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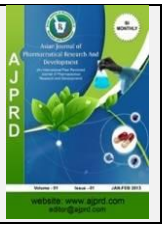

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Review Article

Mucoadhesive Buccal Tablets: Formulation Strategies, Evaluation Parameters, Marketed Products, and Future Prospects

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A B S T R A C T

Mucoadhesive buccal tablets are a promising and patient-friendly drug delivery system designed to improve the effectiveness of medications by enhancing bioavailability, avoiding first-pass metabolism, and providing a controlled release of drugs. The buccal route offers several benefits—it is easy to access, the mucosa is highly vascularized for quick absorption, and drugs can be protected from breakdown in the gastrointestinal tract. This review provides a clear overview of the basics of mucoadhesion, explaining how polymers interact with mucus and the factors that influence how strongly they adhere. Different types of mucoadhesive polymers—including natural, semi-synthetic, and synthetic varieties—are discussed with a focus on their properties and suitability for buccal formulations. The formulation aspects, such as how to choose the right drug, the importance of excipients, and the common methods used to prepare buccal tablets, are also highlighted. Key evaluation parameters like swelling index, mucoadhesive strength, and drug release patterns are explained to help understand how these systems are assessed. Recent developments—including advanced polymers, nanotechnology-based systems, and marketed products such as Fentora® and Belbuca®—show the growing clinical relevance of buccal mucoadhesive tablets. Although challenges remain, such as limited dose capacity and variations in mucosal conditions, ongoing innovations in thiolated polymers, interpenetrating polymer networks, and 3D-printing offer exciting potential to make these systems even more efficient and patient-friendly in the future.

Keyword: Mucoadhesive Buccal Tablets, Mucoadhesive Polymers, Buccal Drug Delivery; Bioavailability; Controlled Release

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INTRODUCTION

The oral cavity is one of the most convenient and effective routes for drug delivery because it allows simple administration and helps avoid drug degradation in the gastrointestinal tract and the liver's first-pass metabolism. In buccal drug delivery, the medication is placed against the inner lining of the cheek, where it can slowly release the drug and improve bioavailability. This not only helps reduce dosing frequency but also minimizes side effects. An added advantage is that if any toxicity or discomfort occurs, the dosage form can be removed immediately, stopping further drug absorption. Due to these benefits, several mucoadhesive systems—such as tablets, patches, films, gels, discs, and ointments—have been widely explored for oral mucosal delivery [1,17].

The buccal route provides several notable advantages compared to traditional oral dosage forms. The buccal mucosa is easy to access and highly vascularized, allowing drugs to be absorbed directly into the systemic circulation while bypassing the liver's metabolism [2,3,18]. Mucoadhesive buccal tablets are specifically designed to stick to the mucosal surface and release the drug slowly and consistently, leading to improved bioavailability and a longer-lasting therapeutic effect [3,19]. Since the concept of mucoadhesion emerged in the early 1980s, it has played a major role in advancing polymer research and formulation strategies [4,5,20].

Although oral drug administration is convenient, many drugs suffer from low bioavailability because they are broken down by enzymes or extensively metabolized in the digestive tract. The buccal region, with its permeable epithelial layer and rich blood supply, provides a reliable alternative for systemic drug delivery [6,7,21]. Additionally, the enzymatic activity in the buccal cavity is much lower than in the gastrointestinal tract, reducing the extent of drug degradation [8,22]. As a result, buccal formulations are especially beneficial for drugs

with short half-lives, poor solubility, or those that undergo significant first-pass metabolism.

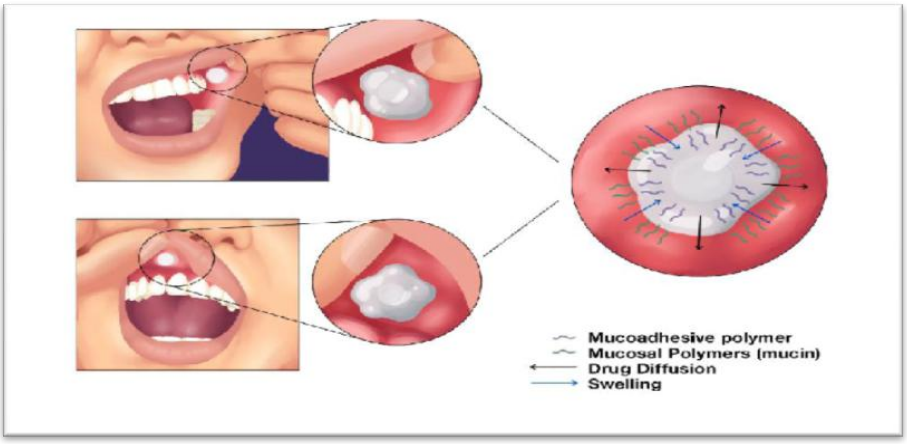

Figure 1: Mucoadhesive Buccal Drug Delivery System

Concept of Mucoadhesion

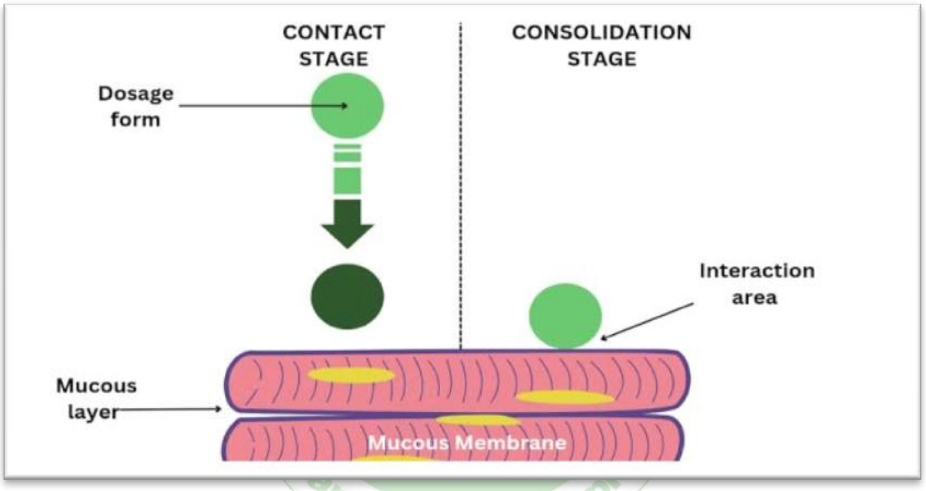

Figure 2: Concept of Mucoadhesion

Mucoadhesion refers to the ability of natural or synthetic polymers to interact with and adhere to the mucin layer that covers biological tissues. In simple terms, it describes how certain macromolecules can attach themselves to mucosal surfaces and remain there for an extended period [4,23]. Incorporating such mucoadhesive polymers into controlled-release formulations helps enhance drug effectiveness by increasing the time the drug stays at the site of absorption, supporting steady and prolonged drug release.

When a mucoadhesive system attaches to the mucosal surface, it ensures closer contact between the formulation and the tissue. This improves local drug concentration and prolongs the residence time, which in turn enhances systemic absorption. Because of this prolonged contact, drugs can be absorbed more efficiently across the mucosa with less enzymatic degradation and slower clearance. As a result, lower doses and less frequent administration are often enough to achieve the desired therapeutic outcomes [9,3,24]. Additionally, drugs delivered through the mucosal route avoid gastrointestinal breakdown and first-pass liver metabolism [6,25], contributing to higher bioavailability and better overall therapeutic performance.

Factors Influencing Mucoadhesion

Mucoadhesion is a multi-step and complex process influenced by numerous physicochemical and environmental factors. These factors determine how effectively a polymer interacts with the mucus layer and how long it can remain attached. Understanding these parameters is essential for designing strong and reliable mucoadhesive systems.

Polymer-Related Factors

a. Molecular Weight

Polymers with higher molecular weight often show stronger mucoadhesivebehavior because they possess more functional groups capable of forming hydrogen bonds with mucinglycoproteins [4]. However, extremely high molecular weights may limit polymer flexibility and reduce penetration into the mucus layer, ultimately lowering adhesion [4,9,26].

b. Polymer Concentration

The polymer must be present at an optimal concentration. Too little polymer leads to insufficient chain overlap, while too much results in entanglement

and loss of flexibility—both conditions can reduce mucoadhesion [8,27].

c. Flexibility of Polymer Chains

Flexible, linear polymer chains interpenetrate the mucus network more effectively than rigid or cross-linked structures, resulting in stronger adhesion [3,28].

d. Functional Groups and Hydrogen Bonding

Polymers that contain hydrophilic groups such as –OH, –COOH, and $–NH_2$ can form hydrogen bonds with mucin, greatly improving adhesion [10,29].

e. Cross-Linking Density

Cross-linking affects swelling and mobility of polymer chains. Lightly cross-linked polymers swell more easily and interact better with mucin, whereas heavily cross-linked polymers may become too rigid for effective adhesion [11,30].

Environmental Factors

a. pH at the Attachment Site

The pH of the mucosal environment influences polymer ionization and mucin charge. For example, polyacrylic acid derivatives adhere best at pH 5–6, where hydrogen bonding is most favorable [31].

b. Ionic Strength

Salts and electrolytes can shield charged groups on the polymer and mucin, reducing electrostatic attraction and weakening mucoadhesion [9,32].

c. Hydration and Swelling Rate

Proper hydration softens the polymer, relaxes its chains, and helps it interpenetrate with mucus. However, excessive swelling may cause premature erosion or detachment of the dosage form [10,33].

Physiological Factors

Applied Force and Contact Time

The duration and pressure applied during placement influence initial wetting and bond formation. Longer contact typically results in stronger mucoadhesion [4,34].

Mucoadhesive Polymers

Mucoadhesive polymers are the foundation of buccal drug delivery systems. Their interaction with mucus—through hydrogen bonding, van der Waals forces, or electrostatic attraction—enables the dosage form to adhere to the mucosal surface. For optimal performance, a mucoadhesive polymer should be non-toxic, biocompatible, and capable of forming a strong but reversible bond with the buccal mucosa [9].

These polymers are generally classified into natural, semi-synthetic, and synthetic categories, each offering unique benefits depending on the formulation's goals.

Natural Polymers

Natural polymers are widely preferred due to their biodegradability, safety, and compatibility with biological tissues.

Common examples include:

- **Chitosan:** A cationic polysaccharide with excellent mucoadhesive properties arising from electrostatic attraction with negatively charged mucin. It also enhances paracellular permeability by temporarily opening tight junctions [12,29].
- **Sodium Alginate:** An anionic polymer that forms gels in the presence of calcium ions. It offers both adhesion and controlled drug release[35].
- **Pectin:** A plant-derived polysaccharide that swells readily and adheres through hydrogen bonding[36].
- **Guar Gum & Xanthan Gum:** High-molecular-weight polysaccharides that form viscous gels upon hydration, improving adhesion[37].

Although effective, natural polymers may vary in composition and purity from batch to batch.

Semi-Synthetic Polymers

Semi-synthetic polymers combine natural polymer safety with the consistency of synthetic manufacturing.

Examples include:

- **HPMC:** A widely used cellulose derivative that swells to form a gel matrix, ensuring sustained release and good adherence [13,14].
- **NaCMC:** An anionic cellulose derivative with high viscosity and excellent hydrogen bonding ability[38].
- **HEC:** Rapidly hydrates and is often used with carbopol; one study found that a Carbopol 934:HEC ratio of 1:2 offered optimal adhesion and controlled release for up to eight hours [14].
- Semi-synthetic polymers are stable, reproducible, and compatible with most drugs.

Synthetic Polymers

Synthetic polymers offer the advantage of high purity, controlled molecular structure, and predictable performance.

Examples include:

- **Carbopol (Carbomer):** A highly versatile polyacrylic acid polymer known for exceptional adhesion and swelling capacity. Carbopol 934P is widely used in buccal tablets [4,8].
- **Polycarbophil:** Similar to carbopol but less irritating and capable of adhering even at neutral pH.[39].
- **PVP K-30:** A hydrophilic polymer used to improve flexibility and wetting when combined with carbopol or HPMC[40].

- **Eudragit RL/RS:** Polymethacrylates that provide controlled release and mechanical strength[35].

Novel and Advanced Polymers

Advances in polymer chemistry have led to the development of materials with stronger and more durable adhesive properties.

- **Thiomers:** Polymers modified with thiol groups that form covalent disulfide bonds with mucin, significantly increasing adhesion duration [11].
- **Graft Copolymers:** For example, chitosan–poly(acrylic acid) improves flexibility, swelling, and bioadhesion [22].
- **Interpenetrating Polymer Networks (IPNs):** Combine two polymers at a molecular level to achieve balanced adhesion and drug release [24,33].

These materials represent the next generation of buccal delivery excipients.

Formulation Aspects of Mucoadhesive Buccal Tablets

Drug Selection Criteria

Selecting a suitable drug is essential for designing an effective buccal system. Key criteria include:

1. **Low Dose Requirement:** Ideally below 25 mg due to the limited surface area of the buccal cavity [3,17].
2. **Molecular Weight:** Drugs under 500 Da diffuse more easily through buccal membranes [10].
3. **Balanced Lipophilicity:** Moderate solubility in both lipid and aqueous phases improves absorption [3,6,18].
4. **Stability in Saliva:** The drug must remain stable at salivary pH (6.5–7.0) [7].
5. **High First-Pass Metabolism:** Drugs extensively metabolized in the liver benefit greatly from buccal delivery [13,21].
6. **Short Biological Half-Life:** Drugs with half-lives under two hours are ideal for sustained buccal systems [14,30].
7. **Frequent Dosing Requirement:**Buccal delivery helps reduce dosing frequency.
8. **Buccal Permeability:** Good permeability enhances absorption [3,36].
9. **Taste and Irritation:** The drug should be non-irritating and either tasteless or easily taste-masked [6,31].
10. **Partition Coefficient:** A log P between 1–3 supports optimal absorption [3,9,32].

Role of Excipients

a. MucoadhesivePolymers

Carbopol, HEC, HPMC, and NaCMC are commonly used. A Carbopol 934P:HEC ratio of 1:2 was found to achieve the best balance of adhesion and sustained release for up to 8 hours [13,14,22].

b. DiluentsandFillers

Lactose, mannitol, and MCC improve compressibility and uniformity. Mannitol enhances mouthfeel[35].

c. BindersandSolubilizers

PVP K-30 and HPMC promote cohesive matrix formation. Cyclodextrins or citric acid improve the solubility of poorly soluble drugs [14,27].

d. LubricantsandGlidants

Magnesium stearate and talc reduce friction during compression but must be used carefully, as excess amounts reduce mucoadhesion [6,28].

e. PermeationEnhancers

Agents like SLS, bile salts, and EDTA temporarily enhance membrane permeability without causing damage [3,25].

f. FlavoringandSweeteningAgents

Aspartame, saccharin sodium, and menthol help improve taste and patient acceptance [17].

Methods of Tablet Preparation

- **Direct Compression:** Most common method due to simplicity and stability [13].
- **Wet Granulation:** Preferred when improved compressibility is needed [14,27].
- **Bilayer Tablets:** One layer contains drug + polymer; the second backing layer (e.g., ethylcellulose) prevents drug loss into the oral cavity [6,37].

Evaluation Parameters

a. **Pre-Compression Studies**

Flow properties such as angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio are assessed to ensure proper compressibility.

b. **Post-Compression Studies**

Tablets are tested for hardness, weight variation, friability, thickness, and drug content uniformity.

c. **Surface pH**

The surface pH should remain close to salivary pH (6.0–7.0) to avoid irritation. In one study, metoprolol tartrate buccal tablets maintained nearly neutral pH throughout testing [13].

d. **Swelling Index &Mucoadhesive Strength**

Swelling behavior reflects hydration ability, affecting both adhesion and drug release[14,33]. Mucoadhesive strength is measured using tissue models such as porcine buccal mucosa [14,26].

e. **In Vitro Drug Release and Ex Vivo Permeation**

f. Dissolution is usually performed in pH 6.8 buffer [13,20]. Ex vivo studies use animal buccal tissue. One

optimized formulation showed 74% drug release over 8 hours [34,36].

Stability Studies

Stability testing at 25°C/60% RH and 40°C/75% RH (ICH guidelines) ensures that the formulation remains stable during storage [27].

Recent Advances and Marketed MucoadhesiveBuccal Tablets

There has been significant progress in mucoadhesivebuccal delivery systems, driven by improvements in polymer science, nanotechnology, and formulation design. These advancements support controlled release, enhanced permeability, and better patient adherence compared to traditional oral forms [8,18].

Several products have already made it to the market:

- **Fentora® (fentanyl buccal tablet):** Provides rapid pain relief.
- **Sitavig® / Oravig® (acyclovir buccal tablets):** Ensure prolonged mucosal retention for antiviral therapy.
- **Belbuca® (buprenorphine buccal film):** Used for chronic pain management and demonstrates excellent mucoadhesive performance [15,25].

Current research continues to explore bilayer tablets, thiolated polymers, and nano-enabled buccal systems to further improve adhesion and permeability[11,34]. Although films and patches dominate the market, mucoadhesive tablets remain a strong and scalable option for delivering cardiovascular, analgesic, and antiviral drugs. With ongoing improvements in polymer design and patient-centric features, the clinical use of buccal systems is expected to expand significantly in the future [14,21].

Limitations and Future Perspectives of MucoadhesiveBuccal Tablets

While mucoadhesivebuccal tablets offer several promising therapeutic advantages, certain limitations still restrict their wider clinical use. One of the most notable constraints is the limited surface area of the buccal cavity, which restricts the amount of drug that can be incorporated into the dosage form. This makes the approach unsuitable for drugs that require high doses or exhibit low potency [3,37]. Additionally, natural physiological factors such as saliva flow, mucus turnover, and mechanical activities like talking, chewing, and swallowing can reduce the residence time of the tablet, leading to inconsistent absorption [16,22]. Taste, mouthfeel, and the potential for local irritation—especially with acidic or strongly adhesive polymers—can also impact patient acceptance [14,31].

On the formulation side, achieving the right balance between mucoadhesion, swelling, and sustained release remains challenging. Hydrophilic polymers may swell excessively, causing the dosage form to lose integrity, while rigid or highly cross-linked polymers may limit drug diffusion and reduce therapeutic effectiveness [8,30]. Manufacturers also face challenges related to maintaining formulation stability, ensuring consistent adhesion, and achieving uniformity during large-scale production [6,26].

Despite these limitations, the outlook for mucoadhesivebuccal systems is highly encouraging. Significant advancements are underway, particularly in the development of thiolated polymers (thiomers), interpenetrating polymer networks (IPNs), and nanoparticle-embedded matrices, all of which promise stronger adhesion, better biocompatibility, and enhanced permeability [11,34,24]. Emerging technologies such as 3D printing and personalized dosage fabrication offer the possibility of precisely tailored drug delivery profiles, while stimuli-responsive hydrogels provide dynamic control over release characteristics [14,38]. With continued improvements in polymer design, patient-centered formulation strategies, and manufacturing technologies, mucoadhesivebuccal tablets are poised to become a more versatile and dependable platform for systemic and targeted drug delivery in the future.

CONCLUSION

Mucoadhesivebuccal tablets have established themselves as a valuable and patient-friendly alternative to traditional oral drug delivery methods. By adhering to the buccal mucosa and enabling controlled, directional drug release, these systems effectively bypass gastrointestinal degradation and first-pass metabolism, resulting in enhanced bioavailability and therapeutic performance. The success of such formulations depends largely on careful selection of polymers, excipients, and manufacturing techniques that strike the right balance between mucoadhesion, hydration, and drug diffusion.Research efforts—such as the design of carbopol–cellulose polymer matrices for drugs like metoprolol tartrate—have shown how synergistic polymer combinations can prolong residence time and sustain drug release. Still, challenges remain. These include the limited drug-loading capacity of the buccal cavity, variability in mucosal conditions among patients, and the need to maintain comfort and acceptability during use.Looking ahead, advancements in polymer engineering, nanotechnology, and innovative fabrication methods like 3D printing are expected to elevate the performance of mucoadhesivebuccal tablets even further. As research continues to refine biocompatible materials and develop patient-oriented designs, buccalmucoadhesive systems are expected to evolve into a reliable and widely used route for both local and systemic drug delivery in the coming years.

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