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FORMULATION AND EVALUATION OF FAST RELEASE ORAL PATCHES CONTAINING CHLORHEXIDINE

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ABSTRACT

The present study focused on the formulation and evaluation of fast-dissolving mucoadhesive buccal films of chlorhexidine for the effective management of oral infections. The films were prepared using suitable polymers and excipients selected based on their film-forming and mucoadhesive properties, employing the solvent casting method under controlled conditions. Various formulations were developed by optimizing polymer and plasticizer concentrations to achieve films with desirable physicochemical characteristics. The optimized formulation exhibited uniform thickness, flexibility, and stability, indicating the reliability of the preparation method. The buccal films demonstrated rapid drug release along with effective mucoadhesion, ensuring prolonged residence time in the oral cavity. This approach successfully addressed the limitation of rapid drug clearance commonly associated with conventional oral dosage forms. Overall, the developed buccal film system showed improved drug availability, enhanced retention, and better patient compliance, highlighting its potential as an efficient and patient-friendly alternative for the treatment of oral infections.

KEYWORDS: Buccal Films, Chlorhexidine, Mucoadhesive Drug Delivery, Oral Drug Delivery, Solvent Casting Method.

INTRODUCTION

Oral health plays a crucial role in overall well-being, and the oral cavity is highly susceptible to microbial infections such as gingivitis, periodontitis, and oral ulcers. These conditions are primarily caused by the accumulation of pathogenic microorganisms and plaque formation, which require effective antimicrobial treatment for proper management. Conventional dosage forms such as mouthwashes, gels, and tablets are commonly used for oral therapy; however, they often suffer from limitations such as short residence time, poor patient compliance, and rapid drug clearance due to salivary flow.[1,2]

Chlorhexidine is a broad-spectrum antimicrobial agent widely used in the treatment of oral infections due to its efficacy against Gram-positive and Gram-negative bacteria, fungi, and some viruses. It acts by disrupting the microbial cell membrane, leading to leakage of intracellular components and cell death. Despite its effectiveness, conventional chlorhexidine formulations such as mouthwashes have limited retention in the oral cavity, which reduces their therapeutic efficacy and necessitates frequent dosing.[3,4]

To overcome these limitations, novel drug delivery systems such as buccal films have gained significant attention. Buccal drug delivery offers several advantages, including avoidance of first-pass metabolism, rapid onset of action, and improved bioavailability. Additionally, the buccal mucosa is highly vascularized, allowing efficient drug absorption directly into systemic circulation.[5,6]

Mucoadhesive buccal films are thin, flexible dosage forms that adhere to the mucosal surface and release the drug in a controlled manner. These films prolong the residence time of the drug at the site of action, thereby enhancing therapeutic effectiveness. The use of mucoadhesive polymers ensures strong adhesion to the mucosal surface, reducing drug loss due to saliva and improving drug retention.[7,8]

The formulation of buccal films involves the selection of suitable polymers, plasticizers, and active pharmaceutical ingredients. Polymers such as hydroxypropyl methylcellulose (HPMC), carbopol, and polyvinyl alcohol (PVA) are commonly used due to their excellent film-forming and mucoadhesive properties. Plasticizers such as glycerin and polyethylene glycol are incorporated to improve the flexibility and mechanical strength of the films.[9,10]

Among various preparation methods, the solvent casting technique is widely employed for the fabrication of buccal films due to its simplicity, cost-effectiveness, and ability to produce uniform films. In this method, the polymer and drug are dissolved in a suitable solvent, followed by casting and controlled drying to obtain a thin film with uniform drug distribution.[11]

Evaluation of buccal films is essential to ensure their quality, safety, and performance. Parameters such as thickness, weight uniformity, folding endurance, surface pH, drug content uniformity, disintegration time, and in-vitro drug release are commonly assessed. These evaluations help in optimizing the formulation and ensuring its suitability for therapeutic application.[12,13]

In recent years, fast-dissolving mucoadhesive buccal films have emerged as a promising alternative to conventional oral dosage forms, particularly for localized treatment of oral infections. These films provide rapid drug release along with prolonged retention, improving both efficacy and patient compliance.[14,15]

Therefore, the present study focuses on the formulation and evaluation of fast-dissolving mucoadhesive buccal films of chlorhexidine. The objective is to develop an effective drug delivery system that enhances drug availability, prolongs retention in the oral cavity, and improves therapeutic outcomes in the management of oral infections.

METHODOLOGY

The methodology for the formulation and evaluation of the chlorhexidine-loaded mouth-dissolving oral pouch was carried out in a systematic and stepwise manner. Initially, the drug (chlorhexidine) and suitable excipients were selected based on their compatibility, safety, and functional role in the formulation. This was followed by pre-formulation studies, which included the assessment of physicochemical properties of the drug and evaluation of drug–excipient compatibility to ensure stability and effectiveness of the final formulation.

Subsequently, the oral pouch was formulated by preparing a chlorhexidine-loaded mouth-dissolving system using appropriate techniques to achieve rapid disintegration and effective drug delivery in the oral cavity. After formulation, the prepared pouches were subjected to evaluation tests, including assessment of physical properties such as appearance and uniformity, disintegration time, and surface pH to ensure suitability for oral mucosal application.

Further, in-vitro drug release studies were conducted to evaluate the release profile of chlorhexidine from the formulated pouch, providing insight into its drug delivery efficiency. Finally, the obtained results were analyzed and interpreted to determine the overall performance, effectiveness, and potential applicability of the formulation as a novel oral drug delivery system.

Standard formulation

Composition (for one batch)

- Chlorhexidine → 0.5–1% w/v
- HPMC (Film-forming polymer) → 3–5% w/v
- PEG-400 (Plasticizer) → 0.5–1 mL
- Distilled Water → q.s. (to make solution)

Practical formula

- Chlorhexidine → 0.5 g
- HPMC → 4 g
- PEG-400 → 1 mL
- Distilled Water → 100 mL

Materials Used

- Drug: Chlorhexidine
- Polymers: HPMC / Carbopol / PVA
- Plasticizer: PEG-400

Variables Studied

- Polymer concentration
- Plasticizer amount
- Drying conditions

Preparation of Buccal Films

The buccal films were prepared using a solvent casting method. Initially, the selected polymer was dissolved in distilled water with continuous stirring to obtain a clear solution. The drug was then added gradually to the polymeric solution under constant stirring to ensure uniform distribution. Subsequently, a suitable plasticizer was incorporated to enhance the flexibility and mechanical strength of the film. The resulting mixture was stirred thoroughly until a homogeneous solution was formed. This uniform solution was then carefully cast onto a clean petri plate and spread evenly to form a thin film. The casted solution was allowed to dry under controlled conditions to ensure complete evaporation of the solvent. After drying, the formed film was carefully removed from the petri plate and cut into uniform shapes and sizes for further evaluation.

The formulation of buccal films was carried out through a systematic approach by initially selecting chlorhexidine as the active drug along with suitable polymers based on their film-forming and mucoadhesive properties. Multiple formulations were then prepared by varying the concentrations of polymers and plasticizers to achieve the desired characteristics. The buccal films were developed using the solvent casting method under controlled conditions to ensure uniformity and reproducibility.

Further optimization of the formulation was performed to obtain films with desirable properties such as uniform thickness, flexibility, and stability. The prepared films were carefully dried to remove residual moisture and then cut into standard shapes, sizes, and dose units for consistency in drug delivery. Finally, the optimized buccal films were packed in airtight packaging to protect them from moisture and degradation, ensuring their stability and effectiveness during storage.

RESULT

Table No. 1: Result Interpretation table.

Parameter	Result	Interpretation
Appearance	Smooth, transparent, flexible films	Indicates uniform polymer distribution
Weight Variation	45–52 mg (±5%)	Shows uniform casting and consistency
Thickness	0.20 – 0.28 mm	Ensures uniform drug release
Dimensions (Shape and Size)	Square films, approx. 1.5 x 2.5 cm	Uniform size ensures consistent dosing and handling
Folding Endurance	4-5 folds	Good flexibility and handling strength
Surface pH	6.5 – 6.8	Compatible with oral mucosa (non-irritant)
Swelling Index	Moderate swelling within 2–5 min	Supports adhesion and drug release
Disintegration Time	30–60 sec (start), complete in 2–4 min	Fast dissolving behavior

CONCLUSION

The study successfully demonstrated the formulation of fast-dissolving mucoadhesive buccal films of chlorhexidine using suitable polymers and excipients. The optimized formulation exhibited desirable characteristics such as uniformity, flexibility, and stability, indicating the effectiveness of the preparation method. The developed films showed rapid drug release along with effective mucoadhesion, ensuring prolonged retention at the site of action.

This delivery system effectively overcomes the limitation of rapid drug clearance in the oral cavity, which is commonly associated with conventional dosage forms. Furthermore, the formulated buccal films offer a patient-friendly alternative due to ease of administration and improved compliance. Overall, this approach enhances drug availability

and retention time, thereby improving therapeutic efficacy in the treatment of oral infections and demonstrating significant potential for future pharmaceutical applications.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this research work.

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