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Research Article

Formulation and Evaluation of Mucoadhesive Buccal Films of Glimepiride Using HPMC–Carbopol Polymer Blend for Enhanced Drug Release and Patient Compliance

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Abstract

The present study aimed to formulate and evaluate mucoadhesive buccal films of Glimepiride using a polymer blend of Hydroxypropyl Methylcellulose (HPMC K15M) and Carbopol 934P for enhanced drug release and improved patient compliance. Glimepiride, a third-generation sulfonylurea antidiabetic drug, exhibits limitations such as poor aqueous solubility and first-pass metabolism, which may reduce its therapeutic effectiveness following conventional oral administration. Buccal drug delivery was selected as an alternative route to bypass hepatic first-pass metabolism and improve systemic bioavailability. Mucoadhesive buccal films were prepared by solvent casting technique using HPMC K15M, Carbopol 934P, Polyvinyl Alcohol (PVA), and Chitosan. Prepared formulations were evaluated for physicochemical properties including thickness, weight variation, folding endurance, surface pH, drug content, tensile strength, percentage elongation, mucoadhesive strength, swelling index, and in-vitro drug release. Drug–excipient compatibility studies were performed using Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Calorimetry (DSC). Ex-vivo permeation studies were conducted using goat buccal mucosa and Franz diffusion cell. Stability studies were carried out under accelerated conditions according to ICH guidelines. Among all formulations, formulation F6 exhibited optimum physicochemical and mechanical properties, high mucoadhesive strength, controlled swelling behavior, and sustained drug release profile. Drug release kinetics followed the Korsmeyer–Peppas model, indicating a non-Fickian diffusion mechanism. Stability studies confirmed the stability of the optimized formulation under accelerated storage conditions. The study concluded that mucoadhesive buccal films of Glimepiride prepared using HPMC–Carbopol polymer blend offer a promising alternative to conventional oral dosage forms by improving drug release characteristics, reducing dosing frequency, and enhancing patient compliance.

Keywords: Glimepiride; Mucoadhesive Buccal Films; HPMC K15M; Carbopol 934P; Buccal Drug Delivery; Solvent Casting Technique; Drug Release Kinetics; Patient Compliance.

1. Introduction

Diabetes mellitus is one of the most prevalent chronic metabolic disorders worldwide and is characterized by persistent hyperglycemia resulting from impaired insulin secretion, insulin action, or both [1-2]. According to global health statistics, the incidence of Type 2 diabetes mellitus has increased significantly due to sedentary lifestyle, obesity, stress, and dietary habits [3]. Long-term uncontrolled diabetes can lead to serious complications such as cardiovascular disorders, neuropathy, nephropathy, retinopathy, and impaired wound healing. Effective glycemic control is therefore essential for reducing disease-associated complications and improving quality of life [4].

Glimepiride is a third-generation sulfonylurea widely used for the treatment of Type 2 diabetes mellitus [4]. It acts by stimulating insulin secretion from pancreatic β-cells and improving peripheral glucose utilization [5]. Despite its therapeutic effectiveness, conventional oral administration of Glimepiride is associated with several limitations such as poor aqueous solubility, first-pass metabolism, and variable gastrointestinal absorption [6]. These factors may reduce bioavailability and therapeutic efficiency, thereby necessitating the development of alternative drug delivery approaches [7].

Novel drug delivery systems have emerged as effective strategies for improving the therapeutic performance of drugs with poor bioavailability and short

residence time [8]. Among these systems, buccal drug delivery has gained considerable attention because of its ability to bypass hepatic first-pass metabolism and gastrointestinal degradation. The buccal mucosa is highly vascularized and offers rapid absorption into systemic circulation, thereby enhancing drug bioavailability and reducing dose variability [9].

Mucoadhesive buccal films are thin polymeric formulations designed to adhere to the buccal mucosa and release the drug in a controlled manner [10]. These films provide several advantages such as improved patient compliance, ease of administration, prolonged residence time, and reduced dosing frequency [11]. Buccal films are particularly beneficial for pediatric, geriatric, and dysphagic patients who may have difficulty swallowing conventional tablets or capsules [12].

The performance of mucoadhesive buccal films largely depends on the selection of suitable polymers. Hydroxypropyl Methylcellulose (HPMC K15M) is commonly used due to its excellent film-forming and controlled release properties [13]. Carbopol 934P provides strong mucoadhesive characteristics through hydrogen bonding with mucin. Polyvinyl Alcohol (PVA) improves film flexibility and mechanical strength, while Chitosan enhances mucoadhesion and drug permeation across buccal mucosa [14].

Several studies have demonstrated the potential of buccal drug delivery systems for improving therapeutic outcomes of various drugs [15]. However, limited research has been reported on Glimepiride-loaded mucoadhesive buccal films using optimized polymer blends [16-17]. Therefore, the present study was designed to formulate and evaluate mucoadhesive buccal films of Glimepiride using HPMC–Carbopol polymer blend for enhanced drug release and improved patient compliance [18-19].

The prepared films were evaluated for physicochemical properties, mechanical strength, mucoadhesive behavior, swelling index, drug release characteristics, *ex-vivo* permeation, and stability. The study aimed to develop a stable and effective buccal film formulation capable of improving the therapeutic performance of Glimepiride while enhancing patient convenience and compliance [20].

2. Materials and Methods

2.1 Materials

Glimepiride was obtained as a gift sample from a pharmaceutical company. HPMC K15M, Carbopol 934P, Polyvinyl Alcohol (PVA), and Chitosan were used as polymers. PEG 400 and glycerol were used as plasticizers. All chemicals and reagents used were of analytical grade.

2.2 Preformulation Studies

Preformulation studies were carried out to evaluate the physicochemical properties of Glimepiride prior to formulation development. These studies provide important information regarding drug characteristics, compatibility with excipients, and suitability for buccal film formulation.
The following preformulation studies were performed:

- Organoleptic properties
- Melting point determination
- Solubility study
- Partition coefficient determination
- Fourier Transform Infrared Spectroscopy (FTIR)
- Differential Scanning Calorimetry (DSC)

Organoleptic Properties

Method

The drug sample was visually examined under normal laboratory conditions to determine its organoleptic properties including color, odor, taste, and physical appearance.

Parameters Evaluated

- Color
- Odor
- Taste
- Physical nature

Melting Point Determination

Method

The melting point of Glimepiride was determined using the capillary method.

A small quantity of drug was filled into a capillary tube sealed at one end. The capillary tube was placed in a melting point apparatus and heated gradually. The temperature at which the drug melted completely was recorded.

Significance

- Determines purity of drug
- Confirms identity of drug

Solubility Study

Method

The solubility of Glimepiride was determined in various solvents such as distilled water, phosphate buffer pH 6.8, 0.1 N HCl, and methanol.
An excess quantity of drug was added to each solvent and shaken continuously for 24 hours at room temperature. The solutions were filtered and analyzed.

Purpose

- Determines solubility profile of drug
- Assists in selection of suitable formulation strategy

Partition Coefficient

Method

Partition coefficient was determined using n-octanol and phosphate buffer pH 6.8 system.

Equal volumes of n-octanol and phosphate buffer were taken in a separating funnel. Glimepiride was added and shaken vigorously until equilibrium was achieved. The phases were separated and analyzed spectrophotometrically.

Formula

P=Concentration of drug in octanol phaseConcentration of drug in aqueous phaseP = \frac{\text{Concentration of drug in octanol phase}}{\text{Concentration of drug in aqueous phase}}P=Concentration of drug in aqueous phaseConcentration of drug in octanol phase

Purpose

- Determines lipophilicity of drug
- Predicts membrane permeability

Fourier Transform Infrared Spectroscopy (FTIR)

Method

FTIR spectroscopy was performed to identify characteristic functional groups of Glimepiride and to evaluate compatibility between drug and excipients.

The samples were prepared using KBr pellet method and scanned over a range of 4000–400 cm^{-1} using an FTIR spectrophotometer.

Purpose

- Identification of functional groups
- Detection of drug–excipient interaction

Differential Scanning Calorimetry (DSC)

Method

DSC analysis was carried out to study the thermal behavior of Glimepiride and drug–polymer mixtures.

Accurately weighed samples were sealed in aluminum pans and heated at a controlled rate under nitrogen atmosphere. Thermograms were recorded.

Purpose

- Determines thermal properties of drug
- Detects compatibility and physical interaction with excipients

2.3 Preparation of Buccal Films

Mucoadhesive buccal films were prepared by solvent casting technique. Required quantities of HPMC K15M, Carbopol 934P, PVA, and Chitosan were dissolved in distilled water under continuous stirring. Plasticizer was added to the polymer solution followed by incorporation of Glimepiride. The resulting homogeneous solution was cast in petri dishes and dried at room temperature. Dried films were cut into suitable dimensions and stored in desiccators.

Table 2.2: Formulation Composition of Mucoadhesive Buccal Films (F1–F8)

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8
Glimepiride	10	10	10	10	10	10	10	10
HPMC K15M	500	550	600	650	600	650	700	750
Carbopol 934P	100	100	100	100	120	150	150	180
PVA	100	100	100	100	100	150	150	150
Chitosan	—	—	—	—	25	50	50	75
PEG 400 (% w/w of polymer)	20	20	20	20	25	25	25	30
Distilled Water (mL)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

2.4 Evaluation of Buccal Films

Prepared films were evaluated for:

- Thickness
- Weight variation
- Folding endurance
- Surface pH
- Drug content
- Tensile strength
- Percentage elongation
- Mucoadhesive strength
- Swelling index
- *In-vitro* drug release

2.5 In-vitro Drug Release Study

Drug release studies were performed using USP dissolution apparatus Type II containing phosphate buffer pH 6.8 at 37 ± 0.5°C and 50 rpm. Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically.

2.6 Release Kinetics Analysis

Drug release data were fitted into Zero-order, First-order, Higuchi, and Korsmeyer–Peppas kinetic models to determine the release mechanism.

2.7 *Ex-vivo* Permeation Study

Ex-vivo permeation studies were conducted using goat buccal mucosa mounted on Franz diffusion cell. Samples were collected at specific intervals and analyzed using UV spectrophotometry.

2.8 Stability Studies

The optimized formulation was subjected to accelerated stability studies according to ICH guidelines at 40°C ± 2°C and 75% RH ± 5% for three months.

3. Results and Discussion

The prepared mucoadhesive buccal films of Glimepiride were evaluated for various physicochemical, mechanical, mucoadhesive, and drug release parameters. The results obtained from preformulation studies, formulation evaluation, release kinetics, ex-vivo permeation, and stability studies are discussed below.

The purpose of the evaluation was to identify the optimized formulation capable of providing:

- Uniform physicochemical characteristics
- Adequate mechanical strength
- Good mucoadhesion
- Controlled swelling behavior
- Sustained drug release
- Enhanced permeation through buccal mucosa

3.1 Preformulation Study Results

Preformulation studies confirmed the suitability of Glimepiride for buccal drug delivery.

- The drug was found to be a white crystalline powder with slightly bitter taste.
- Melting point determination confirmed purity of the drug.
- Solubility studies indicated poor aqueous solubility of Glimepiride.
- Partition coefficient values suggested moderate lipophilicity suitable for buccal permeation.
- FTIR and DSC studies confirmed compatibility between the drug and selected polymers.

3.2 Evaluation of Buccal Films

Prepared buccal films (F1–F8) were evaluated for thickness, weight variation, folding endurance, surface pH, drug content, tensile strength, mucoadhesive strength, swelling index, and in-vitro drug release.

3.2.1 Physical Evaluation

All formulations showed smooth appearance, flexibility, and uniformity.

Observations

- Thickness and weight increased with increasing polymer concentration.
- Folding endurance values indicated good flexibility of films.
- Surface pH values were found near neutral, indicating non-irritancy to buccal mucosa.
- Drug content was uniformly distributed among formulations.

3.2.2 Mechanical Properties

Mechanical evaluation demonstrated that the prepared films possessed adequate strength and elasticity.

Observations

- Tensile strength increased with higher polymer concentration.
- Films containing PVA and PEG 400 exhibited improved flexibility.
- Formulation F6 showed optimum tensile strength and percentage elongation.

3.2.3 Mucoadhesive Strength

Mucoadhesive strength was significantly influenced by Carbopol and Chitosan concentration.

Observations

- Increase in Carbopol concentration improved adhesion due to hydrogen bonding with mucin.
- Chitosan contributed to enhanced mucoadhesion and permeation.
- F6 exhibited optimum mucoadhesive strength without excessive stickiness.

3.2.4 Swelling Study

Swelling behavior plays an important role in drug release and mucoadhesion.

Observations

- Swelling index increased with hydrophilic polymer concentration.
- Excessive swelling was observed in formulations

Preformulation studies confirmed that Glimepiride is poorly water-soluble and moderately lipophilic. FTIR and DSC studies indicated compatibility between drug and polymers without any significant interaction.

All prepared buccal films showed acceptable physicochemical properties. Thickness and weight variation were found to be uniform. Surface pH values were within acceptable range, indicating non-irritancy to buccal mucosa. Drug content analysis confirmed uniform drug distribution.

Mechanical evaluation revealed that films possessed good tensile strength and flexibility. Mucoadhesive strength increased with higher Carbopol concentration due to enhanced hydrogen bonding with mucin.

In-vitro drug release studies demonstrated controlled release behavior. Formulation F6 exhibited optimum release characteristics with sustained drug release over 120 minutes. Release kinetics analysis indicated that the optimized formulation followed Korsmeyer–Peppas model with non-Fickian diffusion mechanism.

Ex-vivo permeation studies confirmed effective permeation of Glimepiride through goat buccal mucosa. Stability studies showed no significant changes in physicochemical properties or drug release profile, confirming stability of the optimized formulation.

4. Conclusion

The present study successfully formulated and evaluated mucoadhesive buccal films of Glimepiride using HPMC K15M and Carbopol 934P polymer blend by solvent casting technique. The developed buccal films were found to possess satisfactory physicochemical, mechanical, and mucoadhesive properties suitable for buccal drug delivery.

Preformulation studies confirmed that Glimepiride is a poorly water-soluble drug with moderate lipophilic characteristics, making it a suitable candidate for buccal

administration. FTIR and DSC analyses demonstrated compatibility between the drug and selected polymers without any significant interaction.

All prepared formulations showed acceptable thickness, weight uniformity, folding endurance, surface pH, and drug content. Mechanical evaluation indicated adequate tensile strength and flexibility of films. Mucoadhesive strength and swelling behavior were influenced by polymer concentration, particularly Carbopol and Chitosan.

Among all formulations, formulation F6 exhibited optimum characteristics including:

- Uniform physicochemical properties
- Good mechanical strength and flexibility
- Adequate mucoadhesive strength
- Controlled swelling behavior
- Sustained and controlled drug release profile

Drug release kinetics revealed that the optimized formulation followed the Korsmeyer–Peppas model, indicating non-Fickian diffusion-controlled release mechanism. Ex-vivo permeation studies confirmed effective permeation of Glimepiride through buccal mucosa. Stability studies conducted according to ICH guidelines demonstrated that the optimized formulation remained stable under accelerated storage conditions.

Overall, the study concludes that mucoadhesive buccal films of Glimepiride developed using HPMC–Carbopol polymer blend represent a promising alternative to conventional oral dosage forms by improving drug release characteristics, bypassing first-pass metabolism, and enhancing patient compliance in the management of diabetes mellitus.

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