

Buccal Patches in NDDS: An Overview

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Abstract

Buccal patches are an advanced drug delivery system designed to administer therapeutic agents through the buccal mucosa, offering a non-invasive, efficient alternative to conventional methods such as oral tablets and injections. These patches provide several advantages, including enhanced bioavailability by bypassing the gastrointestinal tract and first-pass metabolism, controlled drug release, and improved patient compliance due to their ease of use and painless administration. The drug is absorbed directly into the bloodstream through the buccal mucosa, providing rapid onset of action, which is particularly beneficial for drugs requiring quick therapeutic effects. Despite their potential, challenges such as limited drug compatibility, mucosal irritation, and high manufacturing costs remain. Additionally, the formulation of buccal patches must address issues related to drug solubility, permeability, and stability to maximize their effectiveness. Ongoing research is focused on overcoming these limitations through innovative formulations, nanotechnology, and the exploration of personalized medicine to improve patch performance. As technology progresses, buccal patches are expected to become an increasingly viable option for both local and systemic drug delivery, offering significant benefits in the treatment of various conditions.

Keywords: Buccal mucous, buccal patch/film, Evaluation of buccal patches, bioadhesive.

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INTRODUCTION

In recent years, buccal patches have emerged as a significant advancement in drug delivery systems, offering a non-invasive, efficient, and convenient alternative to traditional methods such as oral tablets, injections, or topical applications. These small, thin, adhesive patches are applied to the buccal mucosa, the inner lining of the cheek or gums, providing a direct route for drugs to enter the bloodstream. Unlike conventional oral drug delivery, which involves the gastrointestinal (GI) tract, buccal patches bypass the digestive system entirely, as well as the liver, avoiding the first-pass metabolism that can significantly reduce the efficacy of many drugs. This ability to deliver drugs directly into the bloodstream via the mucosal membrane ensures faster onset of action and improved bioavailability, particularly for medications that are poorly absorbed through the digestive system.

The buccal mucosa offers an ideal site for drug absorption due to its rich blood supply and relatively large surface area, which facilitates the direct uptake of drugs into systemic circulation. Moreover, the buccal patch can be designed for controlled or sustained release, reducing the need for frequent administration and improving patient compliance. This makes buccal patches particularly beneficial for chronic conditions that require long-term medication

management, such as cardiovascular diseases, pain management, and hormone replacement therapy.

Buccal patches consist of several components, including a polymeric matrix that holds the active pharmaceutical ingredient (API), adhesive layers for attachment to the mucosa, and plasticizers to enhance flexibility. The patch can either be a reservoir type, where the drug is stored in a central core, or a matrix type, where the drug is dispersed throughout the patch and released through diffusion. The choice of materials and drug characteristics is crucial for ensuring the desired release profile and maximizing therapeutic effects.

One of the key advantages of buccal patches is their ability to provide consistent drug release over extended periods. This sustained release profile not only enhances the convenience of treatment by reducing dosing frequency but also minimizes the risk of drug fluctuations in the bloodstream, improving therapeutic outcomes. Additionally, the patches can be used for a variety of drugs, including those for pain relief (such as opioids or NSAIDs), cardiovascular treatments (like nitroglycerin), and smoking cessation (nicotine replacement therapy).

Despite their potential, buccal patches are not without challenges. The adhesive properties must be carefully engineered to ensure proper attachment to the buccal mucosa, and issues such as irritation or discomfort

may arise with prolonged use. The drug's properties, such as molecular size, solubility, and permeability, also influence the effectiveness of the patch, limiting the range of medications that can be delivered in this way. Moreover, the sensory experience of wearing the patch, including taste or mouth irritation, may deter some patients from regular use. Nevertheless, the growing interest in buccal patches has prompted ongoing research to address these challenges and expand the scope of their application. By improving the formulation and delivery mechanisms, buccal patches could become a mainstream solution for a variety of therapeutic areas, offering patients an efficient and less invasive option for managing their conditions.

Buccal patches offer several significant advantages

Bypassing First-Pass Metabolism: By delivering drugs directly through the buccal mucosa, buccal patches avoid the liver's first-pass metabolism, significantly enhancing the drug's bioavailability and effectiveness.

Improved Bioavailability: Since the drug enters the bloodstream directly, the bioavailability is often higher than that of oral drugs, especially for those poorly absorbed through the gastrointestinal tract.

Rapid Onset of Action: The direct absorption into the bloodstream ensures that drugs act faster, providing quicker therapeutic relief compared to traditional oral routes.

Controlled and Sustained Release: Buccal patches allow for a consistent and prolonged release of medication, reducing the need for frequent dosing and ensuring stable drug levels in the body.

Reduced Gastrointestinal Side Effects: By bypassing the GI tract, buccal patches minimize gastrointestinal discomfort, irritation, and other related side effects common with oral medications.

Non-Invasive and Convenient: These patches are easy to apply, non-invasive, and ideal for self-administration, offering a more comfortable alternative to injections or oral pills.

Better Patient Compliance: The convenience of fewer doses and the ease of use improve adherence to treatment regimens, especially for long-term therapies.

Minimal Sensory Discomfort: Well-designed buccal patches cause minimal irritation or discomfort to the mucosa and can be made to mask unpleasant tastes.

Targeted Delivery: Buccal patches can provide localized drug delivery, particularly for conditions affecting the oral cavity, enhancing treatment precision.

Social Acceptability: Unlike injections or inhalers, buccal patches are discreet, enhancing patient comfort and reducing social stigma associated with other drug delivery methods.

These advantages make buccal patches an attractive, effective, and convenient solution for drug delivery, particularly for drugs requiring rapid onset,

controlled release, or those with low oral bioavailability.

Buccal patches offer several significant disadvantages:

Buccal patches, while offering a convenient and non-invasive method of drug delivery, come with several disadvantages that can impact their effectiveness and patient acceptance. These include:

Limited Drug Release Profile: The rate and extent of drug release from buccal patches can be inconsistent, potentially leading to suboptimal therapeutic effects. This can result from variations in the patch's formulation, the drug's solubility, or the individual's physiological conditions.

Patient Compliance Issues: Some patients may find buccal patches uncomfortable, especially if they cause irritation or dry mouth. The patch's visibility and placement in the mouth may also lead to social stigma or difficulty in using it discreetly.

Local Irritation and Sensitization: Continuous contact with the mucosal membrane can cause irritation or sensitivity in some individuals. This may lead to adverse reactions like redness, swelling, or burning sensations, limiting the use of buccal patches in certain populations.

Variability in Buccal Mucosa: The composition and permeability of the buccal mucosa can differ significantly between individuals, which can affect the absorption rate of the drug. Factors like age, diet, or oral hygiene may influence the effectiveness of the patch.

Difficulties in Formulation: Formulating buccal patches for specific drugs can be challenging. The drug must be stable in the oral cavity, have sufficient solubility, and not be affected by the enzymatic environment in the mouth, all of which may limit the range of drugs that can be delivered through this method.

Short Duration of Action: Many buccal patches are designed for short-term use, limiting their application in diseases that require prolonged drug delivery. Frequent patch replacement may be required, which could be inconvenient for the patient.

Cost and Manufacturing: The production of buccal patches can be more expensive than conventional oral medications, mainly due to the specialized materials and processes involved. This could limit their widespread adoption, especially in resource-limited settings.

Adhesion Issues: Ensuring the patch stays securely in place during use can be challenging. Poor adhesion or premature detachment can reduce the efficacy of drug delivery and require adjustments to the patch design or its adhesive properties.

Ideal properties of buccal patches:

The ideal properties of buccal patches are essential to ensuring effective drug delivery, patient comfort, and therapeutic efficacy.

Good Adhesion to Buccal Mucosa: The patch must adhere securely to the buccal mucosa to ensure consistent drug release and minimize displacement. The adhesive should be strong enough to resist mastication, salivation, and swallowing but gentle enough to avoid causing mucosal irritation upon removal.

Controlled and Sustained Drug Release: An ideal buccal patch should provide a controlled and sustained release of the active pharmaceutical ingredient (API) over an extended period. This helps maintain therapeutic drug concentrations and minimizes fluctuations that could compromise efficacy or cause side effects.

Non-irritating and Biocompatible Materials: The materials used in the patch should be non-toxic, non-irritating, and biocompatible, causing minimal adverse reactions when in contact with the sensitive buccal mucosa. The patch should not lead to local irritation, inflammation, or allergic responses.

Optimal Drug Permeability: The patch should be designed to facilitate efficient drug absorption across the buccal mucosa. The permeability of the patch must be suitable for the specific drug, considering factors such as molecular size, solubility, and the potential for first-pass metabolism.

Comfort and Ease of Use: The patch should be thin, flexible, and discreet, ensuring patient comfort during use. It should not interfere with normal oral functions such as speaking, eating, or swallowing, and should remain inconspicuous during normal daily activities.

Stability and Shelf-life: The drug formulation within the patch should remain stable under normal storage conditions and maintain its potency over the patch's shelf-life. The material used must protect the drug from degradation due to environmental factors such as humidity, light, and temperature.

Quick Onset of Action: For acute conditions, the buccal patch should allow for rapid absorption of the drug, providing a fast onset of action. This is particularly important for drugs that require immediate therapeutic effects, such as pain relievers or anti-nausea medications.

Safe Removal: The patch should be easy to remove without causing discomfort or damage to the buccal mucosa. Adhesive properties should be designed to prevent any residue from being left behind or causing difficulty during removal.

Compatibility with a Range of Drugs: The formulation should be adaptable to a wide range of pharmaceutical agents, from small molecules to biologics, without compromising stability, release, or absorption. It should also account for drugs that may degrade or interact with the oral environment.

Minimal Taste Disruption: An ideal buccal patch should not significantly alter the taste sensation, as unpleasant tastes can discourage patient adherence. Flavor-masking agents may be used to ensure that the patch remains palatable.

These properties, when integrated into a well-designed buccal patch, can enhance patient

experience, improve therapeutic outcomes, and make buccal drug delivery a viable option for a wide range of medical conditions.

Types of buccal patches:

Buccal patches are a type of drug delivery system that is placed in the buccal cavity (the cheek area) to allow for the absorption of medication through the mucous membranes. There are several types of buccal patches, each designed to cater to different therapeutic needs.

Bioadhesive Buccal Patches: These are designed to adhere to the mucosal lining of the cheek, providing controlled and sustained drug release over time. They are typically made from polymers that enhance adhesion, such as chitosan or polyvinyl alcohol.

Matrix-based Buccal Patches: These patches contain the drug within a matrix of polymers, which slowly release the drug as the patch dissolves or the drug diffuses through the material. They offer sustained release and are typically used for drugs that need to be administered over extended periods.

Reservoir-type Buccal Patches: These patches consist of a drug reservoir separated from the mucosal surface by a rate-controlling membrane. The drug is released in a controlled manner, allowing for a consistent dose over time. This type is often used for more potent drugs that require precise dosing.

Mucoadhesive Buccal Patches: Similar to bioadhesive patches, these adhere to the mucosal surface and release drugs through the buccal mucosa. They are often used for the treatment of local conditions like pain or infection and are typically thinner than other types of patches.

Multilayered Buccal Patches: These patches have multiple layers that may include different polymers and drugs. Each layer may serve a specific purpose, such as enhancing adhesion, controlling the release rate, or providing a combination of medications in a single dose. These patches are often preferred for drugs that need to bypass the gastrointestinal tract, offering advantages such as improved bioavailability and a faster onset of action compared to traditional oral forms of medication.

Components of buccal patches:

Buccal patches are composed of several key components that work together to deliver drugs efficiently through the buccal mucosa (the inside of the cheek).

Polymeric Matrix or Substrate: The polymeric matrix forms the structural backbone of the buccal patch and is responsible for drug release. The choice of polymer affects the patch's mechanical properties, such as flexibility, strength, and adhesive ability. Common polymers used include hydrophilic polymers like hydroxypropyl methylcellulose (HPMC), chitosan, and polyvinyl alcohol (PVA), as well as hydrophobic polymers, ethyl cellulose. These polymers can be tailored to control the rate of drug release and enhance the stability of the patch.

Active Pharmaceutical Ingredient (API): The drug or active ingredient is the central component of the patch. The API is incorporated into the matrix or reservoir of the patch and is designed to be released in a controlled manner once in contact with the mucosal surface. The choice of API depends on the therapeutic purpose, such as pain management, nicotine replacement, or local treatment of oral conditions.

Plasticizers: These are additives used to enhance the flexibility and elasticity of the patch, ensuring it remains comfortable when adhered to the mucosal surface. Plasticizers, such as glycerin or propylene glycol, reduce brittleness and improve the patch's conformability to the contour of the cheek.

Adhesive Agents: Adhesion to the buccal mucosa is crucial for the effectiveness of the patch. The adhesive layer ensures that the patch remains in place during the drug delivery process. Common adhesive materials include polyacrylate, polymethyl methacrylate, and synthetic rubbers. The adhesive must be biocompatible, non-irritating, and capable of providing a strong, long-lasting bond while still allowing for eventual removal of the patch.

Rate-controlling Membranes (for Reservoir Systems): In reservoir-type buccal patches, a rate-controlling membrane surrounds the drug reservoir to regulate the rate at which the drug is released into the mucosa. This membrane helps maintain a consistent and controlled drug delivery over time.

Excipients: These are inactive substances used to formulate the patch. Excipients can include stabilizers, binders, fillers, and preservatives, which help in the preparation, storage, and delivery of the drug. For example, preservatives like benzalkonium chloride may be used to prevent microbial growth, while fillers

Flavoring Agents: In some buccal patches, particularly those intended for long-term wear, flavoring agents may be added to mask any

unpleasant taste of the drug or provide a more pleasant user experience. These may include mint or citrus flavorings.

Each of these components plays a critical role in ensuring the buccal patch delivers the drug effectively, remains comfortable and secure during use, and provides controlled and consistent release. The balance and quality of these ingredients are carefully optimized to suit the specific medication and intended therapeutic outcomes.

Methods of preparing buccal patches:

There are several methods used to prepare buccal patches, each designed to ensure the effective delivery of drugs through the buccal mucosa. These methods vary in terms of the technology used, the type of drug being delivered, and the desired release profile of the drug. Below are the most commonly used methods in detail:

Solvent Casting Method

The solvent casting method is one of the most widely used techniques for the preparation of buccal patches. In this method, a polymer is dissolved in a suitable solvent (like water or ethanol), and the active pharmaceutical ingredient (API) is incorporated into the polymer solution. The mixture is then poured onto a flat surface, such as a glass plate or Teflon sheet, and spread evenly to form a thin film.

Once the mixture is spread, it is left to dry, typically in a controlled environment like an oven or at room temperature, to allow the solvent to evaporate, leaving behind a solid polymer film. The film is then cut into patches of the desired size and shape.

Advantages: Simple and cost-effective; allows for a high degree of control over the thickness and uniformity of the patch.

Disadvantages: Potential for solvent residue; drying conditions need to be carefully controlled to avoid degradation of the drug or polymer.

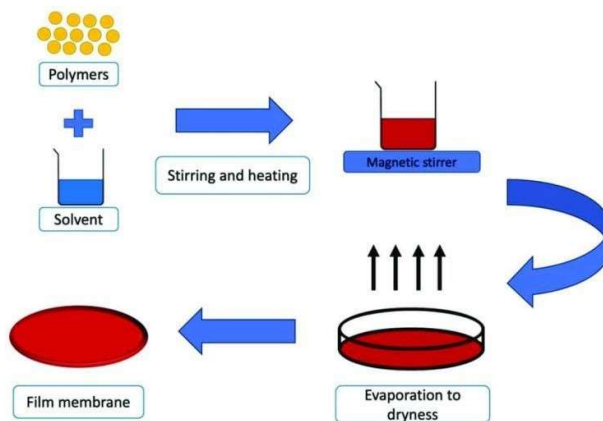


Figure 1: Solvent Casting Method

Hot Melt Extrusion Method

Hot melt extrusion involves melting a mixture of polymers and the drug at an elevated temperature, typically above the melting point of the polymers but below the degradation point of the drug. The polymer-drug mixture is then extruded through a die to form a continuous strip or film. This film is then cooled and cut into patches.

Advantages: Does not require solvents, thus eliminating the need for drying; ideal for drugs with poor solubility, as the extrusion process can improve their dispersion in the polymer matrix.

Disadvantages: High processing temperatures may lead to drug degradation; the method is not suitable for thermolabile drugs.

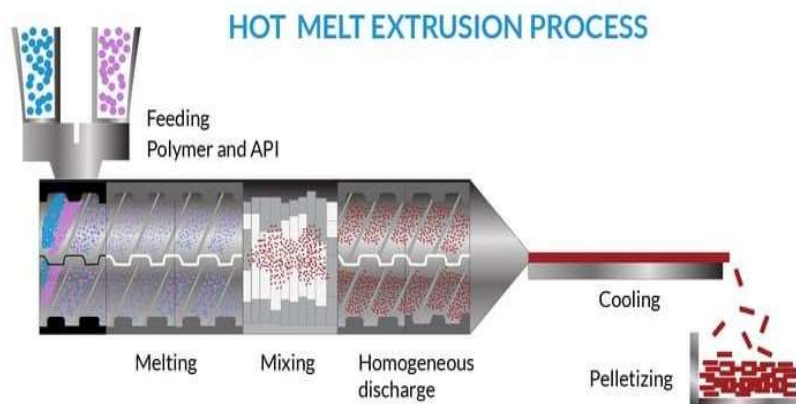


Figure 2: Hot Melt Extrusion Method

Semipermeable Membrane Method

In this method, a drug reservoir is formed between two layers of semipermeable membrane material. The drug is placed in the center and sealed between two layers of polymers, which control the rate of drug release. The drug is slowly released through the membrane, which is selectively permeable to the drug molecules.

Advantages: Provides controlled, sustained release of the drug over an extended period; allows for the use of rate-controlling membranes.

Disadvantages: Complex fabrication process; requires precise control over the amount of drug and the

properties of the membrane to achieve consistent release.

Freeze-Drying (Lyophilization) Method

Freeze-drying is a technique in which the polymer-drug solution is first frozen, and then the solvent is removed by sublimation under a vacuum. This results in a porous, highly stable patch. Freeze-drying is particularly useful when the drug is sensitive to heat or moisture.

Advantages: Ideal for heat-sensitive drugs; results in a highly porous structure that allows for rapid drug dissolution upon contact with the mucosa.

Disadvantages: Expensive equipment and process; longer preparation time compared to other methods.

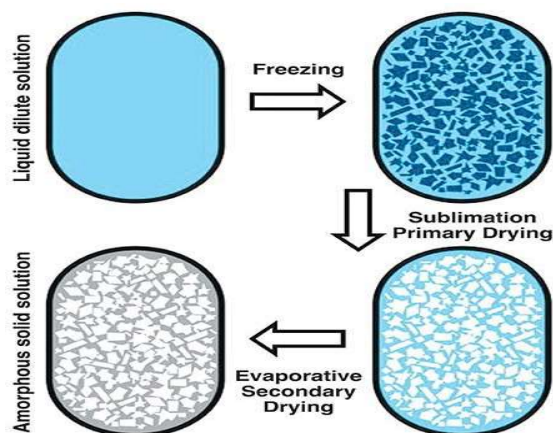


Figure 3: Freeze-Drying (Lyophilization) Method

Electrospinning Method

Electrospinning is a modern technique where a polymer solution is subjected to a high voltage, which causes the solution to form fibers that are collected on a grounded surface, forming a nonwoven mat or patch. The fibers are very fine, providing a high surface area for drug release. The drug can be incorporated either during the electrospinning process or by post-processing.

Advantages: Allows for the creation of very fine, high-surface-area patches that can enhance drug release and absorption; produces patches with excellent mechanical properties.

Disadvantages: Requires specialized equipment; the process can be challenging for large-scale production.

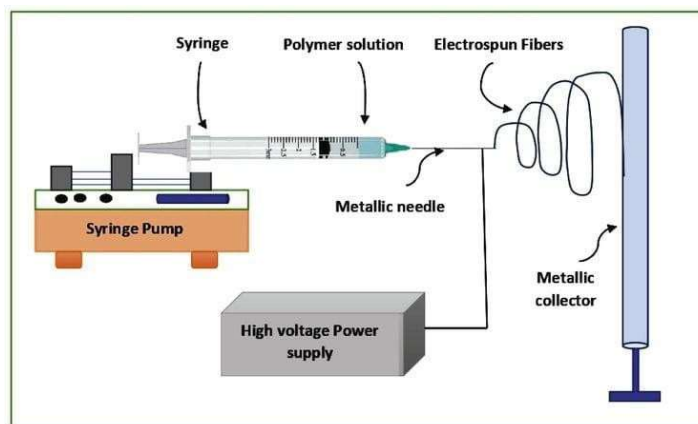


Figure 4: Electrospinning Method

Coating Method

This method involves coating a pre-formed substrate (such as a backing layer or a base polymer film) with a layer of drug-loaded polymer solution. The coating can be applied by spraying or dip-coating techniques. After application, the coated patch is dried, forming a solid layer of drug on the surface.

Advantages: Allows for easy fabrication of multilayered patches; controlled drug release through coating thickness.

Disadvantages: May require multiple steps for uniform coating; the drug might not be evenly distributed, affecting the consistency of release.

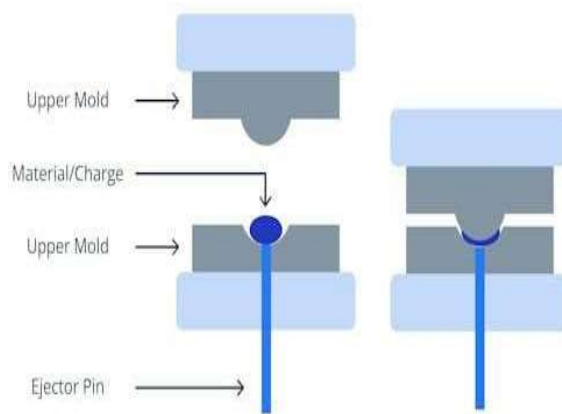


Figure 5: Coating Method

Evaluation of buccal patches:

The evaluation of buccal patches is a critical process to ensure their quality, efficacy, and safety. This involves a series of tests that assess the physical, mechanical, and drug-delivery properties to ensure the patches function as intended and provide reliable

therapeutic outcomes. The following are key parameters for evaluating buccal patches:

Thickness Measurement: The thickness of buccal patches is measured to ensure uniformity and consistency, as variations in thickness can affect the drug release rate and the patch's comfort when applied. Thickness is typically measured using a digital micrometer or other precision instruments to

ensure it remains within an acceptable range for effective drug delivery.

Weight Uniformity: This test ensures that each buccal patch contains the correct amount of drug and excipients. By weighing individual patches using an analytical balance, the consistency of the drug load is checked. Any variation in weight may indicate inconsistencies in formulation, which can impact the dosage and therapeutic efficacy of the patch.

Drug Content Uniformity: To ensure consistent dosing, the drug content in each patch is analyzed. This is done by dissolving the drug from the patch in a suitable solvent, followed by quantification using techniques like spectrophotometry or high-performance liquid chromatography (HPLC). Uniform drug content is crucial to guarantee that each patch delivers the intended therapeutic dose.

Moisture Content and Moisture Uptake: Moisture content is an important factor for the stability and shelf life of buccal patches. Excessive moisture can cause patches to become brittle, while insufficient moisture can reduce adhesion. This test determines the amount of moisture present in the patch and its ability to absorb moisture from the environment, which could affect its performance over time.

Folding Endurance: The folding endurance test assesses the mechanical strength of the buccal patch by repeatedly folding it until it cracks or breaks. This test is important to ensure that the patch can withstand physical stresses, such as bending or movement in the buccal cavity, without compromising its integrity or drug delivery capability.

Tensile Strength and Elongation: These tests measure the patch's ability to resist breaking when stretched and its capacity to elongate before rupture. The tensile strength test determines how much force is required to break the patch, while the elongation test measures the degree of stretch before rupture. These properties are important for ensuring that the patch can withstand the stresses it encounters while in use without tearing.

Adhesion Test: Adhesion is one of the most crucial properties for buccal patches, as they need to remain securely attached to the buccal mucosa during the drug release process. The adhesion strength is tested by placing the patch on a suitable surface, such as human or porcine mucosa, and measuring the force required to peel the patch off. A balance between strong adhesion and easy removal is essential for patient comfort and usability.

In Vitro Drug Release Studies: In vitro drug release testing is conducted to assess how the drug is released from the patch over time. The patch is placed in a diffusion cell, often filled with simulated saliva or another suitable medium, and the release rate of the drug is measured at various time intervals. These studies help to optimize the drug release profile, ensuring that the patch delivers the drug in a controlled, sustained manner.

Ex-Vivo Permeation Studies: Ex-vivo studies using animal or human buccal mucosa are conducted to simulate how the drug permeates through the mucosal barrier. The permeation studies help evaluate the bioavailability of the drug when applied to the buccal mucosa and assess the rate and extent of absorption.

Stability Studies: Stability testing is essential for determining how well the buccal patch maintains its integrity, drug content, and effectiveness over time under various environmental conditions, such as temperature, humidity, and light. These studies provide information on the shelf life of the patch and help ensure that it remains safe and effective until its expiration date.

In Vivo Studies: In vivo studies, usually involving animal models or clinical trials, are essential to assess the pharmacokinetics of the drug delivered through buccal patches. These studies help evaluate the absorption, bioavailability, and therapeutic efficacy of the patch, as well as any potential side effects or adverse reactions.

Sensory Evaluation and Patient Acceptability: Sensory testing is done to assess the comfort and acceptability of the buccal patch. This includes tests for taste, texture, and irritation upon application. Patient feedback is essential, as poor sensory characteristics (such as a bitter taste or discomfort) may lead to poor patient compliance.

CONCLUSION

The conclusion of an article on buccal patches would typically summarize their key characteristics, advantages, limitations, and the future directions in which this drug delivery system might evolve. Buccal patches represent an innovative method of drug delivery, offering a non-invasive, efficient way to administer drugs directly through the buccal mucosa (the lining of the cheek or gums). This system allows for direct absorption into the bloodstream, bypassing the gastrointestinal tract and first-pass metabolism in the liver, which often reduces the bioavailability of many oral drugs. As such, buccal patches can significantly improve the bioavailability of certain drugs, particularly those that would be degraded or poorly absorbed through the gastrointestinal system. The rapid onset of action provided by buccal drug delivery is another major benefit, making this system ideal for drugs requiring fast systemic effects. Moreover, buccal patches are a patient-friendly alternative to injections and oral tablets, offering a painless and convenient method of administration that enhances patient compliance, particularly in long-term treatments.

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