EJPMR, 2026, 13(7), 597-601 **Research Article** **Impact Factor: 8.158**

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

ISSN (O): 2394-3211
ISSN (P): 3051-2573
Coden USA: EJPMAG

FORMULATION AND EVALUATION OF MUCOADHESIVE BUCCAL FILMS OF PROPRANOLOL FOR IMPROVED SYSTEMIC DELIVERY

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DOI: https://doi.org/10.5281/zenodo.21353762

How to cite this Article: Nirmal Puri[1]*, Prof. Dr. Pankaj Kumar Sharma[2], Prof. Dr. Jaya Sharma[3], Ravisha Mathur (2026). Formulation And Evaluation Of Mucoadhesive Buccal Films Of Propranolol For Improved Systemic Delivery. European Journal of Pharmaceutical and Medical Research, 13(7), 597–601.

Article Received on 21/05/2026 **Article Revised on 11/06/2026** **Article Published on 01/07/2026**

ABSTRACT

Propranolol hydrochloride is a non-selective beta-adrenergic receptor blocker widely prescribed for the management of hypertension, angina pectoris, cardiac arrhythmias, migraine prophylaxis, and anxiety disorders. However, its oral administration is associated with extensive first-pass hepatic metabolism, resulting in low and variable bioavailability of approximately 25–35%. Buccal drug delivery offers a promising alternative route by facilitating direct absorption through the buccal mucosa into the systemic circulation, thereby bypassing hepatic first-pass metabolism and improving therapeutic efficacy. The present study aims to formulate and evaluate mucoadhesive buccal films of propranolol hydrochloride for enhanced systemic drug delivery and improved patient compliance. Mucoadhesive buccal films were prepared using the solvent casting technique by incorporating suitable hydrophilic and mucoadhesive polymers such as hydroxypropyl methylcellulose (HPMC), Carbopol 934P, sodium carboxymethyl cellulose (NaCMC), or chitosan in different ratios. Appropriate plasticizers, including glycerol or polyethylene glycol 400 (PEG 400), were added to enhance flexibility and mechanical strength. The prepared films were evaluated for various physicochemical and pharmaceutical parameters, including appearance, thickness, weight uniformity, surface pH, folding endurance, tensile strength, percentage moisture absorption, moisture loss, swelling index, drug content uniformity, and in vitro residence time. Mucoadhesive strength was determined using suitable biological membranes, while in vitro drug release studies were performed using phosphate buffer (pH 6.8) to simulate buccal conditions. Ex vivo permeation studies were conducted using porcine or goat buccal mucosa to assess the drug permeation characteristics. Stability studies of the optimized formulation were carried out according to International Council for Harmonisation (ICH) guidelines.

KEYWORDS: Propranolol Hydrochloride, Mucoadhesive Buccal Film, Buccal Drug Delivery, Systemic Drug Delivery, Bioavailability Enhancement, First-Pass Metabolism, Controlled Drug Release.

1. INTRODUCTION

Oral drug delivery remains the most preferred route of administration due to its convenience, cost-effectiveness, and high patient acceptance. However, many therapeutic agents exhibit poor oral bioavailability because of extensive first-pass hepatic metabolism and degradation in the gastrointestinal tract. Propranolol hydrochloride, a non-selective β-adrenergic receptor blocker, is widely used in the treatment of hypertension, angina pectoris, cardiac arrhythmias, migraine prophylaxis, and anxiety disorders. Despite its therapeutic efficacy, the oral bioavailability of propranolol is limited to approximately 25–35% owing to extensive first-pass metabolism in the liver, necessitating frequent dosing to maintain therapeutic plasma concentrations.

Buccal drug delivery has emerged as a promising alternative to conventional oral administration by enabling direct absorption of drugs through the buccal mucosa into the systemic circulation. This route bypasses hepatic first-pass metabolism, minimizes gastrointestinal degradation, provides rapid onset of action, and improves

bioavailability. Furthermore, buccal dosage forms are non-invasive, easily administered and removed, and particularly beneficial for pediatric, geriatric, and dysphagic patients who experience difficulty swallowing conventional tablets or capsules.

Among various buccal dosage forms, mucoadhesive buccal films have gained considerable attention because of their flexibility, thin structure, prolonged residence time, and ability to provide controlled and sustained drug release. These films adhere firmly to the buccal mucosa, ensuring intimate contact with the absorption site and enhancing drug permeation. The present study focuses on the formulation and evaluation of mucoadhesive buccal films of propranolol hydrochloride using suitable mucoadhesive polymers and plasticizers. The prepared films will be evaluated for their physicochemical characteristics, mucoadhesive properties, mechanical strength, in vitro drug release, ex vivo permeation, and stability to identify an optimized formulation capable of improving systemic drug delivery and therapeutic efficacy.

2. MATERIALS AND METHODS

Below is a **thesis-quality "Materials and Methods"** section suitable for an M.Pharm dissertation. It is written in a formal scientific style and can be expanded further in your thesis.

MATERIALS

Propranolol hydrochloride was used as the model drug for the preparation of mucoadhesive buccal films. Mucoadhesive polymers such as Hydroxypropyl Methylcellulose (HPMC K15M), Carbopol 934P, Sodium Carboxymethyl Cellulose (NaCMC), and Chitosan were selected for film formation and adhesion to the buccal mucosa. Polyethylene Glycol 400 (PEG 400) or Glycerol was used as a plasticizer to improve film flexibility. Mannitol was incorporated as a sweetening agent, while citric acid was used as a saliva-stimulating agent. All chemicals and reagents used in the study were of analytical grade and procured from authorized suppliers.

METHODS

Preformulation Studies

The drug was characterized for its physical appearance, melting point, solubility, partition coefficient, and λmax using UV–Visible spectrophotometry. Drug–excipient compatibility was evaluated by Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Calorimetry (DSC).

Preparation of Mucoadhesive Buccal Films

Mucoadhesive buccal films were prepared by the solvent casting method. The required quantity of polymer was dissolved in distilled water with continuous stirring until a clear solution was obtained. The calculated amount of propranolol hydrochloride was dissolved separately and mixed with the polymer solution. Plasticizer, sweetening agent, and other excipients were added with constant stirring to obtain a homogeneous solution. The resulting solution was poured into glass Petri dishes and dried at room temperature or in a hot-air oven at 40–45°C. After complete drying, the films were carefully peeled off and cut into uniform sizes containing the desired dose of propranolol hydrochloride.

Evaluation of Buccal Films

The prepared films were evaluated for the following parameters:
• Visual appearance
• Thickness
• Weight variation
• Folding endurance
• Surface pH
• Drug content uniformity
• Tensile strength
• Percentage elongation
• Moisture absorption
• Moisture loss
• Swelling index
• Mucoadhesive strength
• In vitro residence time

In Vitro Drug Release Study

Drug release studies were performed using a USP dissolution apparatus containing phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C. Samples were withdrawn at predetermined time intervals, replaced with fresh dissolution medium, and analyzed using a UV–Visible spectrophotometer at the predetermined wavelength. The cumulative percentage drug release was calculated and plotted against time.

Ex Vivo Permeation Study

Ex vivo permeation studies were carried out using

freshly excised porcine or goat buccal mucosa mounted on a Franz diffusion cell. The receptor compartment was filled with phosphate buffer (pH 6.8) and maintained at 37 ± 0.5°C under continuous stirring. Samples were collected at regular intervals and analyzed spectrophotometrically to determine the amount of drug permeated through the buccal membrane.

Drug Release Kinetics

The release data obtained from in vitro studies were fitted into various kinetic models, including Zero-order, First-order, Higuchi, Korsmeyer–Peppas, and Hixson–Crowell models, to determine the mechanism of drug release from the formulated buccal films.

Stability Studies

The optimized formulation was subjected to accelerated stability studies according to ICH guidelines (40 ± 2°C/75 ± 5% RH) for a period of three months. Samples were periodically evaluated for physical appearance, drug content, surface pH, folding endurance, mucoadhesive strength, and in vitro drug release to assess formulation stability.

Statistical Analysis

All experiments were performed in triplicate, and the results were expressed as mean ± standard deviation (SD). Statistical analysis was carried out using one-way Analysis of Variance (ANOVA), and a p-value of less than 0.05 was considered statistically significant.

3. RESULTS AND DISCUSSION

Physical Appearance of Buccal Films

Mucoadhesive buccal films of propranolol hydrochloride were successfully prepared using the solvent casting method. All formulations were smooth, transparent, flexible, and uniform in appearance without any visible cracks, air bubbles, or imperfections. The films could be easily peeled from the casting surface and handled without damage, indicating the suitability of the selected polymers and preparation method.

Physicochemical Evaluation

The prepared films were evaluated for thickness, weight variation, drug content, surface pH, and folding endurance. The thickness and weight of all formulations were found to be uniform, demonstrating consistency in film casting. Drug content analysis indicated homogeneous distribution of propranolol hydrochloride throughout the polymer matrix. The surface pH of the films remained close to the physiological pH of the buccal cavity, suggesting that the formulations are unlikely to produce irritation upon application. Folding endurance studies showed that the films possessed excellent flexibility and mechanical strength, making them suitable for handling, packaging, and administration.

Swelling Behavior and Moisture Studies

Swelling behavior plays a vital role in determining the mucoadhesive performance of buccal films. The swelling index increased with increasing polymer concentration, particularly in formulations containing Carbopol 934P due to its hydrophilic nature. Moisture absorption and moisture loss studies demonstrated that all formulations maintained acceptable moisture balance, preserving their structural integrity during storage. The optimized formulation exhibited moderate swelling, which is desirable for prolonged adhesion without rapid disintegration.

Mucoadhesive Strength and Residence Time

The mucoadhesive strength of the prepared films increased with increasing concentration of mucoadhesive polymers. Carbopol-containing formulations exhibited stronger adhesion compared to formulations containing HPMC alone because of enhanced hydrogen bonding with the buccal mucosa. The optimized formulation showed sufficient residence time on the buccal membrane, ensuring prolonged contact between the dosage form and the absorption site. This prolonged adhesion is expected to improve drug absorption and therapeutic efficacy.

In Vitro Drug Release Study

The in vitro drug release study demonstrated that the polymer composition significantly influenced the release profile of propranolol hydrochloride. Formulations containing higher concentrations of HPMC released the drug more rapidly, whereas Carbopol-containing formulations exhibited a sustained drug release pattern. The optimized formulation provided controlled release over several hours, ensuring prolonged therapeutic drug levels while reducing the frequency of administration. Such a release profile is advantageous for maintaining consistent plasma drug concentrations.

Ex Vivo Permeation Study

Ex vivo permeation studies performed using buccal mucosal tissue demonstrated efficient permeation of propranolol hydrochloride across the membrane. The optimized formulation showed enhanced drug permeation due to prolonged contact with the mucosal surface and controlled hydration of the polymer matrix. Buccal administration effectively bypasses hepatic first-pass metabolism, thereby improving systemic drug availability and enhancing therapeutic effectiveness compared to conventional oral tablets.

Drug Release Kinetic Analysis

The drug release data were fitted into different mathematical models to determine the release mechanism. The optimized formulation followed diffusion-controlled drug release and exhibited non-Fickian (anomalous) transport behavior, indicating that both drug diffusion and polymer relaxation contributed to the overall release process. This release pattern supports sustained delivery of propranolol hydrochloride through the buccal route.

Stability Studies

Accelerated stability studies demonstrated that the optimized buccal film remained physically and chemically stable throughout the storage period. No significant changes were observed in appearance, drug content, surface pH, folding endurance, or drug release characteristics. These findings indicate that the formulation possesses adequate stability for long-term storage under recommended conditions.

OVERALL DISCUSSION

The results obtained from the present investigation demonstrate that mucoadhesive buccal films of propranolol hydrochloride can be successfully formulated using suitable combinations of HPMC and Carbopol polymers. The optimized formulation exhibited desirable physicochemical properties, satisfactory mechanical strength, excellent mucoadhesion, prolonged residence time, controlled drug release, enhanced permeation, and good stability. The buccal route successfully overcomes the limitations associated with conventional oral administration by bypassing first-pass hepatic metabolism, thereby improving systemic bioavailability. Furthermore, the developed formulation offers the advantages of non-invasive administration, improved patient compliance, reduced dosing frequency, and sustained therapeutic effect. Therefore, mucoadhesive buccal films represent a promising and effective alternative drug delivery system for propranolol hydrochloride and have significant potential for improving systemic drug delivery.

4. CONCLUSION

The present study successfully formulated and evaluated mucoadhesive buccal films of propranolol hydrochloride using the solvent casting technique. The developed films exhibited satisfactory physicochemical characteristics, including uniform thickness, drug content, surface pH, mechanical strength, and flexibility. The optimized formulation demonstrated excellent mucoadhesive properties, prolonged residence time, controlled drug release, and enhanced permeation across the buccal mucosa. By bypassing hepatic first-pass metabolism, the buccal delivery system has the potential to significantly improve the systemic bioavailability of propranolol hydrochloride compared with conventional oral dosage forms.

Stability studies confirmed that the optimized formulation remained stable under accelerated storage conditions. Overall, mucoadhesive buccal films represent a promising, patient-friendly, and effective drug delivery system capable of improving therapeutic efficacy, reducing dosing frequency, and enhancing patient compliance for long-term management requiring propranolol therapy.

ACKNOWLEDGEMENT

The authors express sincere gratitude to Apex Institute of Pharmaceutical Sciences, Apex University, Jaipur, for providing the necessary facilities and support to carry out this research work.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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