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Buccal films as an emerging drug delivery platform

Ashutosh Dinkar Nerkar*, Ayush Pratap Singh Sengar, Raghuraj Lovanshi and OP Agrawal

Department of Pharmaceutics, Bhabha Pharmacy Research Institute, Bhabha University, Bhopal-462046, M.P. India

Abstract

Buccal films have emerged as a promising drug delivery platform due to their ability to bypass hepatic first-pass metabolism, improve bioavailability, enhance patient compliance, and provide controlled or rapid drug release. These thin, flexible polymeric films adhere to the buccal mucosa and allow systemic or local delivery of a wide range of therapeutic agents. This review discusses the anatomy and physiology of the buccal mucosa, the advantages and challenges of buccal film systems, polymers used for film development, formulation techniques, evaluation parameters, recent advancements, and applications in modern drug delivery. The review concludes that buccal films offer an efficient, patient-friendly, and technologically adaptable platform that will continue to expand in pharmaceutical applications.

Keywords: Buccal films, Mucoadhesion, Polymeric films, Transmucosal delivery, Drug delivery systems.

***Correspondence Info:**
Mr. Ashutosh Dinkar Nerkar
Department of Pharmaceutics,
Bhabha Pharmacy Research Institute,
Bhabha University, Bhopal-462046, M.P. India

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1. Introduction

Drug delivery through the oral route has traditionally been the most preferred method of administration due to its convenience, non-invasiveness, cost-effectiveness, and high patient compliance [1]. However, many drugs administered orally suffer from extensive hepatic first-pass metabolism, enzymatic degradation in the gastrointestinal (GI) tract, and variable absorption patterns. These limitations have motivated the development of alternative delivery systems capable of enhancing bioavailability, achieving rapid therapeutic effects, and improving dosing accuracy. Among the modern drug delivery strategies, buccal films have emerged as one of the most promising platforms for systemic and local drug delivery [2].

The buccal mucosa, located on the inner lining of the cheeks, provides a unique physiological environment suited for drug absorption. The mucosa is relatively neutral in pH (6.2–7.4), has a rich vascular network, and contains fewer metabolizing enzymes compared to the gastrointestinal tract. As a result, drugs absorbed through the buccal route enter directly into systemic circulation, bypassing hepatic first-pass metabolism. This property enhances the bioavailability of drugs that are otherwise poorly absorbed or extensively metabolized orally [3].

Buccal films are thin, flexible polymeric films designed to adhere to the buccal mucosa. Upon hydration, these films form intimate contact with the mucosal surface and gradually release the drug at a controlled rate [4]. This controlled release mechanism is ideal for drugs that require stable plasma concentrations, have a narrow therapeutic index, or exhibit limited solubility or poor permeability in the gastrointestinal environment [5].

Advances in polymer science have enabled the development of highly functional buccal films with desirable mechanical strength, flexibility, bioadhesion, and swelling characteristics [6]. A variety of natural, semi-synthetic, and synthetic polymers are used in buccal film formulation, including hydroxypropyl methylcellulose (HPMC), Carbopol, chitosan, pectin, guar gum, sodium alginate, and polyvinylpyrrolidone (PVP). The selection and combination of polymers play a critical role in determining drug release kinetics, mucoadhesion time, and film stability [7].

Compared with other oral transmucosal dosage forms—such as lozenges, gels, tablets, and sprays—buccal

films offer distinct advantages. Their thin, flexible, and water-free administration makes them particularly suitable for pediatric, geriatric, and dysphagic patients who have difficulty swallowing conventional tablets [8]. The films dissolve or swell uniformly without posing choking risks. Additionally, since they require no water for administration, buccal films are ideal for emergency treatments and on-the-go use [9].

Buccal films have also demonstrated superior performance in delivering drugs requiring rapid onset of action. They are widely used for pain management (e.g., fentanyl films), antiemetics (e.g., ondansetron films), anticonvulsants (e.g., clonazepam films), and various cardiovascular agents [10]. Research has extended their applications to macromolecules such as peptides, hormones, vaccines, and nanoparticle-loaded biologics. With innovations in nanotechnology, buccal films have shown potential to improve the stability and permeability of therapeutic agents that typically degrade in the gastrointestinal tract [11].

Despite these advantages, the development of buccal films is not without challenges. Film size limitations restrict the drug loading capacity, making them more suitable for potent drugs effective at low doses. Taste masking poses another major challenge because drugs released in the oral cavity must be palatable. Ion-exchange resins, sweeteners, flavors, cyclodextrins, and film coatings are commonly used to mitigate bitterness [12]. Overly strong mucoadhesion or excessive swelling may lead to discomfort or mucosal irritation, requiring careful optimization of polymer ratios. Additionally, the mechanical stability of buccal films can be compromised by high humidity, necessitating moisture-safe packaging [13].

The solvent casting technique remains the most widely used method for preparing buccal films, offering excellent control over film thickness, uniformity, and drug dispersion. Emerging methods such as hot-melt extrusion and 3D printing allow for enhanced precision, solvent-free processing, personalized dosing, and the fabrication of complex multilayered films with improved barrier properties [14].

With growing interest in patient-centric drug delivery and personalized medicine, buccal films continue to evolve. The integration of novel mucoadhesive polymers, nanocarrier-loaded systems, enzyme-protective formulations, and stimuli-responsive materials position buccal films as a forward-looking platform in the pharmaceutical industry. Their unique combination of efficiency, safety, and convenience highlights their potential to transform therapeutic outcomes across multiple clinical indications [15].

In conclusion, buccal films have emerged as a versatile and clinically valuable drug delivery platform. Their capacity to bypass first-pass metabolism, provide rapid or controlled drug release, enhance patient compliance, and accommodate a wide range of therapeutic molecules positions them at the forefront of modern pharmaceutical innovation. Continued research in polymer science, nanotechnology, and fabrication technologies will further expand the scope and applicability of buccal film systems in the coming years [16].

2. Anatomy and physiology of the buccal mucosa

The buccal mucosa, located on the inner lining of the cheeks, represents one of the most suitable routes for transmucosal drug delivery due to its unique anatomical and physiological characteristics. The buccal region offers a combination of permeability, vascularization, and accessibility that supports both systemic and local administration of therapeutic agents. Understanding the structural and functional components of the buccal mucosa is essential for designing effective buccal film formulations [17].

Anatomically, the buccal mucosa form part of the oral mucosal lining and is composed of non-keratinized stratified squamous epithelium. This epithelial layer typically ranges from 500 to 800 μm in thickness and acts as the primary barrier to drug permeation. Beneath the epithelium lies the lamina propria, a connective tissue layer containing collagen fibers, fibroblasts, nerve endings, and small blood vessels. The innermost layer, the submucosa, consists of dense connective tissue rich in larger blood vessels and glands. This layer directly interfaces with the systemic circulation, facilitating rapid absorption of drugs administered through the buccal route [18].

Physiologically, the buccal mucosa maintains a near-neutral pH ranging from 6.2 to 7.4, providing a stable environment for drug dissolution without causing acid-induced degradation. The mucosa contains significantly fewer proteolytic enzymes compared to the gastrointestinal tract, thereby reducing the risk of enzymatic degradation of sensitive drugs such as peptides and proteins. Additionally, the mucosal surface is continuously bathed in saliva, which plays an important role in hydration, lubrication, and maintaining the integrity of mucoadhesive formulations [19].

The permeability of the buccal mucosa falls between that of the sublingual mucosa and skin. While it is less permeable than the highly vascularized sublingual region, it still supports the transport of a wide range of therapeutic molecules, including lipophilic drugs and

certain hydrophilic compounds. Drug permeation primarily occurs through paracellular and transcellular pathways, depending on the physicochemical properties of the drug and the hydration state of the mucosa. One of the most significant advantages of the buccal route is its ability to bypass hepatic first-pass metabolism. Drugs absorbed through the buccal mucosa enter the systemic circulation directly via the facial, maxillary, and jugular veins. This enhances bioavailability and offers rapid therapeutic onset for drugs that undergo extensive hepatic metabolism when administered orally [20].

The presence of mucins—glycoproteins responsible for the gel-like consistency of mucus—further contributes to the mucoadhesive properties of the buccal cavity. These mucins interact with polymers used in buccal film formulations through hydrogen bonding, ionic interactions, and physical entanglement, allowing prolonged retention of drug-loaded films.

Overall, the structural organization, permeability characteristics, and vascularization of the buccal mucosa make it an optimal site for delivering drugs that require rapid onset, controlled release, or enhanced bioavailability. Its accessibility, low enzymatic activity, and patient-friendly nature further support its increasing use in modern pharmaceutical drug delivery systems [21].

3. Advantages of buccal films

- Bypass hepatic first-pass metabolism
- Rapid onset of action
- Improved bioavailability
- Convenient administration for pediatrics, geriatrics, and dysphagia patients
- Flexible and thin dosage form
- Lower dosing frequency
- Enhanced patient compliance
- Controlled or sustained release achievable
- Minimizes gastrointestinal irritation

4. Polymers Used for Buccal Film Development

Polymer	Type	Function
HPMC (Hydroxypropyl Methylcellulose)	Synthetic	Film former, controlled release
Carbopol 934P	Synthetic	Strong mucoadhesion
PVP K30	Synthetic	Binder and solubility enhancer
Chitosan	Natural	Mucoadhesion and permeation enhancement
Sodium Alginate	Natural	Swelling and gelling agent
Pectin	Natural	Biodegradable and mucoadhesive
Pullulan	Natural	Transparent film-forming polymer

5. Methods of Buccal Film Preparation

Several formulation techniques are employed to prepare buccal films depending on the nature of the drug, polymer characteristics, manufacturing feasibility, and desired release profile. The most widely used methods include solvent casting, hot-melt extrusion, semi-solid casting, rolling method, and advanced 3D printing techniques. Each method offers unique advantages and limitations.

5.1 Solvent Casting Technique

This is the most common and widely used method for preparing buccal films due to its simplicity and ability to provide uniform thickness and controlled drug distribution.

• Step 1: Polymers are dissolved in a suitable solvent (e.g., water, ethanol).
• Step 2: Drug is dispersed or dissolved in the polymeric solution.
• Step 3: Plasticizers (e.g., PEG-400, glycerin) are added to improve flexibility.
• Step 4: The mixture is stirred and deaerated to remove air bubbles.
• Step 5: The solution is poured into a glass mold or Petri dish.
• Step 6: Films are dried in a hot-air oven at 40–50°C.
• Step 7: Dried films are cut into desired sizes and stored in a desiccator.

5.2 Hot-Melt Extrusion (HME)

HME is a solvent-free technique suitable for heat-stable drugs. Polymers are melted and mixed with the drug under controlled heating and pressure, followed by extrusion into thin films.

• Drug and polymers are blended uniformly.
• Mixture is fed into an extruder and heated above polymer glass transition temperature.
• Molten mass is forced through a flat die to form thin films.
• Films are cooled, laminated, and cut into dosage forms.

5.3 Semi-Solid Casting Method

In this method, an intermediate gel-like mass is prepared from water-soluble polymers. This gel is then cast into films.

• Prepare a homogeneous gel from hydrophilic polymers.
• Add drug and other excipients into the gel base.
• Cast the gel onto a suitable substrate.
• Dry the film at controlled temperature.

5.4 Rolling Method

This method involves preparing a viscous formulation that is rolled between rollers to form a uniform film.

• Prepare a viscous mixture of drug, polymers, solvents, and additives.

• Feed the mixture between rollers to spread into a thin film.
• Dry the rolled film at room temperature or controlled humidity.
• Cut and package the final product.

5.5 Bilayer and Multilayer Film Preparation

Multilayer films are used for unidirectional release, taste masking, or combining immediate and sustained release.
• Prepare separate solutions for drug-loaded and backing layers.
• Cast the first layer and partially dry it.
• Pour the second layer over the first and dry completely.
• Cut into the required dimensions.

5.6 3D Printing Technique

3D printing is an advanced method used to produce personalized buccal films with precise geometry, dose, and release characteristics.
• Drug-polymer mixture is prepared for semi-solid extrusion or inkjet printing.
• Digital design of film dimensions and drug placement.
• Layer-by-layer deposition of materials using 3D printer.
• Drying, curing, and packaging of printed films.

Table 5.1 Comparison of Buccal Film Preparation Methods

Method	Type	Advantages	Limitations
Solvent Casting	Solution-based	Uniform thickness, widely used	Solvent residue, long drying time
Hot-Melt Extrusion	Solvent-free	Fast, scalable	Not suitable for heat-sensitive drugs
Semi-Solid Casting	Gel-based	Good for natural polymers	Less precise thickness control
Rolling Method	Viscous mass	High uniformity	Equipment requirement
3D Printing	Digital fabrication	Precise, personalized dosing	High cost, slow production

6. Evaluation Parameters of Buccal Films

• Physical Appearance
• Thickness and Weight Variation
• Surface pH
• Tensile Strength
• Folding Endurance
• Swelling Index
• Mucoadhesive Strength
• Drug Content Uniformity
• In Vitro Drug Release
• Release Kinetics Modeling
• Ex Vivo Permeation Studies

7. Applications of Buccal Films

Buccal films have gained widespread acceptance due to their unique advantages, including avoidance of first-pass metabolism, rapid onset of action, ease of administration, and improved patient compliance. Their flexibility, mucoadhesive nature, and controlled release capabilities make them suitable for delivering a broad range of therapeutic agents across various clinical applications [22].

7.1 Systemic Drug Delivery (Rapid and Sustained Action)

Buccal films are ideal for drugs requiring rapid onset or sustained absorption. Examples include analgesics, antihypertensives, CNS drugs, and emergency medications. The buccal route ensures faster therapeutic action compared to conventional oral dosing.

7.2 Pain Management

Drugs such as fentanyl, tramadol, and buprenorphine have been formulated as buccal films to provide rapid relief from acute and breakthrough pain. The high vascularity of the buccal mucosa supports quick absorption.

7.3 Antiemetic Therapy

Ondansetron and granisetron buccal films are widely used for the management of nausea and vomiting, offering faster onset and improved compliance in patients unable to swallow tablets.

7.4 Treatment of Central Nervous System Disorders

Buccal films provide an effective platform for delivering CNS-active drugs like clonazepam, diazepam, and Atomoxetine. Their rapid absorption benefits seizure management, ADHD therapy, and anxiety treatment.

7.5 Cardiovascular Applications

Nitroglycerin and other antianginal drugs are delivered via buccal films to provide immediate relief during angina attacks. This route ensures quick systemic absorption critical for emergency treatment.

7.6 Hormonal and Endocrine Therapies

Buccal films have been developed for hormones such as estradiol and testosterone, improving bioavailability and bypassing hepatic metabolism.

7.7 Vaccines and Peptide/Protein Delivery

Buccal films are being explored for administering vaccines, peptides, and proteins (e.g., insulin, calcitonin) due to the low enzymatic activity of the buccal mucosa, which helps preserve biological activity.

7.8 Local Delivery for Oral Conditions

Buccal films containing antimicrobials, antifungals, or corticosteroids are used for treating local oral conditions such as mouth ulcers, candidiasis, and gingivitis, ensuring prolonged contact with the affected area.

7.9 Pediatric and Geriatric Applications

Buccal films are ideal for populations with swallowing difficulties. The ease of application, thinness, and taste-masked formulations improve adherence compared to syrups or tablets.

7.10 Chronic Disease Management

Buccal films have been explored for long-term therapies such as diabetes management (insulin-loaded films), hypertension, and psychiatric treatments, where controlled and sustained release is beneficial.

Table 7.1 Applications of Buccal Films across Therapeutic Areas

Therapeutic Area	Example Drugs	Key Benefits
Pain Management	Fentanyl, Tramadol	Rapid onset, bypasses first-pass metabolism
CNS Disorders	Clonazepam, Diazepam	Fast absorption, seizure control
Antiemetics	Ondansetron	Useful for vomiting patients
Cardiovascular	Nitroglycerin	Immediate relief during angina
Hormonal Therapies	Estradiol, Testosterone	Improved bioavailability
Vaccines/Proteins	Insulin, Peptides	Protected from GI degradation
Local Oral Treatment	Antifungals, Steroids	Targeted action at the site
Pediatrics/Geriatrics	Various drugs	Improved compliance

8. Recent Advances in Buccal Film Technology

Recent advances in buccal film technology have significantly expanded the scope, precision, and clinical applicability of this dosage form. Innovations in polymer science, nanotechnology, fabrication techniques, and patient-centric design have transformed conventional buccal films into multifunctional, smart drug delivery platforms. These developments aim to overcome traditional limitations related to drug loading, permeability, stability, and patient acceptability [23].

8.1 Nanoparticle-Loaded Buccal Films

The incorporation of nanoparticles (NPs) into buccal films has emerged as a powerful strategy to enhance drug solubility, stability, and mucosal permeation. Polymeric nanoparticles, lipid-based nanoparticles, and solid lipid nanoparticles are commonly embedded within hydrophilic film-forming polymers. These systems provide controlled and targeted release, protect labile molecules from degradation, and improve the permeation of poorly bioavailable drugs, including peptides, proteins, and biologics.

8.2 Advanced Mucoadhesive and Thiolated Polymers

Second-generation mucoadhesive polymers, including thiolated polymers (thiomers), have been engineered to form covalent disulfide bonds with cysteine-rich domains of mucus. These interactions provide stronger and longer mucoadhesion compared to conventional hydrogen-bond-based systems. Thiolated chitosan, thiolated carbomers, and thiolated polyacrylates have shown improved residence time, enhanced permeability, and reduced wash-out, making them promising candidates for next-generation buccal films.

8.3 Stimuli-Responsive and Smart Films

Stimuli-responsive buccal films are designed to alter their properties in response to environmental triggers such as pH, temperature, ionic strength, or enzymatic activity. pH-sensitive polymers can modulate drug release according to the local microenvironment, while thermo-responsive polymers can become more adhesive or swell at physiological temperatures. These smart systems enable on-demand and site-specific drug delivery, potentially improving therapeutic outcomes and minimizing side effects.

8.4 3D Printing and Personalized Buccal Films

3D printing technologies, such as fused deposition modeling (FDM), semi-solid extrusion, and inkjet printing, have been applied to fabricate buccal films with precise geometry, drug distribution, and dosing. This approach supports the concept of personalized medicine, where dose, size, and release profile can be tailored to individual patient needs (e.g., pediatric or geriatric populations). 3D printing also allows for multi-layered and complex structures, including films with separated drug compartments or built-in release-modifying layers.

8.5 Bilayer and Multilayer Buccal Films

Bilayer and multilayer buccal films have been developed to address challenges such as unidirectional release, drug–polymer incompatibility, and taste masking. Typically, one layer contains the drug and mucoadhesive polymers, while the backing layer is made of impermeable or slowly permeable material that promotes unidirectional drug release toward the mucosa. Multilayer designs also allow for incorporation of multiple drugs or support a combination of immediate and sustained release profiles.

8.6 Taste Masking and Patient-Centric Design

Modern buccal film formulations incorporate advanced taste-masking strategies such as ion-exchange resins, microencapsulation, complexation (e.g., cyclodextrins), and flavor–sweetener systems. These techniques are crucial for pediatric and geriatric patient populations who are particularly sensitive to bitter or unpleasant tastes. Thin, transparent, and fast-adhering films are preferred from the patient's perspective, making aesthetic and sensory attributes an important aspect of formulation design.

Table 8.1 Key Recent Advances in Buccal Film Technology

Advance	Description	Key Benefits
Nanoparticle-Loaded Films	Embedding polymeric/lipid nanoparticles in films	Enhanced solubility, permeability, and stability
Thiolated Polymers	Mucoadhesive polymers with thiol groups	Stronger mucoadhesion and prolonged residence
Stimuli-Responsive Films	pH/thermo/ion-sensitive polymers	On-demand and controlled release
3D Printed Films	Digitally designed and printed films	Personalized dosing and complex structures
Bilayer/Multilayer Films	Multiple layers with different roles	Unidirectional release and multifunctionality
Advanced Taste Masking	Ion-exchange, encapsulation, flavors	Improved palatability and patient compliance

Overall, recent advances in buccal film technology have shifted the focus from simple mucoadhesive matrices to highly engineered, multifunctional systems. The convergence of novel polymers, nanotechnology, smart materials, and precision manufacturing techniques such as 3D printing has opened new avenues for delivering small molecules, biologics, and complex therapeutic agents via the buccal route. These innovations are expected to further enhance the clinical utility and commercial potential of buccal films as an emerging drug delivery platform.

9. Challenges and Limitations [24]

9.1 Limited Drug Loading Capacity

The small surface area of the buccal cavity restricts the size of films, thereby limiting the amount of drug that can be incorporated. Buccal films are most suitable for potent drugs effective at low doses; high-dose drugs cannot be efficiently delivered through this route.

9.2 Saliva Wash-Out and Variability

Continuous saliva secretion (0.5–1.5 L/day) can dilute the drug or wash it away prematurely. Excessive saliva may reduce drug residence time, while insufficient saliva may hinder film hydration and mucoadhesion.

9.3 Mucosal Irritation and Sensitivity

Certain polymers, especially strong mucoadhesive agents (e.g., high concentrations of Carbopol), can cause irritation, burning sensation, or tissue damage. Repeated application may also lead to mucosal fatigue.

9.4 Taste Masking Requirements

Since buccal films release the drug in the oral cavity, taste masking becomes essential, particularly for bitter drugs. Ineffective taste masking reduces patient compliance, especially in pediatric and geriatric patients.

9.5 Formulation Stability Issues

Buccal films can be sensitive to moisture, temperature, and mechanical stress. Hygroscopic polymers absorb moisture, leading to stickiness, deformation, or altered drug release profiles.

9.6 Permeability Barriers

Although the buccal mucosa is more permeable than skin, it is still less permeable than sublingual mucosa. Hydrophilic and high molecular weight drugs often exhibit poor permeability without permeation enhancers.

9.7 Manufacturing Complexity

Achieving uniform thickness, consistent drug distribution, and mechanical strength requires precision-controlled manufacturing. Industrial scalability can be challenging, especially for multilayer or nanoparticle-loaded films.

9.8 Short Residence Time for Some Formulations

Improper polymer selection may lead to weak mucoadhesion or rapid detachment, reducing effective drug exposure time and therapeutic outcomes.

9.9 Regulatory and Quality Control Challenges

Buccal films are relatively new, and regulatory guidelines are still evolving. Ensuring batch-to-batch uniformity, mechanical integrity, and reproducibility requires advanced analytical and quality control techniques.

9.10 Patient-Related Factors

Mouth movements, unintentional removal, and individual variations in mucosal thickness and saliva composition may affect drug absorption and film performance.

Table 9.1 Summary of Challenges and Limitations

Challenge	Impact on Buccal Film Performance
Low drug loading	Restricts use to potent molecules
Saliva wash-out	Reduces residence time and bioavailability
Taste masking needs	Affects patient compliance
Mucosal irritation	Limits polymer selection
Stability issues	Affects mechanical properties and drug release
Low permeability	Requires permeation enhancers or nanoparticles
Manufacturing complexity	Raises cost and scalability concerns

10. Conclusion

Buccal films have emerged as an innovative, patient-friendly, and technologically advanced drug delivery platform with the potential to significantly improve therapeutic outcomes across a wide spectrum of diseases. Their unique advantages—including avoidance of first-pass metabolism, rapid absorption, controlled release capabilities, and excellent patient compliance—make them especially suitable for pediatric, geriatric, and dysphagic populations.

The integration of novel polymers, nanocarriers, and smart materials has transformed traditional buccal films into efficient multifunctional systems capable of delivering small molecules, peptides, proteins, and even nanoparticle-based therapeutics. Advances such as bilayer films, thiolated polymers, nanoparticle-embedded matrices, and 3D-printed personalized films have expanded the scope and efficiency of this delivery system. These developments contribute not only to improved drug stability and enhanced bioavailability but also to targeted and sustained drug release tailored to individual patient needs.

Despite tremendous progress, certain challenges persist—such as limited drug loading capacity, variability in mucosal permeability, and formulation stability under environmental stress. Continued research into high-performance mucoadhesive polymers, permeability enhancers, taste-masking technologies, and precision manufacturing methods is essential to fully harness the therapeutic potential of buccal films.

In conclusion, buccal films represent a rapidly evolving and highly promising drug delivery system poised to play a pivotal role in future pharmaceutical development. As innovation continues in polymer science, nanotechnology, and personalized medicine, buccal films are expected to become integral to next-generation drug delivery strategies, offering safer, more effective, and more convenient therapeutic options for global patient populations.

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