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A REVIEW ON MUCOADHESIVE BUCCAL DRUG DELIVERY SYSTEM

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ABSTRACT

Extensive efforts have been focused on targeting Drug delivery system in a particular region of the body for extended period of time not only for local targeting of drug but also for better compliance of systemic drug delivery. Among the various routes of administration, oral route is the most suitable, convenient and widely accepted. Drug actions can be improved by developing new oral drug delivery systems such as the mucoadhesive buccal drug delivery system. Mucoadhesive drug delivery system prolongs the residence time of the dosage form at the site of application or absorption and facilitate an intimate contact of the dosage form with the underline absorption surface and thus contribute to improved and better therapeutic performance of the drug. Buccal dosage forms can be of Matrix or Reservoir types and they involves the administration of the desired drug through the buccal mucosal membrane lining of the oral cavity. This review highlights a brief description of advantages, limitations of buccal drug delivery and theories of bioadhesion, mucoadhesive polymer, mechanism of buccal absorption along with mucoadhesive dosage form, factors affecting mucoadhesion.

KEYWORDS: Anatomy, Mucoadhesion, Bio-adhesion, Mucoadhesive systems, Mucoadhesive polymers and Drug delivery.

INTRODUCTION

Mucoadhesion has become an interesting topic for research over last two decades. This is due to its potential to optimize localized drug delivery by retaining the dosage form at its site of action or systemic delivery, by retaining the formulation in intimate contact with the absorption site. Mucoadhesive formulations are usually prepared with mucoadhesive polymers. These polymers are hydrophilic in nature, having limited solubility in other

solvents forming high viscous liquid in water. These characteristics present challenges in the formulation development of mucoadhesive formulations. Also, permeation enhancer enhances the absorption which has great appeal for systemic drug bioavailability. Among the various routes of drug delivery, oral drug delivery is most preferable route of drug administration due to ease of administration, patient compliance and flexibility in formulation.[1] Significant advancements have been achieved in Bucco-adhesive drug administration to address specific challenges, such as first pass metabolism and low bioavailability, associated with regularly utilized dosage forms. Buccal formulations are placed between the gums and buccal pouch for both local and systemic therapy and Mucoadhesive buccal drug delivery system offers numerous advantages, including a simple and efficient method for administration and ensuring patient compliance. Enzyme activity is limited due to the relatively immobile nature of the mucosa and smooth muscle. Mucoadhesive buccal drug delivery system (MBDDS) allows for the administration of both local and systemic drugs. Ideally, substances with a partition coefficient ranging from 40 to 2000 and pKa value between 2 to 10 are absorbed effectively.[2]

1.1 Anatomy of oral cavity

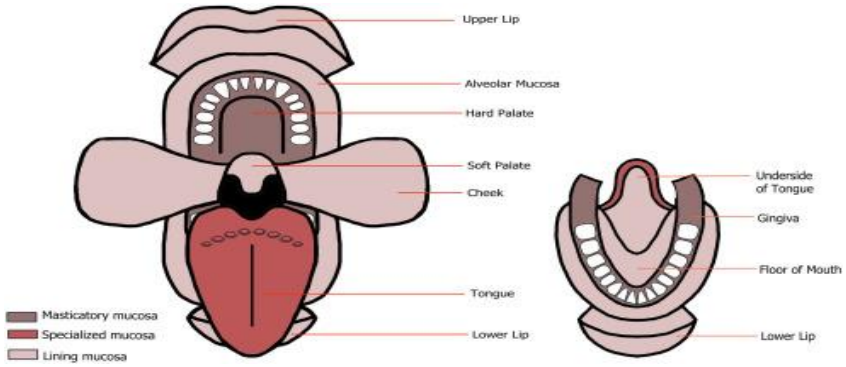

Fig. 1: Schematic representation of the different linings of mucosa in mouth.

The oral cavity comprises the lips, cheek, tongue, hard palate, soft palate and floor of mouth. The oral cavity is lined by relatively thick, dense and multilayered mucous membrane of highly vascularized nature. The mucous secreting region comprises soft palate, floor of mouth underside of tongue and labial and buccal mucosa which have normally non keratinized epithelium. The hard palate region is keratinized epidermis. Specialized zone consists of borders of lips and dorsal surface of tongue which is highly keratinized. The vascular drainage from oral mucosa is by lingual, facial and retromandibular veins. The veins open into the internal jugular vein and thus avoid first pass metabolism. As the stratum

corneum may be potential barrier to mucosal penetration. The drugs are traditionally placed at the non keratinized sites like the buccal and sublingual regions.[3]

1.2 Mucin and Saliva

The mucosal tissues are further covered with mucus, which is negatively charged and contains large glycoprotein termed mucin. These contribute significantly to the viscoelastic nature of saliva and maintain a pH of 5.8 - 7.4. Mucin consists of protein core, rich in O-glycosylated serine and threonine, containing many helix-breaking proline residues. The salivary glands secreting mucus also synthesize saliva, which offer protection to the soft tissues from chemical and mechanical abrasions. The average thickness of salivary film in the mouth varies between 0.07 and 0.10 mm. sustained adhesion of dosage form to the mucosa is an important first step for successful buccal delivery systems. The teeth keratinized epithelium and nonkeratinized epithelium occupies about 20%, 50% and 30% of this surface area respectively.[4]

Table 1: Oral epithelium characteristics.

Tissue	Structure	Epithelial Thickness (µm)	Permeability	Residence Time	Blood (ml/min/cm^2)
Buccal	Non Keratinized	500-600	Intermediate	Intermediate	2.4
Sublingual	Non Keratinized	100-200	Very good	Poor	0.97
Gingival	Keratinized	200	Poor	Intermediate	1.47
Palatal	Keratinized	250	Poor	Very good	0.89

1.3 Mucoadhesion

Mucoadhesive drug delivery systems are the drug delivery systems which utilized the properties of bioadhesion of certain polymers which become adhesive on hydration and hence can be used for targeting the drug to particular region of the body for extended period of time. Bioadhesion is interfacial phenomenon in which two materials of biological nature are held together by interfacial forces. In case of polymer attached to the mucous layer of mucous membrane the term ‘mucoadhesion’ is used. Mucoadhesion can be defined as the ability of material (synthetic or biological) to adhere to a biological tissue for extended period of time. Some drugs which are susceptible to highly acidic condition of stomach and possess high first pass metabolism oral route fails to attain bioavailability. To overcome these problems various mucoadhesive systems are designed which are given by other than oral route like buccal, nasal and vaginal.[5]

1.4 Theories of Mucoadhesion

There are six general theories of adhesion, which have been used for the investigation of mucoadhesion:

a. The electronic theory suggests that electron transfer occurs upon contact of adhering surfaces due to differences in their electronic structure. This is proposed to result in the formation of an electrical double layer at the interface with subsequent adhesion due to attractive forces.

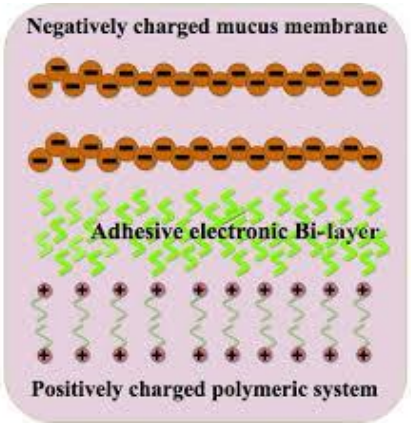

Fig. 2: The electronic theory.

b. The wetting theory is primarily applied to liquid systems and considers surface and interfacial energies. It involves the ability of a liquid to spread spontaneously onto a surface as a prerequisite for the development of adhesion. The affinity of a liquid for a surface can be found using techniques such as contact angle goniometry to measure the contact angle of the liquid on the surface, with the general rule being that the lower the contact angle, the greater the affinity of the liquid to the solid.

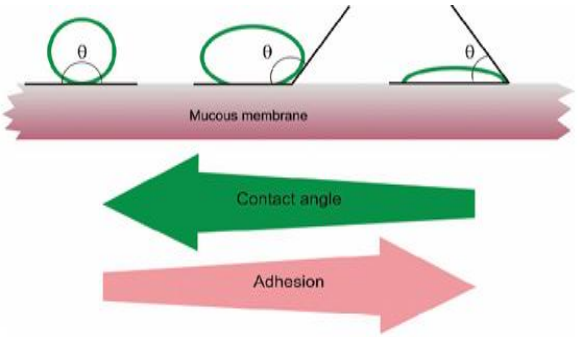

Fig. 3: The wetting theory.

c. The adsorption theory describes the attachment of adhesives on the basis of hydrogen bonding and van der Waals' forces. It has been proposed that these forces are the main

contributors to the adhesive interaction. A subsection of this, the chemisorption theory, assumes an interaction across the interface occurs as a result of strong covalent bonding.

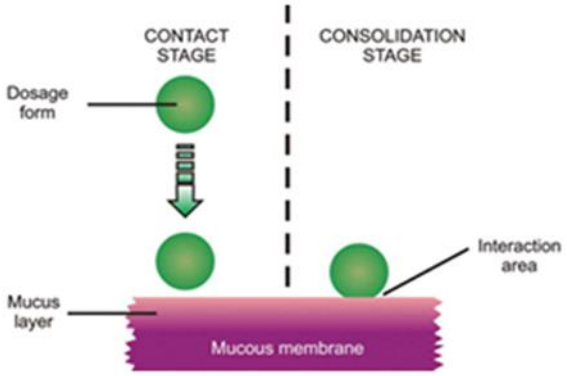

Fig. 4: The adsorption theory.

d. The diffusion theory describes interdiffusion of polymers chains across an adhesive interface. This process is driven by concentration gradients and is affected by the available molecular chain lengths and their mobilities. The depth of interpenetration depends on the diffusion coefficient and the time of contact. Sufficient depth of penetration creates a semi-permanent adhesive bond.

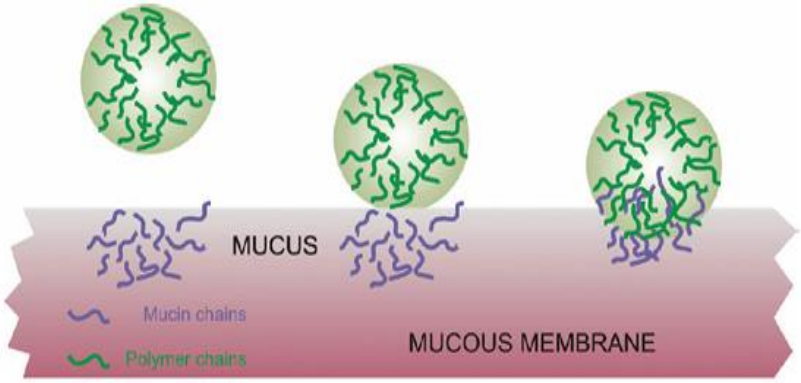

Fig. 5: The diffusion theory.

e. The mechanical theory assumes that adhesion arises from an interlocking of a liquid adhesive (on setting) into irregularities on a rough surface. However, rough surfaces also provide an increased surface area available for interaction along with an enhanced viscoelastic and plastic dissipation of energy during joint failure, which are thought to be more important in the adhesion process than a mechanical effect.

f. The fracture theory differs a little from the other five in that it relates the adhesive strength to the forces required for the detachment of the two involved surfaces after adhesion.[6]

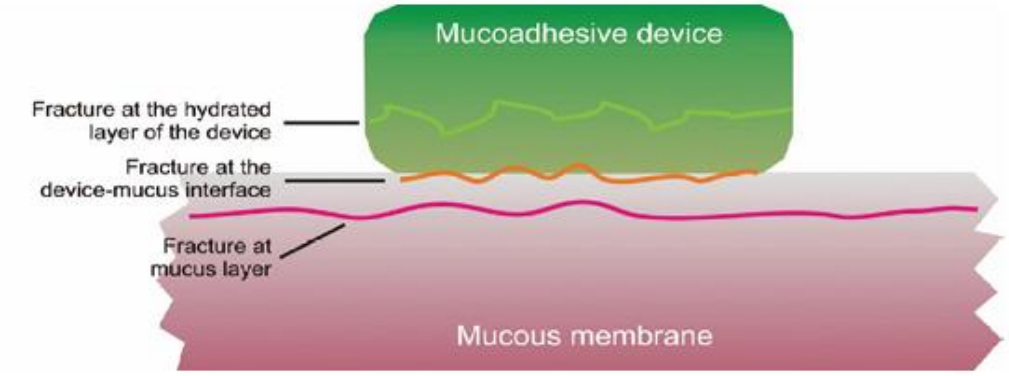

Fig. 6: The fracture theory.

1.5 Mechanism of Mucoadhesion

The mechanism of mucoadhesion is generally divided in two steps:

1. Contact stage
2. Consolidation stage

The first stage is characterized by the contact between the mucoadhesive and the mucous membrane, with spreading and swelling of the formulation, initiating its deep contact with the mucus layer. In some cases, such as for ocular or vaginal formulations, the delivery system is mechanically attached over in other cases, the deposition is promoted by the aerodynamics of the organ to the membrane, the system is administered, such as for the nasal route.

In the consolidation step, the mucoadhesive materials are activated by the presence of moisture. Moisture plasticizes the system, allowing the mucoadhesive molecules to break free and to link up by weak van der Waals and hydrogen bonds.[7]

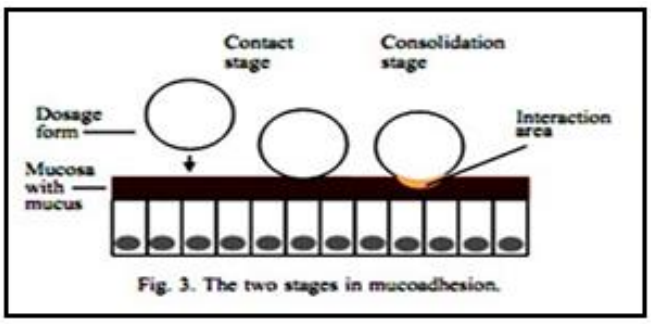

Fig. 7: Two steps of mucoadhesion.

1.6 Different approaches of mucoadhesive drug delivery system

Bioadhesion can be described as adhesion of artificial substances to biological substrates such as adhesion of polymer to skin or other soft tissue, mucoadhesive drug delivery system includes following:

- Buccal drug delivery system.
- Oral delivery system.
- Vaginal delivery system.
- Rectal delivery system.
- Nasal delivery system.
- Ocular delivery system.

Buccal Drug Delivery System

a) Sublingual delivery: The administration of drug is via sublingual mucosa to the systemic circulation.

b) Buccal delivery: The drug administered through the lining of cheek to the systemic circulation.

c) Local delivery: For treatment of conditions of oral cavity such as ulcer, fungal conditions and periodontal diseases by application of bioadhesive system either to the palate, gingival or cheek.

Because of the presence of a smooth and relatively immobile surface for placement of a mucoadhesive dosage form, the buccal region appears to be more suitable for sustained delivery of therapeutic agents using mucoadhesive systems. The buccal and sublingual routes avoid first-pass metabolism. These regions consist of a nonkeratinized epithelium, resulting in a somewhat more permeable tissue than the skin.[8]

1.7 Basic components of buccal drug delivery system

- Drug substance.
- Bioadhesive polymer.
- Backing membrane.
- Permeation enhancers.

Drug substance

It is necessary to determine if the targeted action is for a local or systemic effect as well as for quick or sustained release before developing mucoadhesive drug delivery systems. Pharmacokinetic characteristics should be taken into consideration when choosing a drug for the design of succinyl adhesive drug delivery systems. The medication ought to possess the qualities listed below:

- The medication should be taken in a modest typical single dose.
- Pharmaceuticals with a biological half-life of two to eight hours make excellent candidates for regulated drug delivery.
- When taken orally, the drug's Tmax exhibits larger fluctuations or higher values.
- Drugs taken orally may show signs of presystemic drug clearance or first pass impact.
- When a medicine is taken orally, absorption should be passive.[9]

Bioadhesive Polymer

The important step in the formulation of buccoadhesive dosage form is the selection and characterization of appropriate bioadhesive polymer in the formulation. Polymers are also used in matrix devices in which the drug is embedded in the polymer matrix, which controls the duration of release of drugs. The drug is released into the mucous membrane by means of rate controlling layer or core layer. Bioadhesive polymers which adhere to the mucin are effective and lead to significant improvement in the oral drug delivery.[10]

Table 2: Some oral bioadhesive polymers.

Criteria	Categories	Example
Source	Natural	Agarose, Chitosan, Gelatin, Various gums (guar, xanthan, pectin and alginate).
	Synthetic	**Cellulose derivatives –** Carboxy methyl cellulose (CMC), Hydroxyethyl Cellulose (HEC), Hydroxypropyl cellulose (HPC) and Hydroxypropyl methylcellulose (HPMC).
		Polyacrylic acid derivative – Cellulose propionate (CP), Polycarbonate (PC), Polyacrylic acid (PAA), Polymethacrylate, Co-polymer of acrylic acid and Polyethylene Glycol (PEG).
		Others – Polyvinyl alcohol (PVA), Polyvinyl pyrrolidone (PVP), Polyoxyethylene and Thiolated polymer.
Aqueous solubility	Water Soluble	CP, HEC, HPC, HPMC, PAA and Sodium CMC.
	Water Insoluble	Chitosan and PC.
Charge	Cationic	Aminodextran, Chitosan and Trimethylated Chitosan.
	Anionic	Chitosan, Ethylene Diamine Tetra Acetate (EDTA), CP,

		CMC, PAA and Pectin.
	Non ionic	Hydroxyethyl Starch, HPC, PVP and PVA.
Potential bioadhesive forces	Covalent	Cyanoacrylate.
	Hydrogen	Acrylates, Methacrylic acid, CO, PC and PVA.
	Electrostatic interaction	Chitosan.

Backing membrane

Backing membrane plays very vital role in attachment of bioadhesive devices to the mucus membrane. The material used as backing membrane should be inert and impermeable to the drug and penetration enhancer. Such a membrane on buccal bioadhesive patches prevents the drug loss and offers better patient compliance. The commonly used materials in backing membrane include Carbopol, magnesium stearate, HPMC, HPC and CMC.[6]

Permeation enhancers

Substances that facilitate the permeation through buccal mucosa are called as permeation enhancers. Selection and efficiency of enhancer depends on physiochemical properties of the drug, site of administration, nature of vehicle and other excipients. Though buccal administered drugs bypasses hepatic first pass metabolism and degradation in stomach their, bioavailability is relatively small. Particularly for peptides the co-administration of permeation enhancer is essential.[11]

Table 3: Mucosal permeation enhancers.

Classification	Examples
Surfactants	**Anionic:** Sodium lauryl sulphate, Sodium laurate. **Cationic:** Cetylpyridinium chloride. **Nonionic:** Poloxamer, Span, Tween **Bile salts:** sodium glycodeoxycholate, Sodium taurocholate.
Fatty acids	Oleic acid, Caprylic acid.
Cyclodextrins	a-, b-, g-cyclodextrins, methylated b- cyclodextrins.
Chelators	EDTA, Sodium citrate, Polyacrylates.
Positively charged polymers	Chitosan, Trimethyl chitosan
Cationic compound	Poly L-arginine, L- lysine

1.8 Dosage forms

- Buccal tablets.
- Buccal patches and films.
- Buccal semisolids (ointments and gels).
- Buccal powder.

Buccal tablets

Adhesive tablets are held between the gum and cheek. Tablets are generally flat and elliptical or capsule shaped. Lozenges and troches are other types of tablets used in oral cavity intended to exert a local effect in the mouth or throat. Mucoadhesive tablets may be monolithic or bilaminated. Monolithic is multidirectional release while bilayer contain core layer and backing layer. Backing layer is made up of water insoluble material like Ethyl cellulose or hydrogenated castor oil or may be polymeric coating layer. Backing layer avoids sticking of the tablet to the finger during application.

Buccal patches and films

Buccal patch consists of two poly laminates or multilayered thin film consisting of bioadhesive polymeric layer and impermeable backing layer to provide unidirectional flow of drug across buccal mucosa. Buccal bioadhesive films are formulated by incorporating drug in alcohol solution of bioadhesive polymer.

Buccal semisolid dosage forms

A buccal semisolid dosage form consists of finely powdered natural or synthetic polymer dispersed in a polyethylene or in aqueous solution. Gels are usually clear, transparent, semisolids containing solubilized active substances. Vehicle containing therapeutic agents are especially useful for application to mucus membrane and ulcerated or burned tissues, as their high water content reduces irritancy. The patient compliance rate for gels and ointments that come in bio-adhesive forms is lower than that of solid muco bio-adhesive dosage forms.

Buccal powder dosage forms

Buccal bioadhesive powder dosage forms are a mixture of bioadhesive polymers and drug which are sprayed onto the buccal mucosa. A significant increase in residence time relative to oral solutions was observed.[12]

1.9 Advantages of Buccal drug delivery system

- Ease of administration.
- Termination of therapy is easy.
- Permits localization of drug to the oral cavity for prolonged period of time.
- Can be given to unconscious patient.
- Offers an excellent route to systemic delivery of drugs with high first pass metabolism and provides a great bioavailability.
- A significant reduction in dose can be achieved, therefore reduces dose dependent side effects.
- Drugs with poor bioavailability can be administered conveniently.
- Drugs which are unstable in acidic environment of the stomach can be administered by this route.
- This system does not require any activation for absorption.
- These can also be administered to patients with nausea and vomiting or person with difficulty in swallowing.
- The presence of saliva ensures relatively large amount of water for drug dissolution unlike in case of rectal or transdermal route.[13]

1.10 Disadvantages of Buccal drug delivery system

- The drugs which irritate mucosa or have bitter taste or an obnoxious odor cannot be administered by this route.
- Drugs which are unstable at buccal pH cannot be administered by this route.
- Only drugs with small dose requirement can be administered.
- Only drugs absorbed by passive diffusion can be administered by this route.
- Eating or drinking may become restricted.
- There is possibility of swallowing of the tablet.[13]

1.11 Factors affecting mucoadhesion

Mucoadhesion depends on both bioadhesive polymer and medium in which the polymer will reside.

Polymer related factors

a. Molecular weight

Generally, at particular molecular weight there is maximum bioadhesion. Bioadhesive strength of polymer increases with molecular weight up to 100,000 and beyond this level there is no significant effect on bioadhesive strength.

b. Concentration of active polymer

When the concentration of polymer is too low, the interaction between polymer and mucus is unstable. So more concentrated polymer would result in longer penetrating chain length and better adhesion. As a result, chain penetration of polymer is reduced. Therefore, higher concentration of polymer does not necessarily improve and in some cases actually diminish mucoadhesive properties. In case of solid dosage form such as tablets, higher the polymer concentration stronger is the bioadhesion.

c. Flexibility of polymer chains

Bioadhesion starts with diffusion of the polymer chains in the interfacial region. Therefore, polymer chains must have substantial degree of flexibility in order to achieve the desired entanglement with the mucus. The mobility and flexibility of polymer are related to their viscosity and diffusion coefficients. Cross-linking in water soluble polymer reduces the mobility of polymer chains. As polymer density increases due to cross-linking of molecule, the effective length of chain decreases and further mucoadhesive strength is decreased.

d. Hydrogen bonding capacity

The flexibility of polymer is important to improve its hydrogen bonding potential. Polymers such as poly (methacrylic acid), poly (vinyl alcohol) and their copolymers have good hydrogen bonding capacity.

e. Cross linking density

The inverse relationship exists between degree of swelling at equilibrium and degree of cross linking of polymer. Therefore, as the density increases the diffusion of water in polymer network occurs at lower rate which in turn causes an insufficient swelling of polymer and decreases the rate of interpenetration between polymer and mucin.

f. Charge

The non-ionic polymers show smaller degree of adhesion as compared to anionic polymers. Some cationic polymers have superior mucoadhesive properties in neutral or slightly alkaline medium. In addition, the high molecular weight polymers such as chitosan show good adhesive properties.

Environment related factors

a. pH

pH was found to exert a significant effect on mucoadhesion as observed in studies of polyacrylic polymers cross linked with –COOH group. The pH of medium is determinant factor for degree of hydration of highly cross linked polyacrylic acid polymers and it increases between pH 4 - 5 and decreases more at alkaline pH.

b. Applied strength

The adhesion increases with applied strength or with duration of application. The pressure initially applied to mucoadhesive tissue contact site can affect the depth of interpenetration.

c. Initial contact time

The extent of swelling and interpenetration of polymer chains is determined by initial contact time between mucoadhesive and mucus layer. The mucoadhesive strength increases with initial contact time.

d. Swelling

Swelling is related to both polymer and its environment. Interpenetration of chains is easier as polymer chains are free of interaction. Swelling also depends on presence of water. When swelling is too great decrease in bioadhesion occur.

Physiological variable factors

a. Mucin turnover

The natural turnover of mucin molecules from mucus layer is important because of the two reasons. First, the mucin turnover is expected to limit the residence time of mucoadhesion on the mucus layer. Second the mucin turnover results in substantial amounts of soluble mucin molecules. These molecules interact with mucoadhesive before they interact with mucus layer.

b. Disease states

During the disease conditions such as common cold, ulcerative colitis, gastric ulcers, bacterial and fungal infections of female reproductive tract and inflammatory conditions of eye the physiochemical properties of mucus changes. Mucoadhesive properties of delivery system should be checked under these conditions.[14]

Table No 4: Marketed Buccal drug delivery Products.[15]

Dosage Form	Product	API	Manufacturer	Therapeutic Category
Tablet	Loramyc	Miconazole	bioAliance Pharma	Antifungal
	Buccastem	Prochlorperazine Meleate	Reckitt Benckiser	Antipsychotic
	Aphtach	Triamcinolone Acetonide	Tejin Ltd.	Corticosteroid
	Suboxone	Buprenorphine HCL – Naloxone HCL	Reckitt Benckiser	Opioid Analgesic
	Straint SR	Testosterone	Adrana Bioscience Ltd.	Androgenic Hormone
	Effentora	Fentanyl Citrate	Cephalon	-
	Sabutex	Buprenorphine HCL	Reckitt Benckiser	Opioid Analgesic
	Suscard	Glyceryl Trinitrate	Forest Laboratories	Vasodilator
Spray	Zolpimist	Zolpidem	Novadel Pharmaceuticals	Sedative & Hypnotics
	Sativex	Cannabis based	GW Pharmaceuticals	Cannabinoids
	Nitrostat	Nitroglycerine	Pfizer	Vasodilator
Gel	Bonjela	Cetalkonium Cl & Choline Salicylate	Reckitt Benckiser	Antiulcer
	Corsodyl	Chlorhexidine Digluconate	Glaxo Smith Kline	Antimicrobial
	Fastum	Ketoprofen	Menarini	NSAIDS
Lozenge	Actiq	Fentanyl Citrate	Cephalon	Opioid Analgesic
Pellets	Coralan	Hydrocortisone Sodium Succinate	Celltech	Corticosteroid
Patch	Dentipatch	Lidocaine	Noven	Analgesic
	Coreg	Carvedilol	Glaxo Smith Kline	Antihypertensive

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