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FORMULATION AND EVALUATION OF BUCCAL FILMS CONTAINING LOSARTAN POTASSIUM FOR ANTIHYPERTENSIVE THERAPY

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ABSTRACT

Losartan Potassium, an angiotensin II receptor blocker used in the treatment of hypertension, exhibits limited oral bioavailability due to extensive first-pass metabolism. The present study aimed to formulate and evaluate controlled-release mucoadhesive buccal films of Losartan Potassium using the solvent casting method to enhance bioavailability, provide sustained drug release, and improve patient compliance. The buccal films were prepared using Hydroxypropyl Methylcellulose E15 (HPMC E15), Gelzan CM, Sodium Alginate, Polyvinyl Alcohol (PVA), and Propylene Glycol as a plasticizer. The prepared films were evaluated for thickness, weight variation, folding endurance, surface pH, swelling index, drug content, and in vitro drug release. FTIR studies confirmed the compatibility of Losartan Potassium with the selected polymers, indicating the absence of significant drug–polymer interactions. The prepared films exhibited satisfactory physicochemical and mechanical properties, with thickness ranging from 0.123 to 0.170 mm**,** drug content ranging from 85.51**%** to 91.86**%**, and surface pH values close to the physiological pH of the buccal cavity. The optimized formulation **(**F6**)** showed the highest cumulative drug release of 91.83% over 8 hours, along with excellent folding endurance and satisfactory swelling behaviour. These findings indicate that the developed controlled-release mucoadhesive buccal films of Losartan Potassium are a promising alternative to conventional oral dosage forms for improving bioavailability, providing sustained antihypertensive therapy, and enhancing patient compliance.

KEYWORDS: Losartan Potassium, Buccal Films, Controlled Release, Mucoadhesive Drug Delivery, Solvent Casting, Antihypertensive Therapy.

INTRODUCTION

The oral route is the most preferred method of drug administration due to its convenience, non-invasive nature, cost-effectiveness, and high patient compliance, making it suitable for long-term therapy.[1] Buccal films deliver drugs through the buccal mucosa, bypassing first-pass metabolism and providing controlled drug release, improved bioavailability, and enhanced patient compliance, making them a promising delivery system for Losartan potassium.[2] Buccal mucus is a viscoelastic protective layer composed mainly of water and glycoproteins, playing a crucial role in effective buccal drug delivery.[3]

The oral mucosa consists of stratified squamous epithelium, lamina propria, and submucosa, with the buccal region serving as an effective site for transmucosal drug delivery. It is covered by a viscoelastic mucus layer composed mainly of water and glycoproteins, which protects the mucosa and facilitates mucoadhesion, thereby enhancing drug residence time and absorption.[4] Mucus is a thin viscoelastic gel covering the buccal epithelium, with a thickness of approximately 40–300 µm. It is primarily secreted by goblet cells and salivary glands and consists mainly of high-molecular-weight glycoproteins (mucins), water, and carbohydrates such as L-fucose, D-galactose, N-acetyl-D-glucosamine, N-acetyl-D-galactosamine, and sialic acid, which contribute to mucoadhesion and mucosal protection.[5]

Buccal films are thin, flexible, and mucoadhesive dosage forms that adhere to the buccal mucosa, providing controlled drug release with improved patient convenience and compliance.[6] Buccal films are easy to administer without water and can be removed when required, improving patient safety and convenience.[7] The highly vascularized buccal mucosa enables rapid drug absorption and faster onset of action, while buccal films enhance patient compliance due to their ease of administration, non-invasive nature, and removability.[8]

Therefore, the present study was undertaken to formulate and evaluate controlled-release mucoadhesive buccal films of Losartan Potassium using suitable film-forming polymers and excipients to enhance bioavailability, provide sustained drug release, improve patient compliance, and achieve effective antihypertensive therapy.

MATERIALS AND METHODS

Losartan Potassium was procured from Balaji Drug Store, Gujarat. Gelzan CM, Polyvinyl Alcohol (PVA), and Propylene Glycol were obtained from S.D. Fine-Chem Limited, Mumbai. Hydroxypropyl Methylcellulose E15 (HPMC E15) and Sodium Alginate were procured from Loba Chemie Pvt. Ltd., Mumbai.

PREFORMULATION STUDIES

Determination of melting point of the drug

Melting point of Losartan Potassium was determined by using capillary tube method using melting point apparatus.[9]

Fourier transform infrared spectroscopy (FTIR) studies

FTIR studies were carried out to investigate the compatibility between Losartan Potassium and the selected excipients. The infrared spectra of pure Losartan Potassium and its physical mixtures with HPMC E 15, Gelzan CM, Sodium alginate and Polyvinyl alcohol were recorded over a spectral range of 3500–500 cm^{-1} using a Shimadzu IR Spirit FTIR spectrophotometer.[10]

Determination of absorption maximum (λmax) of the drug

A solution of Losartan Potassium with a concentration of 5 µg/mL was prepared using phosphate buffer (pH 6.8). The prepared solution was scanned in the wavelength range of 200–400 nm using a UV-Visible spectrophotometer to determine the wavelength of maximum absorption (λmax). The absorption spectrum obtained was used to identify the λmax of Losartan Potassium.[11]

METHOD

Solvent Casting Technique

The buccal films were prepared by the solvent casting technique, one of the simplest and most widely used methods for the preparation of buccal films due to its ability to produce films with uniform thickness and good clarity. The required quantities of Hydroxypropyl Methylcellulose E15 (HPMC E15), Polyvinyl Alcohol (PVA), Sodium Alginate, and Gelzan CM were dissolved in distilled water under continuous stirring to obtain a homogeneous polymeric solution. Losartan Potassium was dissolved separately, and Propylene Glycol was added as a plasticizer. The drug solution was then incorporated into the polymeric solution with continuous stirring to obtain a uniform casting solution. The resulting solution was poured into a Petri plate and dried at room temperature. The dried films were carefully removed and cut into the required size. The method for preparation of Losartan Potassium of buccal film given below as follows.[12]

Preparation of Buccal Films[13-16]

The buccal films were prepared by the solvent casting method. First, the required quantities of HPMC E15, polyvinyl alcohol (PVA), sodium alginate, Gelzan CM, losartan potassium, and propylene glycol were measured accurately according to the formulation table. HPMC E15 was dispersed slowly in distilled water with gentle stirring and allowed to hydrate completely to obtain a uniform solution. PVA was dissolved separately in distilled water by heating, and the solution was stirred until it became clear. In another beaker, sodium alginate and Gelzan CM were dispersed in distilled water with slow stirring at room temperature until a homogeneous solution was obtained.

After preparing the individual polymer solutions, the PVA solution was added slowly into the HPMC solution with continuous gentle stirring. The sodium alginate and Gelzan CM solution was then added gradually to the combined polymer mixture. Losartan potassium was dissolved separately in a small quantity of distilled water and added slowly to the polymer mixture with continuous stirring to ensure uniform distribution of the drug. Propylene glycol was then incorporated as a plasticizer and mixed gently until a clear and homogeneous casting solution was obtained. Distilled water was added to make up the final volume.

The prepared solution was stirred slowly for a sufficient time to remove lumps and was then kept undisturbed to allow entrapped air bubbles to rise and escape. If necessary, the solution was sonicated briefly at room temperature to remove residual air bubbles. The deaerated solution was then poured slowly onto a clean, level, dry petri plate and spread uniformly. The petri plate was covered and the formulation was dried at room temperature or in a hot air oven at a low temperature until a film was formed.

After drying, the film was carefully removed from the petri plate. The dried film was then cut into the required size of 2 × 2 cm and stored in an airtight container until further evaluation. The same procedure was followed for all formulations, F1 to F8, by varying the polymer concentrations as per the formulation design.

Table 1: Composition of buccal films

F. Code	Drug (gm)	Gelzan CM (mg)	Sodium alginate (mg)	Polyvinyl alcohol (mg)	HPMC E 15 (mg)	Propylene glycol (%)	Solvent (ml)
F 1	1.6	300	200	250	150	2.5	20
F 2	1.6	150	350	350	150	2.5	20
F 3	1.6	300	200	350	150	2.5	20
F 4	1.6	300	350	250	150	2.5	20
F 5	1.6	150	200	350	150	2.5	20
F 6	1.6	150	200	250	150	2.5	20
F 7	1.6	150	350	250	150	2.5	20
F 8	1.6	300	350	350	150	2.5	20

EVALUATION OF BUCCAL FILMS

The prepared buccal films were evaluated for thickness, weight variation, folding endurance, surface pH, swelling index, drug content, and in vitro dissolution study.

1. Thickness Measurement

The thickness of the buccal films was measured using a digital Vernier caliper. Measurements were taken at five different positions on each film (four corners and the center), and the mean thickness was calculated. The average thickness was recorded to assess the uniformity of the films.[17]

2. In Vitro Dissolution Studies

The invitro drug release study was carried out using a USP Type I dissolution test apparatus (Basket type) containing 400 ml of phosphate buffer (pH 6.8) as the dissolution medium, maintained at 37 ± 0.5°C with a basket rotation speed of 50 rpm. A 5 ml sample was withdrawn at predetermined time intervals from 1 to 8 h and replaced with an equal volume of fresh dissolution medium to maintain sink conditions. The samples were analyzed spectrophotometrically at a λmax of 204 nm using a UV–Visible spectrophotometer, and the cumulative percentage drug release was calculated.[18]

3. Drug content

A film of 2 × 2 cm^2 was accurately cut and transferred into 100 ml of phosphate buffer (pH 6.8). The solution was continuously stirred on a bench-top orbital shaker for 24 hours to ensure complete extraction of the drug from the film. The resulting solution was filtered, and an appropriate dilution was prepared using the same buffer. The absorbance of the diluted solution was measured at 204 nm using a UV–visible spectrophotometer. The drug content was determined from the calibration curve of Losartan potassium and expressed as the percentage of drug present in the film.[19]

RESULT AND DISCUSSION

The present study was carried out to formulate and evaluate controlled-release mucoadhesive buccal films of Losartan Potassium using HPMC E15, Gelzan CM, Sodium Alginate, Polyvinyl Alcohol (PVA), and Propylene Glycol by the solvent casting method.

The melting point of Losartan Potassium was determined by the capillary tube method using a melting point apparatus. The melting point of the pure drug was found to be 263–265°C. The sharp and narrow melting range indicated the purity and identity of Losartan Potassium and confirmed the absence of impurities or degradation products.

Solubility analysis of Losartan Potassium was performed in water, phosphate buffer (pH 6.8), ethanol, and methanol to determine its solubility characteristics. The drug exhibited solubility values of 168.70 mg/ml in water, 4.55 mg/ml in phosphate buffer (pH 6.8), 158.47 mg/mL in ethanol, and 224.25 mg/mL in methanol. Based on the Indian Pharmacopoeia (IP) solubility classification, Losartan Potassium was found to be freely soluble in water, ethanol, and methanol, whereas it was slightly soluble in phosphate buffer (pH 6.8). The results indicate that the drug has excellent solubility in water and organic solvents but comparatively lower solubility in phosphate buffer, which may be advantageous in achieving sustained drug release from the developed buccal films.

Table 2: Solubility analysis of Losartan Potassium.

Media	Solubility (mg/ml)	Volume of solvent in ml/1gm (ml)	Solubility Criteria
Water	168.70	5.928	Freely soluble
pH 6.8	4.55	219.78	Slightly Soluble
Ethanol	158.47	6.310	Freely soluble
Methanol	224.25	4.46	Freely soluble

The absorption maximum (λmax) of Losartan Potassium was determined by scanning a 5 µg/mL solution prepared in phosphate buffer (pH 6.8) using a UV–Visible spectrophotometer over the wavelength range of 200–400 nm. The maximum absorbance was observed at 204 nm. Therefore, 204 nm was selected as the analytical wavelength for the quantitative estimation of Losartan Potassium during drug content determination and in vitro dissolution studies of the formulated buccal films.

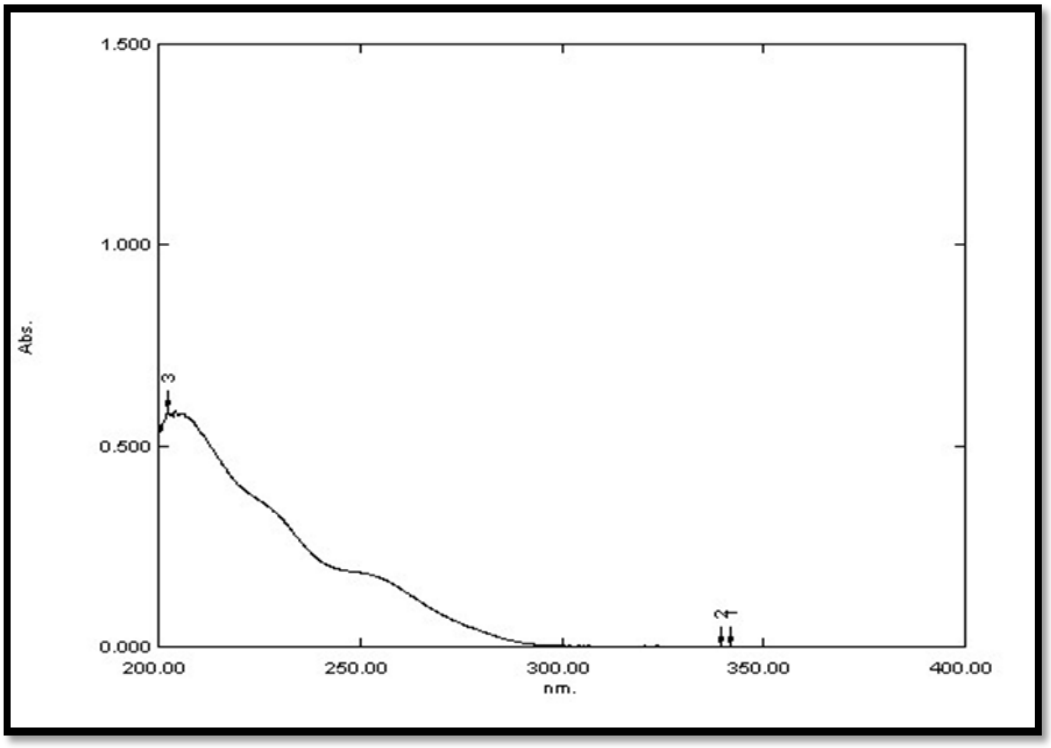

Figure 1: λmax of Losartan Potassium at 5 µg/ml concentration.

The compatibility of Losartan Potassium with the selected polymers was investigated using FTIR spectroscopy with a Shimadzu IR Spirit FTIR spectrophotometer over the spectral range of 3500–500 cm^{-1}. The FTIR spectra of the pure drug and its physical mixture containing HPMC E15, Gelzan CM, Sodium Alginate, and Polyvinyl Alcohol (PVA) were compared. The characteristic absorption peaks of Losartan Potassium were retained in the physical mixture with only slight variations in the wavenumbers. No disappearance of the characteristic peaks or appearance of additional peaks was observed, indicating the absence of any significant drug–polymer interaction. These findings confirmed the compatibility of Losartan Potassium with the selected polymers and demonstrated their suitability for the formulation of controlled-release mucoadhesive buccal films.

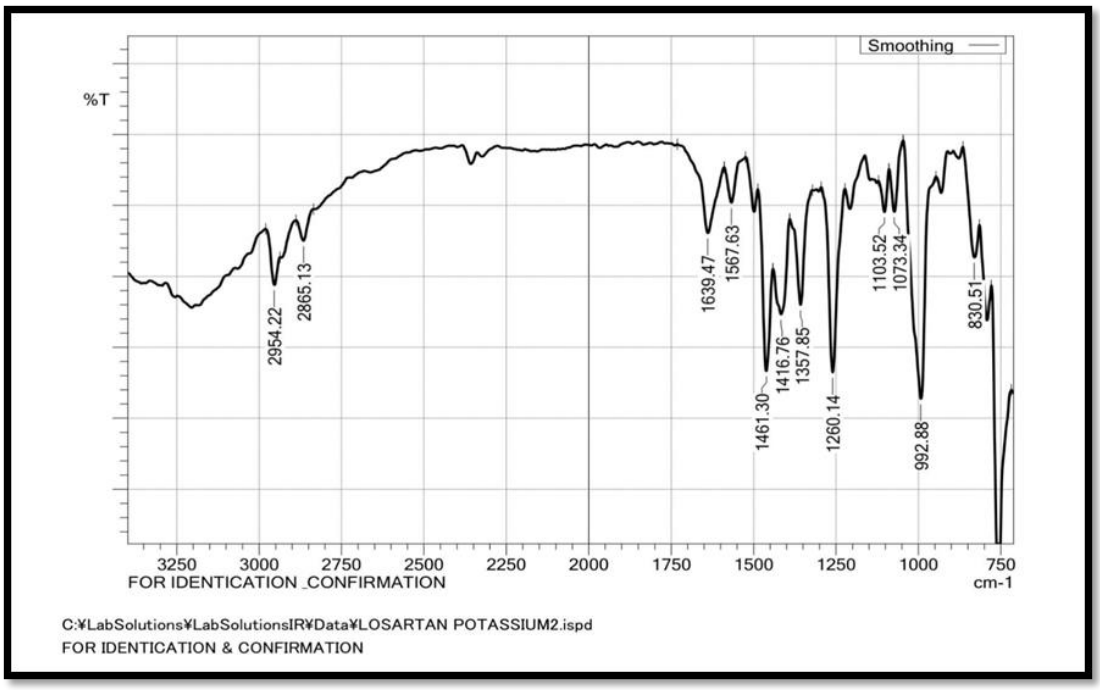

Figure 2: FT-IR Spectra of Losartan Potassium.

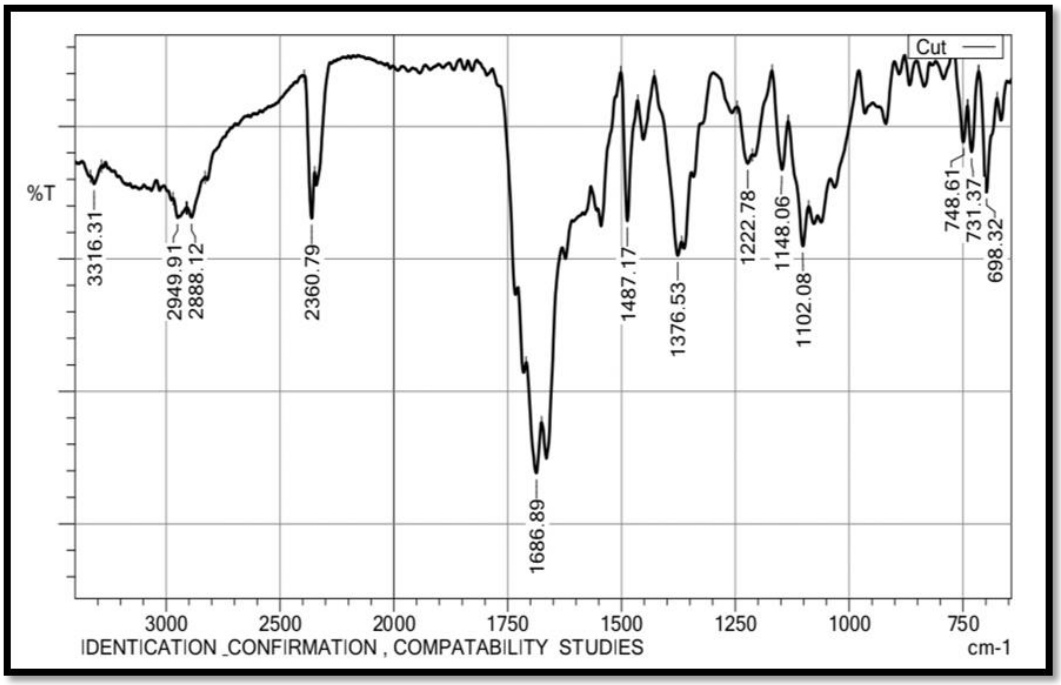

Figure 3: FT-IR Spectra of Losartan Potassium and physical mixture (Gelzan CM, Sodium alginate, Polyvinyl alcohol, HPMC E 15).

The weight of the prepared Losartan Potassium buccal films varied depending on the polymer composition of each formulation. Formulations containing higher amounts of Gelzan CM, Sodium Alginate, and Polyvinyl Alcohol (PVA) exhibited comparatively greater film weights, whereas those with lower total polymer content showed reduced weights. The observed weight variation among the formulations was within acceptable limits, indicating uniform distribution of the casting solution and good reproducibility of the solvent casting technique.

Figure 4: Weight variation of formulation F1-F8.

The thickness of the prepared Losartan Potassium buccal films ranged from 0.123 mm (F6) to 0.170 mm (F8), demonstrating the successful preparation of thin and uniform films suitable for buccal drug delivery. Formulations containing higher concentrations of Gelzan CM, Sodium Alginate, and Polyvinyl Alcohol (PVA), particularly F8, exhibited comparatively greater thickness due to the increased total polymer content. In contrast, F6 showed the lowest thickness, which may be attributed to its lower polymer concentration. Overall, all formulations exhibited satisfactory thickness uniformity, indicating that the solvent casting method produced films with consistent thickness and good film-forming characteristics.

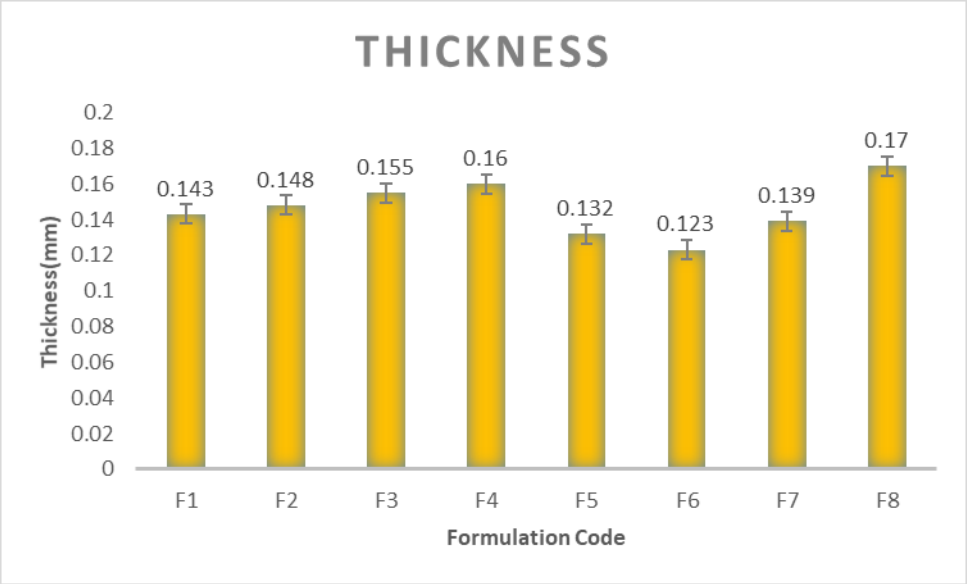

Figure 5: Thickness of formulation F1-F8.

The surface pH of the prepared Losartan Potassium buccal films ranged from 6.3 to 6.48, which is close to the physiological pH of the buccal cavity. All formulations exhibited surface pH values close to neutral, indicating good compatibility with the buccal mucosa. The near-neutral surface pH suggests that the films are unlikely to cause irritation or discomfort during application, making them suitable for buccal administration.

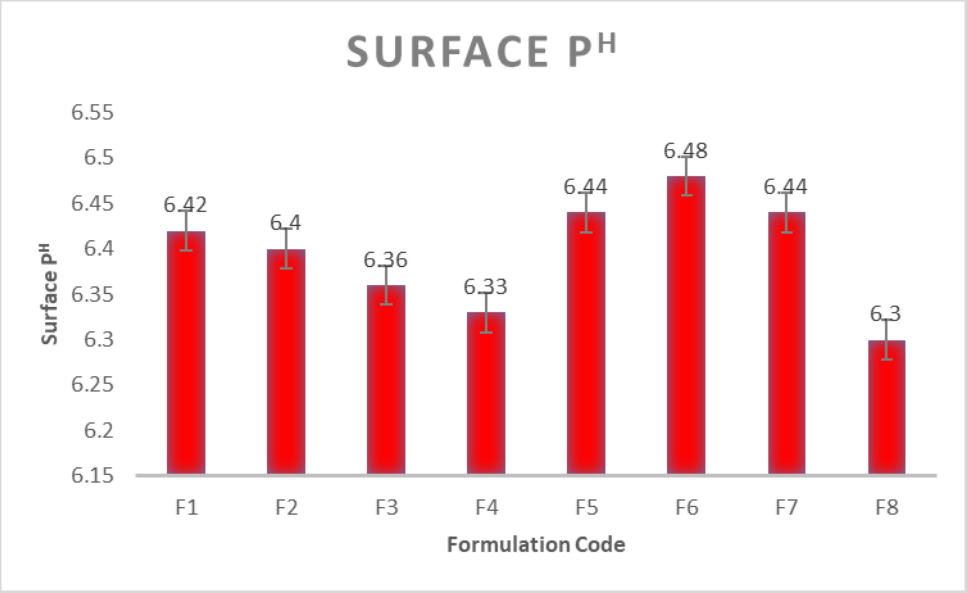

Figure 6: Surface pH of formulation F1-F8.

The drug content of the prepared Losartan Potassium buccal films ranged from 85.51% (F8) to 91.86% (F6). All formulations exhibited drug content within acceptable limits, indicating satisfactory incorporation and uniform distribution of Losartan Potassium throughout the films. Formulations F5, F6, and F7 exhibited comparatively higher drug content, whereas F8 showed the lowest drug content among all the formulations. The minor variation in drug content among the formulations may be attributed to slight differences during the casting, drying, and film-cutting processes. Overall, the results confirmed good content uniformity and reproducibility of the solvent casting method used for the preparation of the buccal films.

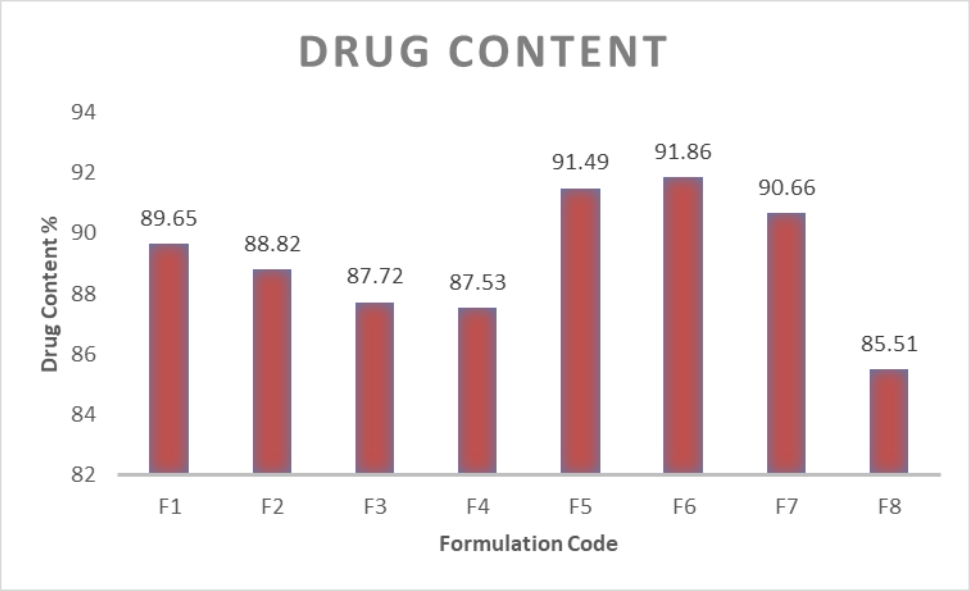

Figure 7: % Drug content of formulation F1-F8.

All the prepared Losartan Potassium buccal films exhibited a folding endurance of 350 folds, indicating excellent mechanical strength and flexibility. The films withstood repeated folding without breaking, demonstrating good elasticity and resistance to mechanical stress. The high folding endurance may be attributed to the combined film-forming properties of HPMC E15, Gelzan CM, Sodium Alginate, and Polyvinyl Alcohol (PVA), together with the plasticizing effect of Propylene Glycol, which imparted sufficient flexibility and mechanical integrity to the prepared buccal films.

Table 3: Evaluation studies of Buccal Films for F1-F8.

F. code	Folding Endurance (no. of fold)	Swelling Index (%)	Drug Content (%)
F1	350	33.28	89.65
F2	350	34.61	88.82
F3	350	35.36	87.72
F4	350	36.85	87.53
F5	350	30.80	91.49
F6	350	27.50	91.86
F7	350	32.80	90.66
F8	350	38.63	85.51

All formulations exhibited a controlled and sustained drug release over a period of 8 hours, demonstrating the effectiveness of the polymeric matrix in regulating the release of Losartan Potassium. The cumulative percentage drug release ranged from 81.79% (F8) to 91.83% (F6) at the end of the dissolution study. Formulations F5 (86.81%), F6 (91.83%), and F7 (89.82%) exhibited comparatively higher drug release, whereas F2 (84.80%), F3 (83.79%), F4 (82.79%), and F8 (81.79%) showed relatively slower release profiles. The higher drug release observed in formulation F6 may be attributed to the optimum ratio of Gelzan CM, Sodium Alginate, Polyvinyl Alcohol (PVA), and HPMC E15, which provided an appropriate balance between polymer hydration, swelling, and drug diffusion. In contrast, formulations containing higher polymer concentrations formed a denser gel matrix that retarded drug release.

Among all the formulations, F6 exhibited the highest cumulative drug release (91.83%), the highest drug content (91.86%), excellent folding endurance (350 folds), satisfactory swelling behaviour, and acceptable physicochemical characteristics. Therefore, F6 was identified as the optimized formulation for the development of controlled-release mucoadhesive buccal films of Losartan Potassium. The optimized formulation demonstrated desirable mechanical properties, uniform drug distribution, and sustained drug release, indicating its potential to improve the bioavailability of Losartan Potassium and enhance patient compliance in the management of hypertension.

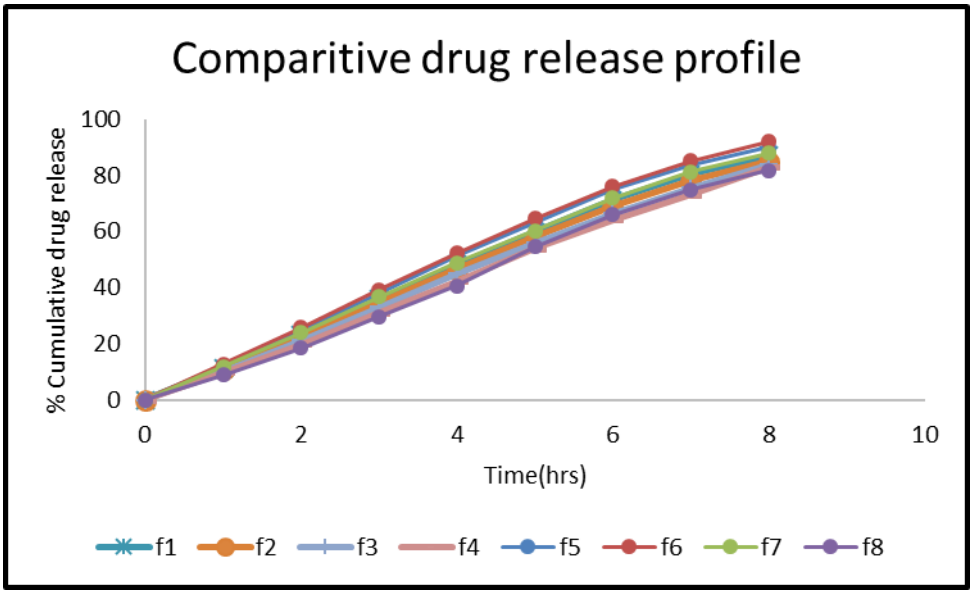

Figure 8: % Cumulative drug release of formulation F1-F8.

CONCLUSION

The present study successfully formulated and evaluated Losartan Potassium controlled-release mucoadhesive buccal films using the solvent casting method. The prepared films exhibited satisfactory physicochemical and mechanical properties, including uniform thickness, acceptable surface pH, excellent folding endurance, satisfactory drug content, and controlled drug release over 8 hours, demonstrating their suitability for buccal drug delivery. Among all the formulations, F6 exhibited the best overall performance with the highest drug content (91.86%), maximum cumulative drug release (91.83%), excellent folding endurance, satisfactory swelling behaviour, and acceptable physicochemical characteristics. Therefore, F6 was selected as the optimized formulation. The developed controlled-release mucoadhesive buccal film of Losartan Potassium can be considered a promising drug delivery system for improving bioavailability by bypassing first-pass metabolism, providing sustained antihypertensive therapy, and enhancing patient compliance.

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