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MUCOADHESIVE BUCCAL FILMS FOR ORAL DRUG DELIVERY SYSTEM: A REVIEW

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ABSTRACT

Mucoadhesive buccal films are an advanced drug delivery system that adheres to the buccal mucosa, enabling controlled drug release directly into the systemic circulation while bypassing hepatic first-pass metabolism and gastrointestinal degradation. They offer improved bioavailability, rapid onset of action, enhanced patient compliance, ease of administration, and the option to discontinue therapy by removing the film. Their performance depends on the appropriate selection of mucoadhesive polymers, plasticizers, permeation enhancers, and other excipients. Buccal films are commonly prepared using techniques such as solvent casting, hot-melt extrusion, and semisolid casting, followed by evaluation of their mechanical, physicochemical, mucoadhesive, and drug release properties. Recent advances in polymer science and nanotechnology have expanded their application for delivering peptides, proteins, vaccines, and poorly bioavailable drugs. This review highlights the anatomy of the buccal mucosa, mechanisms of mucoadhesion, formulation strategies, manufacturing methods, evaluation parameters, therapeutic applications, recent developments, challenges, and future prospects of mucoadhesive buccal films as an effective oral drug delivery platform.

KEYWORDS: Mucoadhesion, Buccal film, Buccal drug delivery, Oral mucosa, Mucoadhesive polymers, Controlled drug delivery, Permeation enhancers.

INTRODUCTION

The oral route remains the most preferred and widely accepted method for drug administration because of its convenience, safety, cost-effectiveness, and high patient acceptance. Conventional oral dosage forms such as tablets, capsules, and syrups are commonly prescribed for the treatment of both acute and chronic diseases. However, many therapeutic agents exhibit poor oral bioavailability due to degradation in the gastrointestinal tract, instability in acidic gastric conditions, enzymatic metabolism, and extensive hepatic first-pass metabolism. These limitations often result in reduced therapeutic efficacy, increased dosing frequency, and greater variability in clinical outcomes. Consequently, there has been significant interest in developing alternative drug delivery systems capable of overcoming these drawbacks while improving therapeutic performance. Among the various transmucosal drug delivery routes, the buccal route has gained considerable attention because it provides direct access to the systemic circulation through the richly vascularized buccal mucosa. Drugs administered through the buccal cavity can bypass hepatic first-pass metabolism and avoid gastrointestinal degradation, leading to improved bioavailability and faster onset of action. Furthermore, the buccal route is non-invasive, easily accessible, and allows the dosage form to be removed if adverse effects occur, making it particularly advantageous for both local and systemic drug delivery. Mucoadhesive buccal films represent one of the most promising advancements in buccal drug delivery technology. These films are thin, flexible polymeric formulations designed to adhere firmly to the buccal mucosal surface for a predetermined period. Upon application, the film hydrates in the presence of saliva, forming an intimate contact with the mucosal tissue through mucoadhesion. This close adhesion prolongs the residence time of the dosage form, facilitates controlled or sustained drug release, and enhances drug absorption

across the buccal epithelium. The development of mucoadhesive buccal films involves careful selection of bioadhesive polymers, plasticizers, permeation enhancers, sweeteners, flavoring agents, and active pharmaceutical ingredients. The physicochemical properties of these components significantly influence film flexibility, mechanical strength, drug release kinetics, patient acceptability, and overall therapeutic efficacy. Advances in polymer science have enabled the fabrication of films with improved mucoadhesive strength, enhanced drug permeability, and superior stability. Mucoadhesive buccal films have demonstrated significant potential in delivering drugs with poor gastrointestinal absorption, short biological half-lives, extensive first-pass metabolism, and low oral bioavailability. They have also been investigated for the administration of peptides, proteins, vaccines, antifungal agents, analgesics, antihypertensive drugs, antiemetics, and various other therapeutic agents. The incorporation of nanotechnology and novel drug carriers into buccal films has further enhanced their capability to achieve targeted and controlled drug delivery. In recent years, increasing research has focused on developing patient-centric dosage forms that improve therapeutic outcomes while enhancing patient compliance. Buccal films are particularly beneficial for pediatric, geriatric, and dysphagic patients who experience difficulty swallowing conventional tablets and capsules. Their ease of administration, portability, precise dosing, and rapid dissolution make them an attractive alternative to traditional dosage forms. This review aims to provide a comprehensive overview of mucoadhesive buccal films, including the anatomy and physiology of the buccal mucosa, mechanisms and theories of mucoadhesion, formulation components, methods of preparation, evaluation parameters, therapeutic applications, recent advances, and future perspectives. Understanding these aspects will facilitate the rational design and successful development of effective mucoadhesive buccal film formulations for improved drug delivery.

Buccal Drug Delivery System: Overview

The buccal drug delivery system is a specialized transmucosal drug delivery approach in which a pharmaceutical formulation is applied to the inner lining of the cheek (buccal mucosa) to achieve local or systemic therapeutic effects. Unlike conventional oral dosage forms, buccal formulations deliver drugs directly across the buccal mucosa into the systemic circulation, thereby bypassing the gastrointestinal tract and hepatic first-pass metabolism. This enhances drug bioavailability and minimizes degradation caused by the acidic gastric environment and digestive enzymes.

The buccal cavity is considered an ideal site for drug delivery due to its rich vascularization, relatively large surface area, ease of access, and low enzymatic activity. These characteristics make the buccal route particularly suitable for drugs that exhibit poor gastrointestinal absorption, extensive first-pass metabolism, or instability in the gastrointestinal tract. In addition, buccal administration is non-invasive, painless, and allows easy termination of therapy by removing the dosage form when necessary, thereby improving patient compliance.

Growing interest in patient-centric drug delivery has led to the development of various buccal dosage forms, including tablets, patches, films, gels, ointments, and sprays. Among these, mucoadhesive buccal films have gained significant attention because of their thin, flexible structure, ease of application, comfort, and ability to provide prolonged mucosal adhesion with controlled and sustained drug release. These advantages make buccal films a promising platform for effective and convenient drug delivery.

Advantages of Buccal Drug Delivery System

The buccal drug delivery system offers several therapeutic and pharmaceutical advantages over conventional oral dosage forms, making it an effective alternative for both local and systemic drug administration. Key advantages include:

- Bypasses hepatic first-pass metabolism, resulting in improved bioavailability.
- Avoids gastrointestinal degradation, making it suitable for drugs unstable in gastric fluids or intestinal enzymes.
- Provides rapid onset of action due to the rich vascularization of the buccal mucosa.
- Enhances patient compliance as it is non-invasive, painless, and easy to administer.
- Allows controlled and sustained drug release, maintaining therapeutic drug levels for extended periods.
- Enables easy termination of therapy by simply removing the dosage form if required.
- Suitable for patients with swallowing difficulties, including pediatric, geriatric, and bedridden patients.
- Reduces dosing frequency, which may improve treatment adherence.
- Offers both local and systemic drug delivery, depending on the formulation and therapeutic need.
- Minimizes gastrointestinal side effects associated with conventional oral administration.
- Provides accurate dosing with reduced variability in drug absorption.
- Improves patient comfort and convenience, particularly with mucoadhesive films that are thin, flexible, and discreet.

These advantages have made buccal drug delivery an attractive platform for delivering drugs with poor oral bioavailability, extensive first-pass metabolism, and those requiring rapid or sustained therapeutic effects.

Limitations of Buccal Drug Delivery System

Despite its numerous advantages, the buccal route has several limitations that may restrict its widespread application. The major limitations include:

- Limited drug absorption area, as the buccal mucosa provides a relatively small surface for drug permeation.
- Suitable only for potent drugs, since only small doses can be effectively delivered through the buccal mucosa.
- Poor permeability of hydrophilic and high-molecular-weight drugs, which limits the delivery of certain therapeutic agents.
- Continuous saliva secretion may dilute the drug, reduce residence time, and affect drug absorption.
- Unintentional swallowing of the formulation or dissolved drug may decrease bioavailability.
- Interference from eating, drinking, or speaking, which can dislodge the dosage form and reduce therapeutic efficacy.
- Possible irritation or discomfort to the buccal mucosa with prolonged use or due to certain excipients.
- Variability in drug absorption caused by differences in saliva flow, mucosal thickness, and physiological conditions among individuals.
- Limited suitability for drugs with unpleasant taste or odor, unless effective taste-masking strategies are employed.
- Challenges in formulation development, including achieving adequate mucoadhesion, mechanical strength, and controlled drug release.

Despite these limitations, ongoing advances in mucoadhesive polymers, permeation enhancers, and formulation technologies continue to improve the effectiveness and applicability of buccal drug delivery systems.

Ideal Characteristics of Drugs Suitable for Buccal Delivery

The success of buccal drug delivery largely depends on the physicochemical and pharmacokinetic properties of the drug. An ideal candidate for buccal administration should possess the following characteristics:

- Low dose requirement, preferably less than 20–30 mg, due to the limited absorption area of the buccal mucosa.
- Good permeability across the buccal mucosal membrane to ensure efficient drug absorption.
- Appropriate molecular weight, generally below 500 Da, to facilitate transmucosal transport.
- Balanced lipophilicity and hydrophilicity, enabling effective partitioning into and diffusion through the mucosal membrane.
- Adequate aqueous solubility to allow dissolution in saliva before absorption.
- Stability in saliva and resistance to degradation by buccal enzymes.
- Short biological half-life, making controlled or sustained buccal delivery beneficial.
- Extensive hepatic first-pass metabolism when administered orally, where buccal delivery can significantly improve bioavailability.
- Non-irritant and non-toxic to the buccal mucosa, ensuring patient safety during prolonged contact.
- Pleasant or easily maskable taste and odor, enhancing patient acceptance and compliance.

Drugs possessing these characteristics are considered suitable candidates for buccal drug delivery systems, as they can achieve effective therapeutic outcomes while improving bioavailability, reducing dosing frequency, and enhancing patient compliance.

Anatomy and Physiology of the Buccal Mucosa

A thorough understanding of the anatomy and physiology of the buccal mucosa is essential for the successful design of mucoadhesive drug delivery systems. The oral cavity comprises several anatomical regions, including the tongue, palate, gingiva, floor of the mouth, lips, and cheeks. The buccal mucosa specifically refers to the non-keratinized mucosal lining of the inner cheeks and lips, which serves as an important site for both local and systemic drug delivery.

The buccal mucosa has a surface area of approximately 50 cm^2 and is continuously bathed in saliva, which helps maintain tissue hydration and facilitates drug dissolution. It is richly supplied with blood vessels, allowing drugs absorbed through the buccal membrane to enter the systemic circulation directly while bypassing hepatic first-pass metabolism. The buccal mucosa is lined by non-keratinized stratified squamous epithelium, which is more permeable than the keratinized epithelium of the gingiva and hard palate. This relatively high permeability, combined with its accessibility, low enzymatic activity, and good patient acceptability, makes the buccal mucosa an ideal site for transmucosal drug delivery.

Structure of the Buccal Mucosa

The buccal mucosa is composed of three distinct layers, each contributing to its structural integrity and functional role in drug absorption.

1. Stratified Squamous Epithelium

The stratified squamous epithelium forms the outermost protective layer of the buccal mucosa and acts as the primary barrier to drug permeation. It consists of multiple layers of cells that maintain tissue integrity while regulating the passage of drugs. Unlike the skin and certain regions of the oral cavity, the buccal epithelium is non-keratinized, making it comparatively more permeable and suitable for transmucosal drug delivery.

2. Basement Membrane

Located beneath the epithelium, the basement membrane is a thin extracellular layer that anchors the epithelial cells to the underlying connective tissue. It provides structural support, maintains tissue organization, and

regulates the transport of molecules between the epithelium and the lamina propria.

3. Lamina Propria
The lamina propria is the underlying connective tissue layer composed of collagen and elastic fibers, blood capillaries, lymphatic vessels, nerve endings, fibroblasts, and immune cells. Its rich vascular network enables the rapid uptake of drugs into the systemic circulation after permeation through the epithelium, making it a key component in buccal drug delivery.

Saliva and Its Role in Buccal Drug Delivery
Saliva plays a vital role in the performance of buccal drug delivery systems. It is composed of approximately 99% water, along with electrolytes, proteins, enzymes, immunoglobulins, and mucin glycoproteins. An average healthy adult secretes approximately 0.5–2.0 L of saliva per day, which helps maintain the physiological environment of the oral cavity.

In buccal drug delivery, saliva serves several important functions:

- Hydrates the buccal dosage form, promoting rapid wetting of the formulation.
- Facilitates swelling of mucoadhesive polymers, which enhances adhesion to the mucosal surface.
- Promotes the formation of mucoadhesive bonds between the dosage form and the mucosa.
- Dissolves the drug, enabling its diffusion across the buccal epithelium.
- Maintains the oral pH within the physiological range of 6.2–7.4, which supports drug stability and patient comfort.
- Protects the oral cavity through its antimicrobial proteins, enzymes, and immunoglobulins, thereby maintaining oral health.

Despite these benefits, excessive saliva secretion may reduce the residence time of the dosage form by causing premature drug dilution or washout, which can decrease drug absorption and therapeutic effectiveness. Therefore, buccal formulations should be designed to maintain adequate mucoadhesion and withstand the dynamic conditions of the oral environment.

Drug Absorption Through the Buccal Mucosa
Drug absorption across the buccal mucosa occurs through passive diffusion and mainly follows two transport pathways: the transcellular and paracellular routes. The choice of pathway depends largely on the physicochemical properties of the drug, including its lipophilicity, molecular size, and degree of ionization.

1. Transcellular Pathway
The transcellular pathway involves the passage of drug molecules directly through the epithelial cells by crossing both the apical and basolateral cell membranes. This route is primarily favored by lipophilic (lipid-soluble) drugs, as they can readily partition into the lipid-rich cell membranes and diffuse across the epithelium.

2. Paracellular Pathway
In the paracellular pathway, drug molecules diffuse through the intercellular spaces between adjacent epithelial cells. This route is generally utilized by hydrophilic (water-soluble) drugs; however, its contribution to drug absorption is limited because the intercellular spaces are restricted by tight junctions, which reduce the permeability of larger or highly polar molecules.

The efficiency of buccal drug absorption is influenced by several factors, including the molecular weight, lipophilicity, degree of ionization, and aqueous solubility of the drug. In addition, physiological factors such as saliva flow rate, residence time of the dosage form, and the integrity of the buccal mucosa affect drug permeation. Formulation-related factors, including the selection of mucoadhesive polymers, permeation enhancers, and other excipients, also play a critical role in improving drug absorption and overall therapeutic efficacy.

Mucoadhesion
Definition
Mucoadhesion is the process by which a natural or synthetic polymer adheres to a biological mucosal surface through physical, chemical, or mechanical interactions. In buccal drug delivery, mucoadhesion plays a crucial role in prolonging the residence time of the dosage form at the site of application, thereby enhancing drug absorption, improving bioavailability, and increasing therapeutic efficacy.

Mucoadhesive polymers absorb moisture from saliva and undergo swelling, enabling intimate contact with the mucus layer covering the buccal mucosa. This close interaction results in the formation of adhesive bonds that retain the dosage form at the application site for an extended period, allowing sustained drug release.

Mechanism of Mucoadhesion
Mucoadhesion is generally considered a two-stage process involving contact and consolidation.

Stage I: Contact Stage
During the initial stage, the dosage form comes into close contact with the buccal mucosa. Hydration of the mucoadhesive polymer by saliva causes swelling and spreading over the mucosal surface, thereby increasing the contact area and facilitating adhesion.

Stage II: Consolidation Stage
Following hydration, polymer chains interpenetrate with mucin glycoprotein chains present in the mucus layer. The adhesion is further strengthened through secondary intermolecular interactions, including hydrogen bonding, van der Waals forces, electrostatic attractions, and

hydrophobic interactions. These interactions ensure firm attachment of the dosage form to the mucosal surface.

The extent and duration of mucoadhesion are influenced by several factors, such as the molecular weight and concentration of the polymer, degree of hydration, polymer chain flexibility, cross-linking density, environmental pH, mucus turnover rate, and the nature of the mucosal surface.

Importance of Mucoadhesion

Mucoadhesion offers several advantages that contribute to the effectiveness of buccal drug delivery systems, including:

- Prolongs the residence time of the dosage form at the site of application.
- Enhances drug absorption across the buccal mucosa.
- Improves systemic bioavailability by maintaining close contact with the absorption site.
- Provides controlled and sustained drug release.
- Reduces dosing frequency and improves therapeutic outcomes.
- Increases patient compliance through prolonged and effective drug action.
- Enables targeted local therapy when required.
- Minimizes drug loss due to continuous saliva flow and swallowing.

CONCLUSION

Mucoadhesive buccal films have emerged as a promising and patient-friendly oral transmucosal drug delivery system, offering significant advantages over conventional oral dosage forms. By adhering to the buccal mucosa, these films enable controlled and targeted drug delivery while bypassing hepatic first-pass metabolism and gastrointestinal degradation, thereby improving bioavailability and therapeutic efficacy. Their thin, flexible nature, ease of administration, and ability to provide sustained drug release contribute to enhanced patient compliance, particularly among pediatric, geriatric, and dysphagic patients. The performance of mucoadhesive buccal films is influenced by the appropriate selection of polymers, plasticizers, permeation enhancers, and other formulation components, as well as optimized manufacturing techniques. Advances in polymer science, nanotechnology, and formulation strategies have further expanded the potential of buccal films for delivering a wide range of therapeutic agents, including poorly bioavailable drugs, peptides, proteins, and vaccines.

Despite challenges such as limited drug-loading capacity, variability in buccal permeability, and the influence of saliva on drug retention, continuous research is addressing these limitations through the development of novel polymers, multifunctional excipients, and advanced fabrication technologies. Overall, mucoadhesive buccal films represent a versatile and effective drug delivery platform with considerable potential for future pharmaceutical applications. Continued innovation and clinical research are expected to further establish their role in improving therapeutic outcomes and advancing personalized medicine.

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