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Review Paper

A Review on Mucoadhesive Buccal Film of Prochlorperazine Mesylate

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ABSTRACT

Prochlorperazine Mesylate is a widely used antiemetic and antipsychotic drug; however, its conventional oral administration is associated with limitations such as first-pass metabolism, reduced bioavailability, and delayed onset of action. Mucoadhesive buccal drug delivery systems have emerged as a promising alternative for overcoming these challenges by allowing direct drug absorption through the buccal mucosa into systemic circulation. This review focuses on the development and potential of Mucoadhesive buccal films of Prochlorperazine Mesylate as an effective drug delivery system. The article highlights the principles of buccal drug delivery, mechanisms of drug absorption through the buccal mucosa, and the role of mucoadhesion in enhancing drug residence time and bioavailability. Various formulation components, including polymers, plasticizers, and penetration enhancers, along with commonly used preparation methods such as solvent casting, are discussed. Additionally, important evaluation parameters of buccal films are summarized. Overall, mucoadhesive buccal films represent a promising, non-invasive, and patient-friendly approach for improving therapeutic efficacy and compliance.

INTRODUCTION

Nausea and vomiting are common clinical conditions that may arise due to various causes such as gastrointestinal disorders, chemotherapy, motion sickness, and postoperative complications. Effective management of these conditions is essential to improve patient comfort and therapeutic outcomes. Prochlorperazine mesylate, a phenothiazine derivative, is widely used as an antiemetic and antipsychotic agent due to its dopamine (D_2) receptor antagonistic activity.

However, conventional oral dosage forms of prochlorperazine mesylate suffer from several limitations, including extensive hepatic first-pass metabolism, variable bioavailability, and delayed onset of action. These drawbacks necessitate the development of alternative drug delivery systems that can enhance therapeutic efficacy.

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The buccal drug delivery system has emerged as a promising approach for systemic drug administration through the buccal mucosa. This route offers several advantages such as bypassing first-pass metabolism, rapid drug absorption, improved bioavailability, and enhanced patient compliance. The buccal mucosa is highly vascularized, allowing direct entry of the drug into systemic circulation.

Mucoadhesive buccal films are thin, flexible dosage forms designed to adhere to the mucosal surface and provide controlled and sustained drug release. The incorporation of mucoadhesive polymers enhances the residence time of the dosage form at the site of application, thereby improving drug absorption and therapeutic effectiveness. Due to these advantages, mucoadhesive buccal films of prochlorperazine mesylate represent a promising alternative to conventional dosage forms.

1. Drug Profile of Prochlorperazine Mesylate[7]

Prochlorperazine mesylate is a phenothiazine derivative widely used as an antiemetic and antipsychotic agent. It primarily acts by blocking dopamine (D_2) receptors in the chemoreceptor trigger zone (CTZ) of the brain, thereby preventing nausea and vomiting.

It is commonly indicated for the management of severe nausea and vomiting associated with chemotherapy, postoperative conditions, and motion sickness. Additionally, it is used in the treatment of schizophrenia and other psychotic disorders.

Despite its therapeutic effectiveness, the conventional oral administration of Prochlorperazine Mesylate is associated with several limitations, including extensive hepatic first-pass metabolism, reduced and variable bioavailability, and delayed onset of action. Furthermore, its use in patients experiencing vomiting may lead to poor drug retention and reduced efficacy.

These limitations highlight the need for an alternative drug delivery approach, such as mucoadhesive buccal films, which can bypass first-pass metabolism and enhance systemic drug availability.

2. Buccal Drug Delivery System[8, 9]

The buccal drug delivery system involves the administration of drugs through the buccal mucosa, which lines the inner surface of the cheeks. This route allows drugs to directly enter the systemic circulation via the rich vascular network, thereby bypassing hepatic first-pass metabolism and improving bioavailability.

Buccal delivery is particularly advantageous for drugs that undergo extensive metabolism in the liver, are unstable in the gastrointestinal tract, or require rapid onset of action. The buccal mucosa offers moderate permeability and a relatively immobile surface, making it suitable for controlled drug delivery systems.

Advantages of Buccal Drug Delivery System

- Bypasses first-pass metabolism
- Rapid onset of action
- Improved bioavailability
- Non-invasive and patient-friendly
- Easy administration and removal
- Suitable for both local and systemic delivery

Limitations

- Limited surface area for drug absorption
- Continuous saliva secretion may dilute the drug
- Possible accidental swallowing of dosage form
- Not suitable for drugs requiring high doses

3. Mucoadhesive Buccal Film[10 – 13]

Mucoadhesive buccal films are thin, flexible polymeric dosage forms designed to adhere to the buccal mucosa and deliver drugs either locally or systemically. These films ensure prolonged residence time at the site of application, thereby enhancing drug absorption and therapeutic efficacy.

Mucoadhesion refers to the adhesion between a polymer and the mucosal surface, which occurs due to various interactions such as hydrogen bonding, electrostatic attraction, and mechanical interlocking. This property helps in maintaining close contact between the dosage form and the mucosa, leading to improved drug permeation.

Types of Buccal Films

- **Single-layered films:** Drug and excipients incorporated in one layer
- **Bilayered films:** Mucoadhesive layer + backing layer for unidirectional release
- **Multilayered films:** Designed for controlled or sequential drug release

4. Composition of Mucoadhesive Buccal Film[14-22]

Mucoadhesive buccal films are composed of various components that contribute to their mechanical strength, adhesion, and drug release characteristics.

- **Active Pharmaceutical Ingredient (API):**Prochlorperazine mesylate is incorporated to achieve the desired therapeutic effect.
- **Mucoadhesive Polymers:**Polymers such as hydroxypropyl methylcellulose (HPMC), Carbopol, sodium carboxymethyl cellulose (NaCMC), polyvinyl alcohol (PVA), and chitosan provide adhesion and control drug release.
- **Plasticizers:**Plasticizers like glycerin, polyethylene glycol (PEG), and propylene glycol enhance flexibility and prevent brittleness of the film.
- **Backing Layer (Optional):**Materials such as ethyl cellulose are used to prevent drug loss and ensure unidirectional drug release.
- **Penetration Enhancers:**Agents like surfactants and fatty acids improve drug permeation across the buccal mucosa.
- **Sweetening and Flavoring Agents:**Added to improve patient acceptability and mask unpleasant taste.

5. Methods of Preparation

Mucoadhesive buccal films can be prepared using various techniques, among which the solvent casting method is most commonly used due to its simplicity and reproducibility.

6.1 Solvent Casting Method[23, 24]

In this method, water-soluble polymers are dissolved in a suitable solvent to form a homogeneous solution. The drug and other excipients such as plasticizers and penetration enhancers are added and mixed thoroughly. The resulting solution is poured onto a flat surface (such as a glass plate or Petri dish) and dried under controlled conditions. After drying, the film is carefully removed and cut into the desired size.

Advantages:

- Simple and reproducible
- Suitable for heat-sensitive drugs

Disadvantages:

- Longer drying time
- Possibility of residual solvent

6.2 Hot-Melt Extrusion Method (Optional)[25]

This method involves the mixing of drug and polymers at elevated temperatures, followed by extrusion to form films. It is a solvent-free technique but is not suitable for thermolabile drugs.

6. Evaluation Parameters of Buccal Film[26]

Proper evaluation of buccal films is essential to ensure their quality, performance, and therapeutic effectiveness.

- **Appearance:**Films are visually inspected for uniformity, smoothness, and absence of air bubbles.
- **Thickness:**Measured using a micrometer at different points to ensure uniformity.
- **Weight Variation:**Individual films are weighed, and average weight is calculated.
- **Folding Endurance:**Indicates flexibility and is determined by repeatedly folding the film until it breaks.
- **Drug Content Uniformity:**Ensures uniform distribution of drug within the film.
- **Surface pH:**Measured to ensure compatibility with buccal mucosa and avoid irritation.
- **Mucoadhesive Strength:**Determines the ability of the film to adhere to mucosal surface.
- **In-vitro Drug Release:**Evaluates the release profile of the drug from the film.

6. Advantages of Mucoadhesive Buccal Film[10, 27, 28]

Mucoadhesive buccal films offer several advantages over conventional dosage forms, making them a promising alternative for drug delivery:

- Bypass hepatic first-pass metabolism, leading to improved bioavailability
- Provide rapid onset of action through direct systemic absorption
- Non-invasive and easy to administer
- Improve patient compliance, especially in pediatric and geriatric patients
- Suitable for patients with nausea, vomiting, or difficulty in swallowing
- Enable controlled and sustained drug release
- Reduce gastrointestinal irritation and drug degradation
- Allow easy termination of therapy by removal of the film

CONCLUSION

Mucoadhesive buccal films represent a promising and innovative drug delivery system for Prochlorperazine Mesylate, addressing the limitations associated with conventional oral dosage forms. By bypassing hepatic first-pass metabolism and enabling direct absorption through the buccal mucosa, this approach significantly enhances bioavailability and provides a faster onset of action. The use of suitable polymers and formulation techniques ensures adequate mucoadhesion, controlled drug release, and improved therapeutic efficacy.

Furthermore, buccal films offer a patient-friendly, non-invasive alternative that improves compliance, particularly in patients experiencing nausea, vomiting, or difficulty in swallowing. Overall, mucoadhesive buccal films of Prochlorperazine Mesylate demonstrate significant potential as an effective and reliable drug delivery system, warranting further research and development for clinical applications.

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