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# AN OVERVIEW OF BUCCAL DRUG DELIVERY SYSTEMS IN MODERN THERAPEUTICS

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**ABSTRACT**

Buccal Drug Delivery System (BDDS) has emerged as an effective alternative to conventional oral drug administration, particularly for drugs undergoing extensive first-pass metabolism and gastrointestinal degradation. Buccal delivery involves the administration of drugs through the buccal mucosa lining the inner cheek, enabling direct entry into systemic circulation. This route enhances bioavailability, reduces dose requirements, and provides rapid onset of action. The buccal mucosa is highly vascularized and easily accessible, making it suitable for both local and systemic drug delivery. BDDS utilizes bioadhesive polymers to prolong residence time at the site of absorption, thereby improving drug permeability and therapeutic efficacy.



## INTRODUCTION

Bio adhesion is a process characterised by interfacial molecular attracting interactions between the biological substrate surfaces and naturally or synthetically occurring polymers, allowing polymer to stick to the surface biological layers over a delayed period (Mukhopadhyay et al., n.d.). Buccal dose forms are placed into the cheek and upper gums in the mouth to treat systemically and locally occurring diseases. For big, hydrophilic oligonucleotides, unstable proteins and tiny drug molecules, as well as polysaccharides the buccal route is one of the possible routes (Smart, 2005).

- Buccal drug delivery systems delivering drugs via mucosal membranes in blood stream by placing drug in between gums and the cheeks.
- Sublingual drug delivery systems delivering drugs via mucosal membranes that lined the flooring of mouth inside the blood stream.
- The local drug delivery systems delivering drugs inside the oral cavities.

The latter releases the drug into the bloodstream only through the hepatic system, so the amount in the blood stream may be significantly less than the amount that was included in the tablet's formulation. Additionally, a common side effect of many soluble tablet drugs is liver damage. Other approaches to drug distribution into the body were looked into to get around some of these restrictions. Those are

1. Trans Dermal Drug Delivery System.
2. Trans Mucosal Drug Delivery System

**Transmucosal drug delivery system**

It offers the advantage of avoiding the hepatic gastrointestinal first pass elimination associated with oral administration when medications are delivered through the absorptive mucosa in a variety of readily accessible body cavities, such as the buccal, ocular, nasal, rectal, and vaginal mucosae.

Different types

- Buccal Drug Delivery System.
- Ocular Drug Delivery System.
- Vaginal Drug Delivery System.
- Rectal Drug Delivery System.
- Nasal Drug Delivery System.
- Gastro Intestinal Drug Delivery System.

Considering the low patient compliance for controlled medication delivery via nasal, sublingual, vaginal, and the buccal mucosa is relatively porous and has a high blood supply. Delivery of drug through Buccal mucosa of oral cavity is called Buccal drug delivery system. Buccal mucosa line the inner region of the cheeks and buccal formulation are placed in mouth between the upper gums and cheek to treat local and systemic conditions. In 1947, the Buccal Drug Delivery System was introduced for the administration of Penicillin to the oral mucosa through dental adhesive powder mixed with Gum tragacanth [1,2]. Among various drug delivery systems, the oral approach is best convenient and safety way of delivering medication covers a wider patient group from Pediatrics to Geriatrics. But some drug has low bioavailability in oral administration there undergo hepatic metabolism or some are GI degradation, unpredictable and erratic absorption. To overcome this problem to deliver drugs systemically via an alternate route of administration such as intranasal, buccal, sublingual, pulmonary or transdermal.

## ANOTOMY OF BUCCAL MUCOSA

1. The outermost layer of the stratified epithelium makes up the oral mucosa. Underneath the skin, there is a foundation membrane, a lamina propria, and the submucosa, which is the inmost layering. The epithelia are identical to the stratified squamous epithelium seen throughout. It starts with mitotically active basal cellular layers and goes via several growing intermediate layer to superficial layer, here cell shed off the epithelial surfaces. The buccal mucosa is 500-800m thick, while the mucosa thickening of soft and hard palate, the roof of the mouth, the ventral tongue, and also gingiva is 100-200m thick.

2. Epithelium: About 40–50 layers of stratified squamous epithelial cells make up the epithelium. The cuboidal-shaped basal cells, which have a layer beneath them and undergo continuous mitosis before rising to the surface, give rise to the epithelial cells.

Basement membrane: Between the connective tissues of the lamina propria and the sub mucosa and the basal layer of epithelium, the basement membrane (BM), a continuous layer of extracellular materials, serves as a border. The BM is composed of three layers: the lamina lucida, lamina densa, and a sublayer of fibrous material.

3. Connective tissue: If present, the lamina propria and sub mucosa make up the connective tissues. The lamina propria is a continuous strip of connective tissue that supplies the oral mucosa with blood vessels and nerve fibres. Lingual, frontal, and retromandibular veins are primarily responsible for vascular drainage from the oral mucosa. These veins evade first-pass metabolism because they open into the internal jugular vein.

4. Permeability barriers: The buccal mucosa's permeability falls between that of the intestinal mucosa and the skin's epidermis. Epithelium makes up roughly the outer one-third of the epithelium, where it acts as the main barrier to drug diffusion [3-4].

## MECHANISM OF BUCCAL ABSORPTION

The epithelial cells of the oral mucosa were closely compacted on the top quarter to one-third of the epithelium form the main barrier for penetration. Oral epithelium is not a uniform hydrophobic barrier. The epithelial cell membrane is lipophilic in nature. So, lipophilic drugs are more readily absorbed [5].

1. Transcellular route: Paracellular route Transcellular route: Drug permeation through the epithelial cells involves transport across the apical cell membrane. It is also known as an intracellular pathway.

Paracellular route: Drug permeation through the epithelial cells involves transport through in between the epithelial cells. It is the primary route for hydrophilic compounds because it is difficult to penetrate the lipophilic cell membrane.

## FACTORS AFFECTING BUCCAL ABSORPTION

The oral cavity is a complicated environment for drug delivery because of a number of interrelated and independent factors that lower the absorbable concentration at the site of absorption.

1. Membrane Factors: This includes the degree of keratinization, the amount of absorbable surface area, the mucus layer of the salivary pellicle, the intercellular lipids of the epithelium, the basement membrane, and the lamina propria [6].

Environmental factors;

A. Saliva: Also known as the salivary pellicle or film, saliva coats the whole buccal mucosa lining. The salivary film is 0.07 to 0.10 mm thick. The rate of buccal absorption is influenced by the film's thickness, composition, and motion.

B. Minor salivary glands: The buccal mucosa's epithelium or deep epithelial region is home to these glands. On the buccal mucosa's surface, they continuously release mucus. Despite the fact that mucus aids in the retention of mucoadhesive dose forms, it may act as a barrier to medication penetration [7].

## THEORIES OF ADHESION

1.Wetting theory: this theory describes the affinity to the surface in order to spread over it. The wetting theory applies to liquid systems. The affinity is measured by the techniques is contact angle.

2. Diffusion theory: Diffusion theory describes the interpenetration of polymer chains and the mucus to a sufficient depth to create a semi-permanent adhesive bond. The exact depth to which the polymer chains penetrate the mucus depends on the diffusion co-efficient and the contact time.

3. Electronic theory: According to this theory, electronic transfer leading to the building of a double electronic layer at the interface, where the attractive forces within this electronic double layer determines the mucoadhesive strength [8].

## POLYMERS IN BUCCAL DRUG DELIVERY SYSTEM

1. Molecular weight: In linear polymers, the bio-adhesiveness improves as the molecular weight increases. The optimal molecular weight for maximal mucoadhesion varies depending on the tissue and the kind of mucoadhesive polymer. High molecular weight polymers enhance physical entanglement, while lowering molecular weight polymer permeate the mucosal layer easier. Higher molecular weight polymers will not wet as fast as lower molecular weight polymers, exposing free groups for substrate contact. Low molecular weight polymers, on the other hand, disintegrate fast [9].
2. Active polymer concentration: The type of dosage form has an impact on this element. The higher the polymer content in a solid dosage form, the stronger the mucoadhesion. However, when using a liquid dose form, maximal mucoadhesion is achieved when an appropriate polymer concentration is used to induce the highest degree of bio adhesion.
3. Polymer chain flexibility: This is required for growth and interpenetration. If water-soluble polymers are cross-linked, the individual polymer chains reduce in mobility, reducing the effective length of the chain that show penetration of the mucosal layers and therefore lowering bio adhesive strength.
4. Hydration (Swelling): Swelling of Polymer allows mechanical entanglement and expose the bio adhesive sites for hydrogen bonding and/or electrostatic interaction in both the polymer and the mucosal system. Though, optimal swelling and bio attachment need a certain level of hydration of the mucoadhesive polymer.
5. Environmental factor:
pH
Contact time
Applied strength
6:Physiological factors:
i) Mucin turnover

## METHODS OF PREPARATION

1) Solvent casting: In this process, the medication and all patch excipients are co-dispersed in an organic solvent and coated on a release liner sheet. A thin coating of the protective backing material is laminated onto the sheet of coated release liner after the solvent has evaporated to create a laminate. To create patches with the specified size and geometry, it is die-cut.
2) Direct milling: This eliminates the need for solvents in the manufacturing of patches. Direct milling or kneading is typically used to mechanically combine the drug and excipients without the use of any liquids.
Evaluation of Mucoadhesive Formulations:
a. pH of surface:
The buccal patches are to be expanded for 2 hours at room temperature on an agar plate surface which is in contact with 1 ml of distilled water.
b. Measurements of thickness: This test is applied for the mucoadhesive patch formulations. Each film's thickness is measured at five separate spots using an electronic digital micrometre.
c. Folding Endurance: It's determined manually. The patch is folded at the same location over and over until it ruptures or breaks.
d. Swelling Study: Swelling causes weight gain. Buccal patches are independently weighed (W1) and put in 2 percent and for 37°C 1°C agar gel plates are incubated, and evaluated for physically occurring changes. To quantify the growth in the area, graph paper is placed beneath the Petri dish. Patches are taken from the gel plates at 3-hour intervals, & excess surface water using filter paper is removed carefully. The swollen patches are then again weighed (W2) and using the following formula swelling index (SI) was calculated.

$$SI = \{(W2-W1)/W1\} X 100$$

Due to water absorption and patch swelling, the weight differential causes the weight to grow.
e. Study of thermal Analysis: Using a differential scanning calorimeter (DSC) thermal analysis study is performed.
f. Morphological Characteristics:Using scanning electron microscope (SEM) morphological characters are studied.
g. Test for water absorption capacity:
Circular Patches with 2.3 cm2 surface area and is allowable to swell on the agar plate surface with preparation of simulated saliva and incubated at 37°C 0.5°C in an incubator. Samples are weighed at different intervals (0.25, 0.5, 1, 2, 3, and 4 hours) and then dried in desiccators over anhydrous calcium chloride at RT for 7 days before the final constant weights are recorded.
Thickness measurement: Using a screw gauge/micrometer the thickness of each film is measured five separate places (the centre and the four corners) [10].

## TYPES IN BUCCAL DRUG DELIVERY SYSTEM

1. Buccal films: They have saliva that is easy to remove and wash, and their residence times are short. On the oral mucosa gels. The area around the wound is shielded primarily through movies when the medication is taken orally.
2. Buccal tablets: Buccal tablets have a diameter of about 5-8 mm and are tiny, flat, and oval in shape. The most used method for creating buccal tablets is direct compression; other additionally, methods like wet granulation can be used.
3. Semi-solid buccal adhesive dosage forms:
Gels: Bioadhesive polymers that create gels in which cross-linked polyacrylic acid is employed for an extended period of time, mucosal surfaces are fixed to deliver the release in a controlled manner [11].

## ADVANTAGES OF BUCCAL DELIVERY SYSTEM

1. Compared to other mucosal tissues, the buccal mucosa is robust and moderately permeable, with a plentiful blood supply.
2. Avoid exposing the medications to gastrointestinal fluids and the first-pass effect.
3. Simple membrane site access allows the Delivery system to be applied and localized

## DISADVANTAGES OF BUCCAL DELIVERY SYSTEM

1. Limited absorption surface area: The total surface area of the oral cavity membranes that can be used for medication absorption is 170 cm2, of which 50 cm2 represents non-keratinized tissues, including buccal membrane.
2. Mucosal barrier qualities.
3. The continual dilution of the saliva (0.5-2 l/day) from continuous salivation causes drug [12].

## CLINICAL APPLICATIONS

1. Systemic Treatment (Rapid Action): Used for fast-acting drugs, such as pain relievers (e.g., buprenorphine, fentanyl) and antianginal agents (e.g., nitroglycerin).
2. Systemic Treatment (Sustained Action): Utilized for controlled release, including hormonal therapies (e.g., nicotine, hormonal patches).

## CHALLENGES AND LIMITATIONS

- Resource Constraints: Limited financial, human, or technical resources.
- Data/Access Issues: Difficulty in gathering data or accessing, for example, wildlife for conservation studies.
- Implementation Difficulties: Technical or human factors, such as resistance to new, for example, psychological tools in management [13].

## FUTURE PERSPECTIVES

- Nanotechnology Integration: Nanoparticles and nanostructured carriers are being embedded into films, patches, and gels to significantly improve drug permeability across the buccal epithelium.
- Targeted Therapy & Biologics: The buccal route is increasingly viewed as a viable, non-invasive alternative to injections for delivering sensitive macromolecules, including nucleic acids, antibodies, and proteins.

## CONCLUSION

Buccal drug delivery has various benefits,that includes comfort of administration, accessibility and withdrawal, retentivity, high patient compliance, cost, and low enzymatic activity. This method can be utilised to avoid 1st-pass metabolism in liver as well as pre-systemically occurring clearance in the GIT. This site is also seen to be appropriate for a retentive device and is agreeable to any patient. . Buccal drug administration offers a viable and alluring alternative for the non-invasive delivery of powerful peptide and protein therapeutic molecules as well as significant potential for the systemic distribution of medications that are ineffective when taken orally.

## AUTHOR CONTRIBUTIONS

All authors are contributed equally.

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## CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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