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Review Article

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REVIEW ON BUCCAL DRUG DELIVERY SYSTEMS

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ABSTRACT

Buccal drug delivery represents a highly promising and patient-compliant approach for both local and systemic drug administration, offering distinct advantages over conventional routes. This review provides a comprehensive overview of the current landscape of buccal drug delivery, highlighting its physiological basis, formulation strategies, and ongoing advancements. The unique anatomy and physiology of the buccal mucosa, characterized by rich vascularization, avoidance of hepatic first-pass metabolism, and a relatively less hostile enzymatic environment compared to the gastrointestinal tract, make it an attractive site for drug absorption. This article synthesizes recent developments in various buccal dosage forms, including mucoadhesive patches, films, tablets, gels, and sprays, emphasizing the role of bioadhesive polymers and permeation enhancers in optimizing drug residence time and absorption. Furthermore, the review discusses the factors influencing buccal drug absorption, such as physicochemical properties of the drug, physiological barriers, and formulation excipients. Challenges associated with buccal delivery, including limited surface area, salivary washout, and patient acceptability for certain formulations, are also addressed. Finally, this review explores emerging trends and future perspectives in the field, including novel manufacturing technologies and the potential for delivering challenging molecules like proteins and peptides. This compilation aims to serve as a valuable resource for researchers and formulators interested in developing efficient and effective buccal drug delivery systems.

Keywords: Buccal drug delivery Buccalmucosa MucoadhesionBioadhesion Oral drug delivery Transmucosal delivery.

INTRODUCTION

Among the various routes of drug delivery, the oral route is perhaps the most preferred by patients and clinicians alike. However, peroral administration of drugs has disadvantages, such as hepatic first-pass metabolism and enzymatic degradation within the gastrointestinal tract (GIT). So, there has been a growing interest in the use of delivery of therapeutic agent through various transmucosal routes to provide a therapeutic amount of drug to the proper site in body to promptly achieve and then maintain the desired concentration. Consequently, other absorptive mucosa is considered as potential sites for drug administration. Transmucosal routes of drug delivery (i.e. the mucosal linings of the oral, nasal, rectal, vaginal and ocular cavities) offer distinct advantages over peroral administration for systemic effect.[1]

The unique environment of the oral cavity offers its potential as a site for drug delivery.

These advantages include:

1) The drug is not subjected to the destructive acidic environment of the stomach.
2) Therapeutic serum concentration of the drug can be achieved more rapidly.
3) The drug enters the general circulation without first passing through the liver.[2]

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In general, drugs penetrate the mucous membrane by simple diffusion and are carried in the blood, which richly supplies the salivary glands and their ducts into the systemic circulation via the jugular vein. Active transport, pinocytosis and passage through aqueous pores usually play only insignificant roles in moving drugs across the oral mucosa.3 Two sites within the buccal cavity have been used for drug administration. Using the sublingual route, in this the medication is placed under the tongue, usually in the form of rapidly dissolving tablet. The second anatomic site for drug administration is between the cheek and gingival.

Mucoadhesive drug delivery systems:

Bioadhesion can be described as adhesion of artificial substances to biological substrates such as adhesion of polymers to skin or other soft tissue.

These may be defined as drug delivery systems, which utilize the property of bioadhesion of certain water soluble polymers which become adhesive on hydration and hence can be used for targeting of drug to particular regions of body for extended periods of time.[3]
The mucoadhesive drug delivery system includes following:

1. Buccal drug delivery system
2. Rectal delivery system
3. Oral delivery system
4. Nasal delivery system
5. Vaginal delivery system
6. Ocular delivery system

Table1: Comparison of some routes for systemic drug delivery available to the formulation scientist

Parameters	Gastrointestinal	Dermal	Nasal	Oral mucosal	Vaginal
Accessibility	+	+++	++	++	+
Surfacearea	+++	+++	+	++	+++
Surface environment	+	++	+	+++	+
Permeability	+++	+	+++	++	+++
Reactivity	++	++	+	+++	++
Vascular drainage	+++	+	+++	++	+++
Firstpass clearance	+	+++	+++	+++	+
Patient acceptability	++	+++	++	+++	++

(+)poor, (++)good, (+++)excellent.

Overview of oral cavity:

Oral cavity is that area of mouth delineated by the lips, cheeks, hard palate, soft palate and floor of mouth. The oral cavity consists of two regions.

1. Outer oral vestibule, which is bounded by cheeks, lips, teeth and gingival.
2. Oral cavity proper, which extends from teeth and gums back to the faces with the roof comprising the hard and soft palate. The tongue projects from the floor of the cavity.[4]

Figure 1: Oral cavity

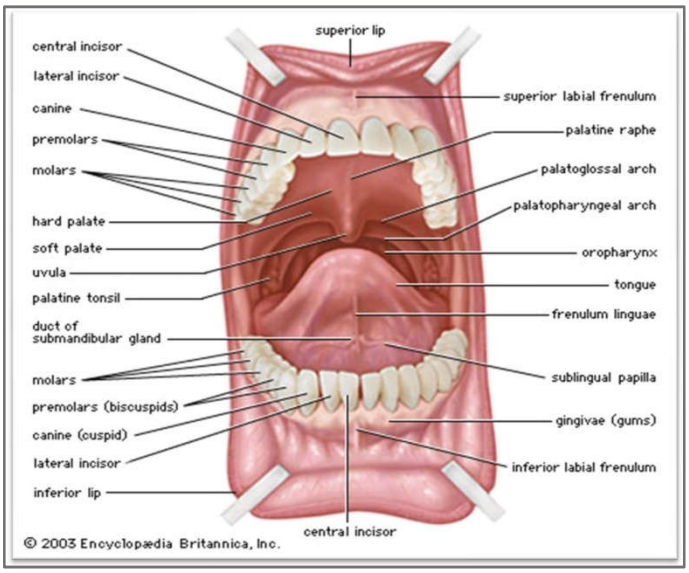

Figure 2 : Structure of the oral cavity

Advantages of buccal drug delivery system:

1 Termination of therapy is possible.
2 Ease of administration.
3 Avoids first pass metabolism.
4 Reduction in dose can be achieved, thereby reducing dose dependent side effects.
5 Drugs which's how poor bioavailability by oral route can be administered by this route.
6 The presence of saliva en sure large amount of water ford is solution of drug unlike in case of rectal and transdermal route.
7 Drugs with short half life can be administered by this method.
8 From the formulation point of view a thin much in film exist on the surface of oral cavity.
9 Provides opportunity to retain delivery system in contact with mucosa for prolonged period of time with the help of mucoadhesive compounds.

Disadvantages:

1 Over hydration may lead to formation of slippery surface and structural integrity of the formulation may get interrupted by the swelling and hydration of bio adhesive polymer.
2 Eating and drinking may become restricted.
3 Patient may swallow the tablet.
4 Only drug with small dose requirement can be administered.
5 Drugs which are unstable at buccal pH cannot be administered by this route.
6 Drugs irritate mucosa, have bitter or unpleasant taste, obnoxious odour cannot be given. 5

MECHANISM OF BUCCALABSORPTION

Buccal administration involves systemic or local administration via or to the buccal membrane.

Mechanism:

Oral mucosal drug absorption occurs by passive diffusion of the nonionized species, a process governed primarily by a concentration gradient, through the intercellular spaces of the epithelium. The buccal mucosa has been said to behave predominately as ellipsoidal barrier to the passage of drugs; as is the case with many other mucosa and (within limits) the more lipophilic (or less ionized) the drug molecule, the more readily it is absorbed. It has been concluded that the passive diffusion in accordance with the pH partition theory of drug absorption is the major route of drug absorption for most drugs. However, it has been reported that certain molecules e.g., some sugars and vitamins may be transported by a specialized transport system capable of saturation.

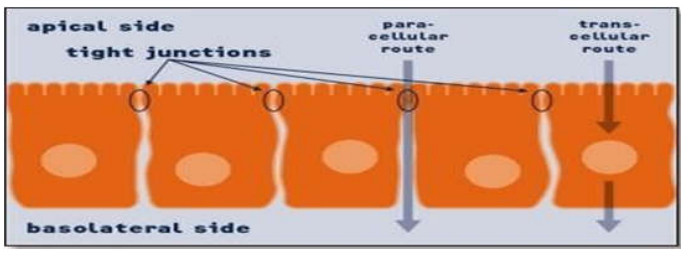

Figure 3 : MECHANISM OF BUCCALABSORPTION

It has been proposed that the intercellular route, rather than the trans-cellular route, is the predominant route for drug absorption. Large hydrophilic molecules in particular are believed to be

transported by the intercellular route and the presence of the contents of membrane-coating granules in the intercellular space may inhibit penetration in both keratinized and non-keratinized mucosa.[6]

CURRENTELY AVAILABLE BUCCAL DRUG DELIVERY SYSTEM

The novel type buccal dosage forms include buccal adhesive tablets, patches, films, semisolid ointments, gels and powders.

Mucoadhesive tablets:

Buccalmuco adhesive tablets are dry dos age form that move to be moistened prior to placing in contact with buccal mucosa. A double layer tablets, consisting of adhesive matrix layer of hydroxypropyl cellulose and poly (acrylic acid) with an inner core of cocoa butter containing insulin and a penetration enhancer (sodium glycolate) has been described by Wagai.

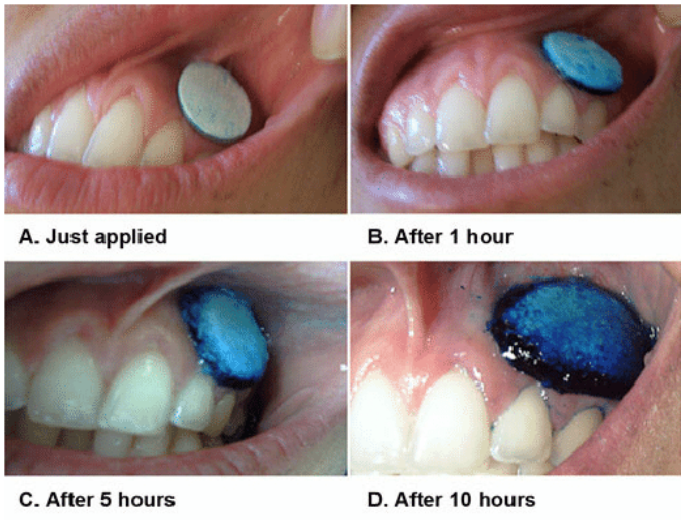

Figure 4: MUCO ADHESIVE TABLETS Buccal patches and films:

Buccal patches consist of two poly laminates, with an aqueous solution of an adhesive polymer being cast on to an impermeable baking sheet. A novel mucosal adhesive film called 'Zilactin'- consisting of an alcoholic solution of hydroxy propyl cellulose and three organic acids, forms a film which applied to the oral mucosa surface which can be retained in place for at least 4 hr, even when challenged with fluids.

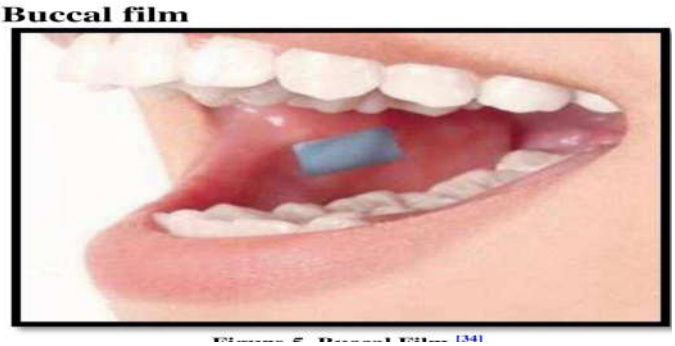

Figure 5: BUCCAL FILMS

Semi solid preparation (ointments and gels):

Bioadhesive gels or ointments have less patient acceptability than solid dosage adhesive form, and most are used only for localized drug therapy with in the oral cavity. One of the original oral mucosal - adhesive delivery systems - 'orabase' - which can be maintained as its site of application for 15-150 min.7

Advances in Formulation Strategies:

- **Mucoadhesive Polymers:** This is a cornerstone. Modern research focuses on developing novel and improved bioadhesive polymers (e.g., thiolated polymers, lectins, stimuli-responsive systems) that provide stronger, longer-lasting adhesion to the buccal mucosa, enhancing drug residence time and absorption.
- **Diverse Dosage Forms:** The landscape includes a wide array of buccal formulations:
  - **Films and Patches:** These are highly favored due to their flexibility, comfort, lightness, and ability to provide controlled or sustained drug release. Advances in manufacturing (e.g., hot-melt extrusion, solvent casting) are leading to more sophisticated designs.8
  - **Tablets (Buccal/Mucoadhesive):** Designed to adhere to the cheek or gum, offering a solid, unit-dose alternative.
  - **Gels and Ointments:** Semi-solid formulations for local application, often incorporating mucoadhesive properties.
  - **Sprays and Solutions:** Provide rapid onset of action, though residence time can be a challenge.
- **Permeation Enhancers:** Research continues into identifying and optimizing safe and effective permeation enhancers that temporarily open tight junctions or increase membrane fluidity to facilitate drug passage across the buccal epithelium.
- **Enzyme Inhibitors:** To combat enzymatic degradation within the oral cavity (e.g., by proteases), co-formulation with enzyme inhibitors is an active area of investigation, particularly for peptide and protein drugs.
- **Taste Masking:** Crucial for patient acceptance, especially for drugs with unpleasant tastes.

Emerging Technologies and Future Directions:

- **Nanotechnology:** Nanocarriers (nanoparticles, liposomes, micelles) are increasingly integrated into buccal formulations. These can enhance drug solubility, improve permeation, protect drugs from degradation, and offer targeted delivery.
- **3D Printing:** This technology allows for personalized medicine, enabling the fabrication of customized buccal dosage forms with precise drug loading and release profiles, potentially leading to on-demand manufacturing.
- **Intelligent/Stimuli-Responsive Systems:** Development of systems that can respond to physiological triggers (e.g., pH, temperature, enzyme activity) to release drugs in a controlled and responsive manner.
- **Delivery of Biologics:** A major frontier is the buccal delivery of macromolecules like peptides, proteins, and even vaccines, which traditionally require injectable routes. This involves overcoming significant absorption barriers.
- **Combination Therapies:** Designing buccal systems to deliver multiple drugs simultaneously for synergistic effects or to treat complex conditions.
- **Advanced Characterization and Evaluation:** Sophisticated *in vitro* models (e.g., artificial buccal mucosa, cell cultures) and *in vivo* studies are continually being refined to accurately predict

and assess drug permeability, mucoadhesion, and bioavailability.[9]

Challenges that Remain:

- **Limited Surface Area:** Compared to the vast surface area of the small intestine, the buccal mucosa has a smaller area for absorption.
- **Salivary Washout:** Constant saliva flow and swallowing can reduce the residence time of formulations, impacting drug absorption. Mucoadhesive strength is critical to counteract this.
- **Barrier Properties:** While non-keratinized, the buccal epithelium still presents a formidable barrier, especially for large, hydrophilic, or highly charged molecules.
- **Patient Acceptability:** Factors like taste, mouth feel, thickness, and potential for irritation or discomfort can affect patient compliance.
- **Formulation Stability:** Maintaining the stability of sensitive drugs within the buccal formulation over time is a continuous challenge.
- **Regulatory Hurdles:** Navigating the regulatory landscape for novel buccal drug delivery systems can be complex.[10]

CONCLUSION

Buccal tablets represent a highly promising and continuously evolving platform within the broader landscape of transmucosal drug delivery. This review has highlighted their unique advantages, primarily the ability to bypass hepatic first-pass metabolism, facilitate rapid systemic absorption, and offer a non-invasive, patient-friendly alternative to conventional routes. The advancements in polymer science, particularly the development of highly effective mucoadhesive and bioadhesive excipients, have been pivotal in enhancing the residence time and bioavailability of drugs delivered via this route.

Significant progress has been made in designing buccal tablets that optimize drug release profiles, improve patient comfort, and overcome physiological barriers such as salivary washout. The successful development of these formulations relies heavily on a thorough understanding of the buccal mucosal environment, the physicochemical properties of the drug, and the intricate interplay between the formulation components. Furthermore, the capacity of buccal tablets to deliver a diverse range of therapeutic agents, from small molecules to increasingly complex biologics like peptides and proteins, underscores their versatility and growing importance in modern pharmacotherapy.

Despite these advancements, challenges persist. Optimizing mucoadhesion for consistent drug release, ensuring taste masking for patient compliance, and enhancing permeability for a wider spectrum of drugs remain active areas of research. Future directions in buccal tablet development are likely to focus on integrating cutting-edge technologies such as nanotechnology for improved drug solubility and permeation, 3D printing for personalized medicine, and stimuli-responsive systems for smart drug delivery. As research continues to unravel the complexities of buccal absorption and novel materials become available, buccal tablets are poised to play an even more significant role in providing effective, convenient, and patient-centric drug delivery solutions, ultimately improving therapeutic outcomes across various disease states.

RECOMMENDATIONS

In summary, the current landscape of buccal drug delivery is dynamic and rapidly evolving. It's characterized by a strong emphasis on smart material design, advanced manufacturing techniques, and the exploration of new therapeutic applications, particularly for challenging molecules, while continually addressing the inherent physiological and formulation challenges.

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