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Buccal Patch: A Novel Approach for Sustained Drug Delivery – A Comprehensive Review

Miss. Pranali Rushi Ghate[1], Dr. Pankaj M. Pimpalshende[1], Snehal Sudhakar Soor[1], Sakshi Ramsingh Naik[1], Ajit Kishor Khapne[2]
Hi-Tech College of Pharmacy, Morwa, Chandrapur, India[1]
Sage University, Indore, MP[2]

Abstract: *Buccal patches represent an innovative and effective platform for sustained drug delivery, offering advantages such as improved bioavailability, prolonged therapeutic effects, and patient compliance. These patches utilize the buccal mucosa as a non-invasive route, bypassing first-pass metabolism and gastrointestinal degradation. This review explores the anatomy and physiology of the buccal mucosa, various types of buccal drug delivery systems, formulation aspects, polymers used, evaluation parameters, and therapeutic applications. Furthermore, challenges associated with buccal patches and emerging technologies such as nanotechnology and bio-responsive polymers are discussed. Future research directions emphasize advancements in permeability enhancers, smart polymers, and personalized medicine approaches to optimize buccal drug delivery.*

Keywords: Buccal patch, sustained drug delivery, mucoadhesion, polymers, bioavailability, nanotechnology, permeation enhancers, formulation development, controlled release

I. INTRODUCTION

Buccal drug delivery is a promising alternative to conventional oral and parenteral routes, offering controlled and sustained drug release through the mucosal lining of the inner cheek. This system is particularly advantageous for drugs with poor gastrointestinal stability, low bioavailability, or extensive first-pass metabolism. The buccal mucosa, with its rich vascularization and relatively permeable epithelial layer, serves as an ideal site for systemic drug absorption. Unlike oral administration, where drugs are subjected to enzymatic degradation and hepatic metabolism, buccal delivery bypasses these processes, ensuring enhanced therapeutic efficacy and improved patient compliance.[1,2]

Buccal patches, in particular, have gained attention as an effective formulation for delivering drugs via the buccal mucosa. These thin, flexible, and bioadhesive dosage forms adhere to the mucosal surface, allowing for prolonged retention and controlled drug release. Compared to other buccal drug delivery systems, such as tablets, gels, and lozenges, buccal patches provide a more consistent and sustained release profile, minimizing fluctuations in plasma drug concentration. Furthermore, their ease of administration, non-invasive nature, and ability to accommodate a wide range of therapeutic agents make them a suitable choice for both systemic and local drug delivery applications.[3,4]

The effectiveness of buccal patches is influenced by several factors, including the physicochemical properties of the drug, the choice of bioadhesive polymers, and the formulation design. An ideal buccal patch should possess sufficient mucoadhesive strength to maintain its position for an extended period while ensuring adequate drug permeation without causing discomfort or irritation. Recent advancements in polymer technology and formulation techniques have further enhanced the efficiency of buccal patches, leading to improved bioavailability and patient convenience. Despite these advantages, challenges such as limited drug loading capacity, variations in mucosal permeability among individuals, and potential discomfort during prolonged use remain areas of active research.

With continuous innovations in pharmaceutical technology, buccal drug delivery is emerging as a viable alternative to traditional drug administration methods. Its ability to provide a controlled release of drugs while bypassing gastrointestinal degradation highlights its potential for treating a variety of conditions, ranging from pain management and hormone therapy to cardiovascular and anti-inflammatory treatments. As research progresses, further optimization

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of buccal patches will likely lead to their broader clinical application, reinforcing their role as a novel and effective drug delivery system.[5,6]

Advantages of Buccal Patches Over Conventional Dosage Forms

Buccal patches offer several advantages over conventional drug delivery systems, making them a preferred choice for both systemic and local drug administration. One of the most significant benefits is the **avoidance of first-pass metabolism**, as drugs absorbed through the buccal mucosa directly enter the systemic circulation via the internal jugular vein, thereby enhancing bioavailability. This is particularly beneficial for drugs with poor oral absorption or extensive hepatic metabolism. Additionally, buccal patches provide a **controlled and sustained release** of the drug, maintaining a steady plasma concentration and reducing the frequency of dosing, which improves therapeutic outcomes and patient compliance.

Another key advantage is their **non-invasive nature**, eliminating the discomfort and potential complications associated with injections or intravenous administration. Unlike tablets or capsules, which may cause gastrointestinal irritation or degradation due to acidic pH and enzymatic activity, buccal patches offer **protection against harsh gastrointestinal conditions**, ensuring drug stability and efficacy. Furthermore, buccal patches **facilitate rapid onset of action**, especially for drugs that require immediate therapeutic effects, as absorption through the buccal mucosa is faster than oral ingestion.

Buccal patches also provide **enhanced patient convenience**, as they are discreet, easy to administer, and do not require water for ingestion, making them suitable for elderly patients or those with swallowing difficulties (dysphagia). Additionally, these patches allow for **dose termination at any time**, as they can be easily removed from the buccal mucosa if adverse effects occur. They also minimize systemic side effects by ensuring localized drug delivery, which is advantageous for conditions such as oral infections, ulcers, or periodontal diseases.[7-10]

Challenges and Limitations of Buccal Patches

Despite their numerous advantages, buccal patches also present certain challenges and limitations that must be addressed to ensure their optimal effectiveness. One of the primary concerns is the **limited surface area of the buccal mucosa**, which restricts the amount of drug that can be absorbed. This makes it difficult to formulate buccal patches for drugs requiring high doses, as only small amounts can permeate the mucosal layer at a given time.

Another significant limitation is **interindividual variability in buccal permeability**, as factors such as age, diet, salivary flow rate, and mucosal thickness can influence drug absorption. The presence of **saliva and continuous mucosal turnover** can also affect the retention time of the patch, leading to inconsistent drug delivery. Additionally, patients may experience **discomfort, irritation, or an unpleasant taste**, which could lead to poor compliance, especially for long-term therapies.

Formulation challenges also exist, particularly in achieving **optimal mucoadhesion without causing excessive stickiness or difficulty in removal**. The selection of suitable polymers and excipients is crucial to ensure prolonged adhesion without compromising patient comfort. Moreover, **enzyme degradation within the oral cavity** may affect the stability and efficacy of certain drugs, requiring the incorporation of enzyme inhibitors or protective coatings.

From a manufacturing perspective, the development of buccal patches involves **specialized formulation techniques and polymer selection**, which may increase production costs compared to conventional oral dosage forms. Additionally, **regulatory hurdles and standardization issues** pose challenges in ensuring uniform drug release, stability, and patient acceptability across different formulations.

Despite these challenges, ongoing research in polymer science, drug permeation enhancers, and innovative formulation techniques continues to improve the effectiveness of buccal patches. By addressing these limitations, buccal drug delivery systems have the potential to become a mainstream alternative to traditional dosage forms, particularly for drugs requiring controlled and targeted release.[11-15]

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II. ANATOMY AND PHYSIOLOGY OF THE BUCCAL MUCOSA

The buccal mucosa serves as a promising route for drug delivery due to its unique anatomical and physiological characteristics. Understanding its structure, permeability, and factors influencing drug absorption is crucial for designing effective buccal drug delivery systems.

Structure and Function of the Buccal Mucosa

The buccal mucosa refers to the inner lining of the cheeks, which plays a vital role in protecting the oral cavity while facilitating essential functions such as mastication, lubrication, and speech. It consists of multiple layers, primarily the **epithelium, basement membrane, lamina propria, and submucosa**, each contributing to its barrier properties and permeability.

Epithelium: The outermost layer of the buccal mucosa is composed of stratified squamous epithelium, which is non-keratinized in most areas, making it more permeable than keratinized regions like the gingiva and hard palate. The epithelium functions as a protective barrier while allowing selective drug absorption.

Basement Membrane: This thin layer of connective tissue supports the epithelium and plays a role in cellular adhesion and filtration of substances.

Lamina Propria: This layer consists of connective tissue rich in blood capillaries and lymphatic vessels, facilitating rapid drug absorption and systemic distribution.

Submucosa: The deepest layer contains minor salivary glands, blood vessels, and nerves, contributing to mucosal hydration and local immune responses.

The buccal mucosa is **highly vascularized**, which enables direct systemic drug absorption while bypassing hepatic first-pass metabolism. Additionally, it exhibits **moderate enzymatic activity**, which is lower than that found in the gastrointestinal tract, making it a suitable route for drugs that are susceptible to enzymatic degradation.

Permeability and Drug Absorption Mechanisms

Drug absorption through the buccal mucosa occurs primarily via **passive diffusion**, where molecules traverse the epithelial membrane down a concentration gradient. Two key pathways facilitate this process:

Transcellular Pathway (Intracellular Transport):

Drugs diffuse across the lipid bilayer of epithelial cells, making this route more favorable for **lipophilic (fat-soluble) drugs** with low molecular weight.

The presence of tight junctions between epithelial cells limits the permeability of hydrophilic and large molecules.

Paracellular Pathway (Intercellular Transport):

Hydrophilic drugs and macromolecules diffuse through the intercellular spaces between epithelial cells.

This pathway is less efficient due to the presence of tight junctions that restrict drug movement.

Additionally, **carrier-mediated transport and endocytosis** may play a role in the uptake of certain drugs, particularly peptides and proteins. However, enzymatic degradation within the mucosa and saliva can limit the bioavailability of such molecules.

Factors Affecting Drug Permeation

Several factors influence the rate and extent of drug permeation through the buccal mucosa, which must be considered in buccal drug delivery system design:

1. Physiological Factors

Mucosal Thickness: The buccal mucosa is thicker (~500–800 µm) than the sublingual mucosa, resulting in slower drug absorption.

Blood Supply: High vascularization ensures rapid systemic absorption once the drug crosses the epithelial barrier.

Salivary Flow: Continuous saliva secretion (~0.5–1.5 L/day) can dilute drugs, affecting retention time and absorption.

2. Physicochemical Properties of the Drug

Molecular Weight and Size: Smaller molecules (<500 Da) diffuse more easily through the mucosal membrane.

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Lipophilicity: Lipid-soluble drugs exhibit better transcellular absorption, whereas hydrophilic drugs rely on limited paracellular transport.
Ionization and pH: Drugs in their **unionized form** exhibit higher permeability compared to their ionized counterparts. The pH of saliva (~6.2–7.4) affects drug ionization and absorption efficiency.

3. Formulation Factors
Use of Mucoadhesive Polymers: Enhances drug retention and prolongs mucosal contact time.
Penetration Enhancers: Substances like surfactants, fatty acids, and bile salts can modify epithelial lipid structures, improving drug permeation.
Enzyme Inhibitors: Reduce enzymatic degradation of peptide-based drugs, enhancing bioavailability.
By understanding the structure, permeability, and influencing factors of the buccal mucosa, researchers can optimize buccal drug delivery systems to achieve sustained and effective therapeutic outcomes.

III. TYPES OF BUCCAL DRUG DELIVERY SYSTEMS

Buccal drug delivery systems are designed to deliver drugs through the mucosal lining of the cheek for either **local** or **systemic effects**. These systems bypass hepatic first-pass metabolism, offer sustained drug release, and improve patient compliance. The selection of a suitable buccal formulation depends on factors such as drug properties, intended therapeutic effect, and patient convenience.

1. Buccal Tablets
Buccal tablets are **small, flat, and compact dosage forms** designed to adhere to the buccal mucosa and gradually release the drug over time. They are typically formulated using bioadhesive polymers that allow prolonged contact with the mucosa, ensuring effective drug absorption.
Advantages:
Provide **controlled and sustained drug release**.
Avoid **gastrointestinal degradation and first-pass metabolism**.
Can be easily removed in case of adverse reactions.
Limitations:
May cause **discomfort or irritation** at the application site.
Saliva production may **affect adhesion and drug retention**.
Limited to **small doses of highly potent drugs**.

2. Buccal Gels and Ointments
Buccal gels and ointments are **semi-solid formulations** that can be applied directly to the buccal mucosa for local or systemic drug delivery. These formulations are useful for treating oral infections, inflammation, and pain.
Advantages:
Provide **rapid drug absorption** for immediate therapeutic effects.
Can be **easily applied and spread over a larger area**.
Suitable for **localized treatment** of oral ulcers, fungal infections, and periodontal diseases.
Limitations:
Poor **residence time** due to dilution and removal by saliva.
Drug **distribution may be uneven**, leading to variable absorption.
Less effective for **sustained drug release** compared to patches and films.

3. Buccal Films and Patches (Focus on Patches)
Buccal films and patches are **thin, flexible, and mucoadhesive formulations** designed to adhere to the buccal mucosa and deliver drugs in a controlled manner. These systems are particularly advantageous for **prolonged drug release and improved bioavailability**.

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Buccal Films

Buccal films are **polymeric strips** that dissolve or erode over time, releasing the drug into the mucosa. They are commonly formulated with **water-soluble polymers** like hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), and polyethylene glycol (PEG).

Advantages:

Thin and flexible, making them comfortable for patients.

Provide **rapid or controlled drug release**, depending on formulation.

Can be **designed for unidirectional or bidirectional release**.

Limitations:

Fragile and prone to **mechanical damage** during handling.

Limited drug-loading capacity.

Buccal Patches (Primary Focus)

Buccal patches are **mucoadhesive polymeric films** that adhere to the buccal mucosa, ensuring **sustained and controlled drug release**. These patches are categorized into **reservoir and matrix-type systems** based on drug incorporation.

Matrix-Type Patches: The drug is uniformly dispersed in the polymer matrix and released gradually as the polymer dissolves or swells.

Reservoir-Type Patches: The drug is contained in a separate reservoir, allowing for **controlled release through a rate-controlling membrane**.

Advantages of Buccal Patches:

Prolonged retention time due to strong mucoadhesion.

Controlled and sustained drug release, enhancing therapeutic efficacy.

Bypass of first-pass metabolism, increasing bioavailability.

Improved patient compliance, as they are discreet and non-invasive.

Minimized systemic side effects due to localized drug action.

Limitations of Buccal Patches:

Formulation challenges in achieving **optimal adhesion and flexibility**.

Variability in **saliva flow and mucosal permeability** may affect drug absorption.

Unpleasant taste or irritation may reduce patient acceptability.

Among various buccal drug delivery systems, **buccal patches** are emerging as one of the most effective and patient-friendly dosage forms due to their **controlled drug release, bioadhesion, and ease of use**. Ongoing advancements in **polymeric formulations, penetration enhancers, and novel drug-loading techniques** continue to enhance their potential in both **local and systemic drug delivery applications**.[16-25]

IV. BUCCAL PATCHES: AN OVERVIEW

Buccal patches are **mucoadhesive drug delivery systems** designed to adhere to the buccal mucosa and release drugs in a controlled manner for **local or systemic effects**. They provide **prolonged drug retention**, enhance **bioavailability**, and avoid **first-pass metabolism**, making them an attractive alternative to conventional oral drug delivery methods.

1. Definition and Classification

Definition:

Buccal patches are **thin, flexible polymeric films** that adhere to the buccal mucosa, allowing the drug to be absorbed either **directly into the systemic circulation** or **locally at the site of application**. They are primarily designed for **sustained and controlled drug release**, ensuring improved therapeutic efficacy and patient compliance.

Classification of Buccal Patches:

Buccal patches can be classified based on:

A. Drug Incorporation Method

Matrix-Type Patches – The drug is uniformly dispersed within the polymeric matrix, and release occurs through **diffusion and erosion**.

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Reservoir-Type Patches – The drug is stored in a separate **reservoir layer**, with release controlled by a **rate-controlling membrane**.

B. Bioadhesion Mechanism

Hydrophilic Patches – Composed of **water-soluble polymers** that swell upon hydration and adhere to the mucosa.

Hydrophobic Patches – Made from **water-insoluble polymers**, providing **prolonged adhesion and slower drug release**.

C. Degradation Mechanism

Non-Dissolving Patches – Remain intact after drug release and must be removed after use.

Dissolving Patches – Gradually dissolve in saliva, leaving no residue.

2. Mechanism of Drug Release

The drug release from buccal patches follows **three primary mechanisms**:

1. Diffusion-Controlled Release

The drug diffuses from the polymeric matrix or reservoir system **through the polymer membrane** into the buccal mucosa.

This is commonly observed in **matrix and reservoir-type patches**.

2. Swelling-Controlled Release

The polymer swells upon contact with saliva, forming a **gel layer** through which the drug gradually diffuses.

This mechanism is observed in **hydrophilic patches**.

3. Erosion-Controlled Release

The polymeric matrix **gradually erodes**, leading to **drug release** over time.

Seen in **water-soluble and biodegradable polymer-based patches**.

3. Factors Influencing Formulation Design

1. Drug Properties

Solubility: Highly soluble drugs diffuse faster, while poorly soluble drugs may require **solubilizers** or **permeation enhancers**.

Molecular weight: Lower molecular weight drugs penetrate the mucosa **more easily**.

pKa and ionization: Unionized drugs have **higher permeability** than ionized forms.

2. Polymer Selection

Mucoadhesive Polymers (e.g., chitosan, HPMC, PVA) ensure **strong adhesion and prolonged drug retention**.

Biodegradable Polymers (e.g., PCL, PLGA) allow for **controlled degradation and release**.

Hydrophilic vs. Hydrophobic Polymers: Selection depends on **desired drug release rate and mucoadhesion properties**.

3. Mucoadhesive Strength

Optimal **bioadhesion time** ensures **prolonged drug absorption** while avoiding discomfort or excessive irritation.

Polymers like **carbopol, chitosan, and sodium alginate** are commonly used for strong adhesion.

4. Drug Permeability Enhancers

Agents such as **surfactants (e.g., sodium lauryl sulfate), bile salts, and fatty acids** improve drug permeation through the buccal mucosa.

Careful selection is necessary to **avoid mucosal irritation**.

5. Patch Thickness and Size

Thinner patches ensure patient comfort, but **sufficient thickness is needed for drug loading**.

Patch size should allow ease of application without affecting speech or saliva flow.

6. Release Modifiers

Hydrophilic polymers like **PEG** accelerate drug release, while hydrophobic agents like **ethyl cellulose** slow down the process.

Crosslinking agents and **pH modifiers** can be used to tailor drug release profiles.

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7. Stability and Storage Conditions

Buccal patches must maintain **mechanical integrity** and **drug stability** under varying temperature and humidity conditions.

Protective **packaging materials** (e.g., aluminum foil, blister packs) help prevent degradation.

Buccal patches represent a **novel, patient-friendly approach** for **controlled and sustained drug delivery**. Their **mucoadhesive properties**, ability to **bypass hepatic metabolism**, and **enhanced bioavailability** make them a promising drug delivery system. Further advancements in **polymers, permeation enhancers, and nanotechnology** continue to improve their efficacy and expand their therapeutic applications.

Polymers Used in Buccal Patch Formulations

Polymers play a crucial role in **buccal patch formulations**, influencing their **mucoadhesion, drug release, mechanical strength, and overall effectiveness**. The choice of polymer depends on factors such as **drug solubility, permeability, and intended duration of action**. Polymers used in buccal patches can be broadly classified into **natural polymers**, **synthetic polymers**, and **mucoadhesive polymers**.[26-32]

1. Natural Polymers

Natural polymers are widely used in buccal patches due to their **biocompatibility, biodegradability, and non-toxic nature**. These polymers often exhibit excellent **mucoadhesive properties**, ensuring prolonged drug retention.

Commonly Used Natural Polymers:

Chitosan

A **cationic polymer** derived from chitin.

Exhibits **mucoadhesion** due to ionic interactions with negatively charged mucosal surfaces.

Enhances **drug permeation** through tight junction modulation.

Gelatin

A **protein-based polymer** with excellent **film-forming properties**.

Provides **good mechanical strength** but may require crosslinking to control swelling.

Sodium Alginate

A **polysaccharide** derived from brown algae.

Forms **gel-like structures** in the presence of divalent cations (e.g., Ca^{2+}), improving **mucoadhesion**.

Offers **controlled drug release** in hydrophilic formulations.

Pectin

A plant-derived polysaccharide with **bioadhesive and gelling properties**.

Enhances **hydration and swelling** for prolonged **drug release**.

Xanthan Gum & Guar Gum

Used as **viscosity enhancers** and **mucoadhesive agents**.

Improve **film elasticity** and **hydration capacity** for controlled release.

2. Synthetic Polymers

Synthetic polymers are often preferred due to their **consistent quality, tunable properties, and controlled degradation rates**. These polymers improve **film strength, drug stability, and flexibility** of buccal patches.

Commonly Used Synthetic Polymers:

Hydroxypropyl Methylcellulose (HPMC)

Most commonly used **film-forming polymer**.

Provides **excellent mucoadhesion** and **controlled drug release**.

Available in different viscosity grades (HPMC K4M, K15M, K100M) for modifying release properties.

Polyvinyl Alcohol (PVA)

A **water-soluble, flexible polymer** with **good film-forming capacity**.

Often combined with other **mucoadhesive polymers** for enhanced adhesion.

Polyvinylpyrrolidone (PVP)

Acts as a **binder and film-forming agent**.

Improves **drug solubility** and enhances **patch flexibility**.

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Eudragit Polymers (Eudragit RL, RS, E, and L series)
Eudragit RL and RS: Used for **controlled drug release**.
Eudragit E: Provides **mucoadhesive properties** and is soluble in acidic pH.
Eudragit L: Allows **pH-dependent drug release**, protecting drugs from degradation.
Ethyl Cellulose (EC)
A **water-insoluble polymer** providing **prolonged drug release**.
Used in **reservoir-type buccal patches** to control drug diffusion.

3. Mucoadhesive Polymers and Their Role in Bioadhesion

Mucoadhesive polymers are essential in buccal patches as they **prolong drug retention**, **improve absorption**, and **enhance patient compliance**. They interact with the buccal mucosa through:

Mucoadhesion Mechanisms:

Electrostatic Interaction: Ionic interactions between **cationic polymers (e.g., chitosan)** and **negatively charged mucosal surfaces**.

Hydrogen Bonding: Polymers like **HPMC, PVP, and carbopol** form hydrogen bonds with mucosal glycoproteins.

Hydrophobic Interactions: Hydrophobic polymers, such as **Eudragit RL and RS**, can enhance mucoadhesion through **van der Waals forces**.

Diffusion and Entanglement: Polymers like **carbopol and alginate** penetrate mucosal glycoproteins, leading to **strong adhesion**.

Key Mucoadhesive Polymers:

Carbopol (Carbomer 934, 940, 971P)
One of the most effective **mucoadhesive agents**.
Exhibits **strong bioadhesion** due to hydrogen bonding and swelling.
Often combined with **HPMC or chitosan** for optimized drug release.
Chitosan
Enhances **mucoadhesion and permeation** due to its cationic nature.
Used in **bioadhesive patches** for controlled release formulations.
Sodium CMC (Carboxymethyl Cellulose)
Forms **viscous, bioadhesive gels** for sustained **drug release**.
Pectin and Xanthan Gum
Used in combination with other polymers to **enhance mucoadhesion**.
HPMC and PVP
Act as **mucoadhesive binders**, improving film strength and adhesion.

The selection of an **appropriate polymer or combination of polymers** is crucial in **designing effective buccal patches**. While **natural polymers** offer **biocompatibility**, **synthetic polymers** provide **mechanical strength and tunable release properties**. **Mucoadhesive polymers** enhance **drug retention and absorption**, making them essential for **sustained and controlled buccal drug delivery systems**.[33-45]

Formulation and Development of Buccal Patches

Buccal patches are **mucoadhesive drug delivery systems** designed for **sustained and controlled drug release** via the buccal mucosa. The formulation and development of these patches involve **careful selection of drug candidates, excipients, and preparation methods** to ensure **optimal adhesion, drug permeation, and patient compliance**.

1. Selection of Drug Candidates

The selection of drugs for buccal patch formulation depends on the **physicochemical properties and therapeutic requirements**. Ideal candidates should:

Exhibit **high first-pass metabolism** (e.g., propranolol, nitrates).
Have **low molecular weight (<500 Da)** for better permeability.
Possess **moderate lipophilicity** (Log P between 1-3) to enhance absorption.
Have **good solubility in both aqueous and lipid phases**.
Require **prolonged action and controlled release**.

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Be **chemically stable and non-irritating** to the buccal mucosa.

Examples of Drugs Suitable for Buccal Patches:

Analgesics: Fentanyl, Buprenorphine

Cardiovascular drugs: Propranolol, Nifedipine

Hormones: Testosterone, Insulin

Anti-inflammatory drugs: Diclofenac, Ketorolac

Antiemetics: Ondansetron

Antihypertensive agents: Captopril

2. Excipients Used in Buccal Patch Formulations

Excipients play a crucial role in **patch flexibility, drug stability, mucoadhesion, and permeation enhancement**.

Key Excipients and Their Functions:

Mucoadhesive Polymers

Provide **adhesion to the buccal mucosa**.

Examples: **Chitosan, HPMC, PVP, Carbopol, Sodium CMC, Pectin**.

Plasticizers

Improve **patch flexibility and mechanical strength**.

Reduce **brittleness** and enhance **film-forming properties**.

Examples: **Glycerin, Propylene Glycol, Polyethylene Glycol (PEG 400, PEG 600), Dibutyl Phthalate**.

Permeation Enhancers

Improve **drug absorption** through the buccal mucosa.

Examples: **Sodium Lauryl Sulfate (SLS), Tween 80, DMSO, Azone, Menthol, Oleic Acid**.

Stabilizers

Enhance **drug stability** and prevent **degradation**.

Examples: **Ascorbic Acid, EDTA, Citric Acid, BHT (Butylated Hydroxytoluene)**.

Backing Layer

Ensures **unidirectional drug release** by preventing drug loss.

Examples: **Ethyl Cellulose, Eudragit RS100, Polyvinyl Acetate**.

3. Methods of Preparation

Several methods are employed in the formulation of buccal patches, depending on **drug properties, excipients, and desired release profile**.

A. Solvent Casting Method *(Most Commonly Used)*

Steps:

Drug and polymers are dissolved in a **suitable solvent** (e.g., water, ethanol).

Excipients like **plasticizers and permeation enhancers** are added.

The mixture is **poured into a casting mold** or Petri dish.

It is **dried at a controlled temperature** to form a **thin patch**.

The dried film is **cut into desired shapes and sizes**.

Advantages:

Simple and cost-effective.

Produces **uniform thickness patches**.

Suitable for **heat-sensitive drugs**.

Disadvantages:

Residual solvent may remain in the final formulation.

Longer drying time required.

B. Hot-Melt Extrusion (HME) Method

Steps:

The drug and polymer are **melted together** in an extruder.

The molten mass is **extruded through a die** into a thin film.

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The film is **cooled and cut** into patches.

Advantages:

Solvent-free process (no residual solvents).

Produces **highly uniform films**.

Enhances **drug solubility** (suitable for poorly soluble drugs).

Disadvantages:

High processing temperature (may degrade heat-sensitive drugs).

Requires **specialized equipment**.

C. Spray Drying Method

Steps:

The drug and polymer are dissolved in a **volatile solvent**.

The solution is **atomized into fine droplets** using a spray nozzle.

Droplets are rapidly dried using **hot air**, forming microparticles.

The microparticles are **compressed into thin films**.

Advantages:

Suitable for **thermally sensitive drugs**.

Produces **fine, uniform films**.

Allows **modification of particle size** for better control of drug release.

Disadvantages:

High production cost.

Complex process requiring precise control of drying conditions.

4. Optimization Techniques for Buccal Patch Formulation

To achieve an **optimized buccal patch formulation**, various techniques are employed:

A. Factorial Design (DOE - Design of Experiments)

Example: 3^2 factorial design (evaluates the effect of two independent variables at three levels each).

Helps in optimizing **drug release, adhesion time, and mechanical strength**.

B. Response Surface Methodology (RSM)

Used to analyze the **interaction effects of formulation variables**.

Helps in achieving **optimal drug release and mucoadhesive properties**.

C. Box-Behnken Design

A **statistical optimization tool** for understanding **multiple formulation parameters**.

D. Artificial Neural Networks (ANN)

Uses computational modeling to **predict drug release behavior**.

Helps in **fine-tuning formulation parameters**.

The formulation and development of buccal patches require **careful selection of drugs, excipients, and manufacturing methods**. **Solvent casting remains the most widely used technique**, while **hot-melt extrusion and spray drying offer advanced formulation advantages**. Optimization techniques like **factorial design and RSM** ensure **effective drug release and enhanced bioavailability**, making buccal patches a **promising alternative to conventional oral dosage forms**.[46-49]

Evaluation and Characterization of Buccal Patches

The successful development of a buccal patch requires **comprehensive evaluation and characterization** to ensure **optimal drug release, bioadhesion, and mechanical stability**. Various **physicochemical, mechanical, in vitro, ex vivo, and in vivo tests** are conducted to assess the quality, efficacy, and performance of the formulation.

1. Physicochemical Properties

A. Thickness

Measured using **digital micrometers or Vernier calipers**.

Ensures **uniformity of drug distribution** across the patch.

Acceptable range: 0.1–1 mm (depending on formulation).

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B. Weight Uniformity

Determined by **weighing multiple patches individually** using an analytical balance.

Ensures **dose uniformity** and **consistency**.

C. Folding Endurance

Assesses the **flexibility and durability** of the patch.

Determined by **repeatedly folding** the patch at the same place until it breaks or cracks.

A **higher number of folds (>200)** indicates better **mechanical strength and flexibility**.

2. Mechanical Properties

A. Tensile Strength

Measures the **force required to break the patch**.

Evaluated using a **texture analyzer or universal testing machine**.

Higher tensile strength ensures **patch integrity during application**.

B. Swelling Index

Determines the **hydration ability of the patch** in simulated saliva.

Patch weight is measured **before and after swelling** in phosphate buffer (pH 6.8).

Higher swelling may enhance **drug release and mucoadhesion**.

C. Bioadhesive Strength

Assesses the **adhesion capability** of the patch to the buccal mucosa.

Measured using a **bioadhesion tester or modified balance method**.

A **higher bioadhesive force** ensures prolonged retention on the buccal mucosa.

3. In Vitro Drug Release Studies

A. Dissolution Studies

Performed using a **USP dissolution apparatus (Type I or Type II)**.

Simulated **buccal fluid (pH 6.8 phosphate buffer)** is used as the dissolution medium.

Samples are withdrawn at specific time intervals and analyzed using **UV-Vis spectroscopy or HPLC**.

B. Release Kinetics

To determine the **drug release mechanism**, the data is fitted into different mathematical models:

Zero-order kinetics (constant drug release).

First-order kinetics (release rate depends on drug concentration).

Higuchi model (release by diffusion mechanism).

Korsmeyer-Peppas model (mechanism based on polymer swelling and diffusion).

4. Ex Vivo and In Vivo Studies

A. Ex Vivo Permeation Studies

Conducted using **excised porcine, bovine, or human buccal mucosa**.

Mucosal tissue is mounted on a **Franz diffusion cell** filled with buffer solution.

Drug permeation is analyzed using **HPLC or spectrophotometry**.

B. Pharmacokinetic Studies (In Vivo)

Determines **bioavailability, Tmax, Cmax, and AUC** of the drug.

Conducted in **animal models (rats, rabbits) or human volunteers**.

Drug levels in plasma are measured using **LC-MS or HPLC**.

C. Pharmacodynamic Evaluations

Assesses **therapeutic efficacy and drug response** in vivo.

Performed in **disease models or healthy volunteers**.

A thorough **evaluation of buccal patches** ensures their **safety, efficacy, and stability**. **Physicochemical, mechanical, in vitro, and in vivo studies** help optimize the formulation, ensuring **consistent drug release and bioadhesion** for effective buccal drug delivery.[50-59]

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Applications of Buccal Patches in Drug Delivery

Buccal patches serve as an **innovative and efficient drug delivery system**, offering both **systemic and local drug delivery** advantages. Their ability to **bypass first-pass metabolism, enhance bioavailability, and provide controlled drug release** makes them a promising alternative to conventional dosage forms.

1. Systemic vs. Local Drug Delivery

A. Systemic Drug Delivery

Buccal patches allow **direct absorption of drugs into systemic circulation**, bypassing the gastrointestinal (GI) tract and hepatic first-pass metabolism. This leads to **improved bioavailability and rapid onset of action**.

Advantages:

Suitable for drugs with **poor oral bioavailability**.

Provides **controlled and prolonged release**.

Reduces **dose frequency**, improving patient compliance.

Examples of drugs for systemic delivery:

Opioid analgesics (e.g., fentanyl for chronic pain).

Hormones (e.g., testosterone and estradiol for hormone replacement therapy).

Cardiovascular drugs (e.g., propranolol for hypertension).

Anti-emetics (e.g., ondansetron for nausea and vomiting).

B. Local Drug Delivery

Buccal patches can be used to **deliver drugs locally**, targeting the buccal mucosa to treat **oral infections, ulcers, and inflammatory conditions**.

Advantages:

Provides **high local drug concentration at the site of action**.

Reduces **systemic side effects**.

Ensures **prolonged contact time with the buccal mucosa**.

Examples of drugs for local delivery:

Antifungals (e.g., miconazole for oral candidiasis).

Analgesics (e.g., benzocaine for oral ulcers and mucosal pain relief).

Anti-inflammatory agents (e.g., corticosteroids for oral lichen planus).

2. Drug Categories Delivered via Buccal Patches

A. Analgesics and Anti-Inflammatory Drugs

Used for **pain relief and inflammation management**.

Examples: **Fentanyl, ketorolac, flurbiprofen, ibuprofen**.

B. Cardiovascular Drugs

Helps in **managing hypertension and angina**.

Examples: **Propranolol, nitrates, verapamil**.

C. Hormonal Therapy

Used for **hormone replacement therapy and endocrine disorders**.

Examples: **Testosterone, estradiol, insulin**.

D. Antiemetics

Effective for **preventing nausea and vomiting**.

Examples: **Ondansetron, metoclopramide**.

E. Antimicrobials and Antifungals

Treats **oral infections and periodontal diseases**.

Examples: **Miconazole, chlorhexidine, acyclovir**.

F. Neurological and Psychiatric Drugs

Used for **seizures, depression, and neurological disorders**.

Examples: **Buprenorphine (opioid dependence), clonazepam (seizures, anxiety disorders)**.

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Buccal patches have **diverse applications** in systemic and local drug delivery. They provide **enhanced bioavailability, controlled release, and patient-friendly administration**, making them a promising alternative to **conventional dosage forms**. The growing number of **clinical studies and marketed products** supports their **therapeutic potential** across multiple drug categories.

Challenges and Future Perspectives of Buccal Patches

Buccal patches offer several advantages for drug delivery; however, **they also face challenges that limit their widespread adoption**. Overcoming these limitations through **novel strategies and technological innovations** is crucial for their future development.

1. Barriers in Buccal Drug Delivery

Despite the promising benefits, **buccal patches encounter several challenges**, including:

A. Physiological Barriers

Limited Surface Area: The buccal mucosa provides a **small absorption area**, restricting the amount of drug that can be delivered.

Saliva Flow and Swallowing: Continuous saliva secretion **dilutes the drug concentration**, leading to **unintended swallowing** and reduced bioavailability.

Mucosal Turnover: The rapid turnover of buccal epithelial cells can **limit drug retention time**.

B. Drug-Related Barriers

Low Permeability: Some drugs have **poor permeability** through the buccal mucosa, limiting their effectiveness.

Taste and Irritation Issues: Many drugs have an **unpleasant taste or cause irritation**, affecting patient compliance.

C. Formulation and Manufacturing Barriers

Adhesion Issues: Achieving optimal **mucoadhesion** without causing discomfort is challenging.

Drug Stability: Drugs with **low stability in saliva** or susceptibility to **enzymatic degradation** face formulation difficulties.

Scalability and Cost: The **high cost of polymers and excipients** used in buccal patches can affect large-scale production.[60-82]

2. Strategies to Overcome Limitations

A. Enhancing Drug Permeability

Use of Permeation Enhancers: Compounds such as **surfactants, bile salts, and cyclodextrins** can improve drug absorption.

Lipid-Based Formulations: Liposomal or nanoemulsion systems **enhance drug transport across the buccal mucosa**.

B. Improving Mucoadhesion and Retention

Mucoadhesive Polymers: Advanced polymers like **thiolated chitosan and carbopol** improve adhesion and retention time.

Multilayer Patches: Combining **backing layers and drug-releasing layers** ensures **prolonged residence and controlled drug release**.

C. Addressing Taste and Irritation

Taste-Masking Technologies: Microencapsulation, complexation with **cyclodextrins**, or polymer coatings help **mask unpleasant tastes**.

pH Modifiers: Adjusting the pH of formulations **reduces irritation** and enhances drug solubility.

3. Innovations in Buccal Patches

A. Nanotechnology-Based Approaches

Nanoparticle-Loaded Buccal Patches: Nanoformulations improve **drug solubility, bioavailability, and controlled release**.

Nanofibers and Electrospun Patches: Offer **higher drug loading and faster dissolution**, ideal for rapid drug absorption.

B. Smart and Bio-Responsive Buccal Patches

Stimuli-Responsive Polymers: Patches that release drugs in response to **pH, temperature, or enzyme activity** provide **controlled drug delivery**.

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3D-Printed Buccal Patches: Advanced **personalized medicine** approach that enables **customized drug dosing**.

C. Multifunctional Buccal Patches

Combination Therapy Patches: Co-delivery of multiple drugs in a **single patch** for synergistic effects.

Self-Healing Hydrogels: Mucoadhesive hydrogels that **repair themselves upon mucosal interaction**, improving drug retention.[83-96]

V. CONCLUSION

Buccal patches offer a promising strategy for sustained and controlled drug delivery, ensuring improved patient compliance, reduced dosing frequency, and enhanced drug bioavailability. Despite challenges such as limited absorption area, salivary washout, and formulation complexities, advancements in permeation enhancers, mucoadhesive polymers, and nanotechnology are driving innovation in this field. The integration of bio-responsive materials, personalized 3D-printed patches, and AI-driven optimization techniques will further enhance their potential in pharmaceutical applications. Future research should focus on overcoming physiological barriers and regulatory challenges to facilitate widespread clinical adoption.

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