is particularly useful for thermoplastic polymers that can be softened and reshaped under heat. However, the high processing temperatures may not be suitable for heat-sensitive drugs.

Reference: Repka, M.A.; Prodduturi, S.; Stodghill, S.P. "Production and Characterization of Hot-Melt Extruded Films Containing Clotrimazole." Drug Dev. Ind. Pharm., 2003, 29(7), 757-765.

3. Direct Milling Method – This technique involves dry blending the NSAID with a polymer without using any solvents. The blended mixture is then subjected to compression using a roller mill or a tablet press to form a continuous thin film. The film is further processed by applying an adhesive layer and cutting it into patches of desired dimensions. The direct milling method is advantageous because it avoids the use of organic solvents, making it an environmentally friendly process. Additionally, it is suitable for thermolabile drugs that degrade in the presence of heat or solvents. However, achieving uniform drug dispersion can be a challenge, and the mechanical strength of the final patch may depend on the properties of the polymer used.

Reference: Perumal, D. "Preparation and Characterization of Ibuprofen Polymethacrylate Transdermal Systems." Int. J. Pharm., 2001, 228(1-2), 33-44.

4. Electrospraying Method – This is a nanotechnology-based method that enhances transdermal drug delivery. The NSAID is dissolved in a suitable polymeric solution and loaded into a syringe, which is connected to a high-voltage power source. As the solution is passed through the syringe, an electric field generates fine nanoscale droplets, which are deposited onto a collector plate. These droplets quickly dry, forming a thin film of nanostructured polymer containing the drug. The electrospraying technique allows for precise control over film thickness and drug loading, leading to enhanced skin penetration. This method is particularly useful for poorly soluble NSAIDs, as it can enhance drug dissolution and bioavailability. However, it requires specialized equipment and may not be suitable for large-scale manufacturing.

Reference: Moghe, A.K.; Gupta, B.S. "Co-axial Electrospinning for Nanofiber Structures: Preparation and Applications." Polym. Rev., 2008, 48(2), 353-377.

5. Matrix-Type Patch Preparation – In this method, the NSAID is uniformly dispersed in a polymer matrix, which serves as a drug reservoir and controls its release. The drug-polymer mixture is either dissolved in a solvent and cast into a film or blended in a dry state and compressed into a sheet. After drying, the sheet is laminated with a protective backing and an adhesive layer. The drug release from matrix-type patches occurs through diffusion and erosion of the polymer matrix. This method is widely used because it provides a sustained drug release profile, reducing dosing frequency and improving patient compliance. However, controlling the exact release rate can be challenging, as it depends on polymer degradation and drug diffusion properties.

Reference: Mutalik, S.; Udupa, N. "Formulation Development, In Vitro and In Vivo Evaluation of Membrane-Controlled Transdermal Systems of Glibenclamide." J. Pharm. Pharmaceut. Sci., 2005, 8(1), 26-38.

6. Reservoir-Type Patch Preparation – This method involves incorporating the NSAID into a liquid or gel-based reservoir enclosed between a backing membrane and a rate-controlling membrane. The backing membrane prevents drug leakage, while the rate-controlling membrane regulates drug diffusion into the skin. This system provides a steady and controlled drug release over an extended period. Reservoir patches are particularly useful for potent NSAIDs that require precise dosing. However, the complexity of this design makes manufacturing more challenging, and there is a risk of drug leakage if the reservoir membrane is damaged.

Reference: Chien, Y.W. "Transdermal Drug Delivery and Delivery Systems." In Novel Drug Delivery Systems; Chien, Y.W., Ed.; Marcel Dekker: New York, 1992; pp. 301-380.

7. Ethosomal Systems – Ethosomes are lipid-based carriers containing high concentrations of ethanol, which enhances drug solubility and penetration through the skin. The ethanol content disrupts the lipid structure of the stratum corneum, allowing deeper drug penetration. Ethosomes are prepared by dissolving the NSAID in a hydroalcoholic solution, followed by the addition of phospholipids to form vesicles. These vesicles are then incorporated into a patch formulation. This method is particularly useful for delivering both lipophilic and hydrophilic drugs transdermally. However, ethanol-induced skin irritation can be a drawback.

Reference: Touitou, E.; Dayan, N.; Bergelson, L.; Godin, B.; Eliaz, M. "Ethosomes—Novel Vesicular Carriers for Enhanced Delivery: Characterization and Skin Penetration Properties." J. Control. Release, 2000, 65(3), 403-418.

8. Invasomal Systems – Invasomes are vesicular carriers composed of phospholipids, ethanol, and terpenes. These components work together to enhance skin permeability, allowing for effective transdermal delivery of NSAIDs. The preparation involves dissolving the drug in an ethanolic solution, followed by the addition of phospholipids and terpenes to form small vesicles. These vesicles are then integrated into a patch formulation. Invasomes improve drug bioavailability and penetration through the skin barrier. However, their stability may be affected by environmental conditions such as temperature and humidity.

Reference: Jain, S.; Tripathi, S.; Tripathi, P.K. "Invasomes: Potential Vesicular Systems for Transdermal Delivery of Drug Molecules." J. Drug Deliv. Sci. Technol., 2021, 61, 102162.

Types of nsaids patch

1. **Diclofenac Patches:** Diclofenac is a widely used NSAID known for its efficacy in reducing inflammation and pain. Transdermal patches containing diclofenac have been formulated to provide sustained drug release, enhancing therapeutic outcomes in conditions like arthritis and musculoskeletal disorders. Studies have demonstrated that these patches can effectively deliver diclofenac through the skin, maintaining therapeutic drug levels over extended periods.
2. **Naproxen Patches:** Naproxen is another NSAID commonly used for its analgesic and anti-inflammatory properties. Transdermal patches containing naproxen have been developed to improve patient compliance and provide consistent drug delivery. Research indicates that these patches can effectively release naproxen over time, offering a viable alternative to oral administration.
3. **Ibuprofen Patches:** Ibuprofen is a popular NSAID used to alleviate pain and reduce inflammation. Transdermal patches delivering ibuprofen have been formulated to enhance skin permeation and provide targeted relief. Studies have shown that these patches can successfully administer ibuprofen transdermally, achieving therapeutic effects while potentially reducing gastrointestinal side effects associated with oral intake.
4. **Ketoprofen Patches:** Ketoprofen is an NSAID known for its potent anti-inflammatory effects. Transdermal patches containing ketoprofen have been designed to treat conditions such as musculoskeletal pain and osteoarthritis. Clinical evaluations suggest that these patches provide effective pain relief with a favorable safety profile, making them a valuable option in pain management.
5. **Piroxicam Patches:** Piroxicam is an NSAID utilized for its long-acting analgesic properties. Transdermal patches delivering piroxicam have been developed to manage chronic pain conditions. Research indicates that these patches can maintain steady-state plasma concentrations of piroxicam, offering sustained pain relief and improved patient adherence

Conclusion :

Transdermal patches for NSAID delivery represent a significant advancement in pain management and anti-inflammatory therapy. By bypassing first-pass metabolism and reducing gastrointestinal side effects, these patches offer a safer and more effective alternative to traditional oral and injectable NSAIDs. Various novel formulation strategies, including liposomes, ethosomes, and nanoemulsions, have enhanced drug penetration and bioavailability. Despite challenges like skin permeability and regulatory constraints, ongoing research continues to improve transdermal drug delivery systems. With their ability to provide controlled drug release, improved patient compliance, and reduced systemic toxicity, NSAID transdermal patches hold great promise for the future of pain relief and inflammatory disease management.

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