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Review Paper

Design and Characterization of Mucoadhesive Buccal Tablets

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ABSTRACT

The buccal route of drug delivery has become an effective alternative to oral delivery, for both systemic and local therapies. Mucoadhesive buccal tablets have unique benefits in adhering to the buccal mucosa, prolonging the residence of the dosage form, and facilitating controlled drug release. These systems first-pass metabolism in the liver, improve bioavailability, and are convenient for patients. Formulation development incorporates bioadhesive polymers, controlled drug release, and mechanical/ physicochemical properties as part of their nature. This review article will discuss the concept, mechanism, formulation strategies, and evaluation parameters of mucoadhesive buccal tablets. Recent advances in testing and characterization including mucoadhesion strength, swelling index, in vitro drug release, and ex vivo permeation studies are also discussed. Future perspectives will focus on the development of smart polymers and nanocomposite-based mucoadhesive systems, for improved therapeutic activities.

INTRODUCTION

The oral route continues to be the most favoured route of drug administration because of its simplicity, safety, and ease of patient acceptance. However, limitations such as hepatic first-pass metabolism, enzymatic degradation, and the lack of bioavailability of some drugs have led to the development of various alternative routes of delivery. One example is administration via the buccal route—using the mucosa of the cheek—for drugs that undergo significant hepatic metabolism or have low oral bioavailability. Buccal delivery systems (BDDS) provide for the direct absorption of drugs through the buccal mucosa into the systemic circulation, avoiding the gastrointestinal tract. The addition of mucosal adhesive polymers can also provide retention of dosage forms at the absorption site for prolonged contact and controlled release. Mucoadhesive buccal tablets are particularly suited for drugs such as nitro-glycerine, fentanyl, and propranolol, that undergo extensive first pass metabolism. The present review will provide insight into the design,

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formulation concerns, evaluation, and trends in mucoadhesive buccal tablets.

1.2 Concept of Mucoadhesion

Mucoadhesion is the process by which synthetic or natural polymer materials become attached to a mucosal surface, mediated by molecular interactions such as hydrogen bonding, van der Waals forces, and electrostatic interactions between polymer chains and resurfaced by the mucin layer.

1.3 Mechanism of Mucoadhesion

Mucoadhesion occurs in two stages:

1. **Contact Stage –** the polymer wets and spreads on the mucosal surface.
2. **Consolidation Stage –** polymer chains interpenetrate with mucin chains, reinforcing adhesive interactions with secondary (e.g, pharma) bonding.

Several theories have been proposed to explain mucoadhesion:

- **Electronic theory** – the development of attractive forces arises from the transfer of electrons between the polymer and mucin.
- **Wetting theory** – the ability of the polymer to spread on the mucosal surface improves adhesion.
- **Diffusion–interlocking theory** – the interpenetration of polymer chains with mucin glycoprotein chains.
- **Adsorption theory** – bond formation between the polymer and mucin occurs via weak van der Waals forces and hydrogen bonding.
- **Fracture theory** – the energy needed to separate the adhesive bonds determines the observable mucoadhesive strength.

1.4 Buccal Mucosa; Anatomy and Physiology

The buccal mucosa is a non-keratinized epithelial layer with a thickness between 500–800 μm. It consists of:

- **Epithelium** – A barrier that permits permeability.
- **Lamina propria** – Contains connective tissue and blood capillaries.
- **Basement membrane** – Provides structural support.

The buccal mucosa has a great vascular supply, rapid drug absorption, and accessibility for dosing. However, limited surface area and washing effects of saliva are drawbacks to be addressed in the formulation.

1.5 Advantages

- Circumvent hepatic first-pass metabolism.
- Extended residence time and controlled drug release.
- Enhanced bioavailability of inadequately absorbed drugs.
- Ease of administration and drug removal.
- Appropriate for patients with dysphagia.
- Possibilities for both local as well as systemic delivery.

1.6 Limitation

- Reduced absorption surface area compared to the intestine.
- Salivary secretion could dilute or wash off drug.
- Limited for high dose medications.
- Possible irritation of the mucosa.
- Variation between mucosal conditions (e.g., pH, enzyme activity)

1.7 Ideal Properties of Buccal Tablet

A perfect mucoadhesive buccal tablet should:

- Adhere to the mucosa tightly for the appropriate period of time.
- Release drugs in a controlled way.
- Be soft and non-irritable for the mucosa.
- Withstand salivary washout.
- Have sufficient mechanical strength and flexibility.
- Be easy to remove after use.

1.8 Polymers Used in Mucoadhesive Tablets

Polymers play a crucial role in determining adhesion, swelling, and drug release. They are classified as:

1. Natural Polymers

- Chitosan
- Sodium alginate
- Guar gum
- Xanthan gum
- Pectin
- Gelatin

2. Synthetic Polymers

- Hydroxypropyl methylcellulose (HPMC)
- Carbopol (Carbomer 934, 940)
- Polycarbophil
- Polyvinyl alcohol (PVA)
- Eudragit RL/RS
- Polyethylene oxide (PEO)

These polymers form hydrogen bonds with mucin, providing strong adhesion and controlled release.

1.9 Factor Affecting Mucoadhesion

- Polymer-related factors: molecular weight, flexibility, charge, and hydration capacity.
- Environmental factors: pH, ionic strength, and the presence of saliva.
- Physiological factors: mucin turnover rate, disease state, and application site.

2. FORMULATION AND CHARACTERIZATION

2.1 Desing and Formulation of Mucoadhesive Buccal Tablet

The formulation entails several important steps:

1. Select the drug: The drug should have a short biological half-life, low oral bioavailability, and sufficient permeability through mucosa.
2. Select the polymer: Based on mucoadhesion strength, swelling, and release profile.
3. Method of preparation:

a. Direct compression: Most widely employed; it entails blending the drug, polymer, and excipients followed by compression.
b. Wet granulation: Applied if the polymers need binding.
c. Melt extrusion or solvent casting for specialized designs.

2.1.1 Typical Excipients:

- Bioadhesive polymers: For adhesion factor (HPMC, Carbopol).
- Backing layer: Prohibits drug loss into the oral cavity (ethyl cellulose).
- Plasticizers: Enhance flexibility (PEG, glycerol).
- Permeation enhancers: Aid in mucosal absorption (sodium lauryl sulfate, bile salts).
- Sweetening/flavoring agents: For palatability.

2.2 Characterization and Evaluation

2.2.1 Preliminary Compression Assessments

- Bulk density, tapped density, Carr's index, Hausner ratio, and angle of repose.

2.2.2 Post-compression Analyses

- Thickness, hardness, friability, and weight variation.

2.2.3 Surface pH

- Should be close to neutral (6.5-7.5) to reduce the risk of mucosal irritation.

2.2.4 Swelling Index

- Indicates hydration and expansion of the polymer which can be measured as weight gain in buffer solution.

2.2.5 Mucoadhesive Strength

- Can be determined with a texture analyzer but can also be measured on a modified balance as the force for the tablet to lift off of excised mucosal tissue.

2.2.6 In-vitro Drug Release

- Is performed on the drug product in a dissolution apparatus with phosphate buffer (pH 6.8).

2.2.7 Ex-vivo Permeation Studies

- Are conducted with porcine or goat buccal mucosa in Franz diffusion cells.

2.2.8 Stability Studies

- Are conducted according to ICH guidelines at accelerated stability conditions (40°C/75% RH).

3. APPLICATION

- Systemic delivery of cardiovascular drugs (propranolol, nifedipine).
- Hormone replacement (estradiol).
- Analgesic and anti-inflammatory agents (ketoprofen, diclofenac).
- Local treatment of oral infections and ulcers (miconazole, chlorhexidine).

4. FUTURE PROSPECTS

The future of mucoadhesive buccal tablets could be based on smart polymer systems that are responsive to environmental stimuli (pH, temperature). The incorporation of nanotechnology could also help to enhance bioavailability and drug targeting. Bioengineered mucoadhesive peptides and 3-D printing could allow for the development of individualized formulations for patient specific therapies.

CONCLUSION

Which definition of buccal smoestos is likely to become an attractive and viable option for controlled and targeted delivery of drugs? These systems offer means to circumvent the first-pass metabolism, improve bioavailability, and maintain therapeutic plasma concentrations for drugs with poor oral absorption. The right choice of polymers, the optimization of formulation parameters and evaluations, and rigorous characterization are key components towards the development of viable products buccal tablets of mucoadhesive delivery systems. Based on the continuing innovation in materials and design, it is likely that mucoadhesive buccal delivery systems will have a significant place to play in modern pharmaceutical formulations.

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