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FORMULATION AND CHARACTERIZATION OF BUCCAL FILM CONTAINING ANTIHYPERTENSIVE AGENT FOR IMPROVED SOLUBILITY AND THERAPEUTIC EFFICACY

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Abstract

The present study aimed to formulate and evaluate buccal films of Spironolactone using solvent casting technique for improved solubility and bioavailability. HPMC was used as film-forming polymer, PEG 400 as plasticizer, Tween 80 as surfactant and β-Cyclodextrin as solubility enhancer. Nine formulations (F1–F9) were prepared and evaluated for thickness, weight variation, folding endurance, surface pH, swelling index, drug content, tensile strength, ex-vivo permeation and in-vitro drug release. FTIR, DSC and SEM studies confirmed compatibility and uniform drug distribution. Formulation F8 exhibited optimum physicochemical properties and maximum drug release of 98.7% within 8 hours.

Keywords: Spironolactone, Buccal Films, Mucoadhesive Drug Delivery System, Solvent Casting Method, HPMC, β-Cyclodextrin, PEG 400, Tween 80, Solubility Enhancement, Bioavailability Enhancement

Introduction

Buccal drug delivery systems offer several advantages including avoidance of first-pass metabolism, enhanced bioavailability, prolonged residence time and improved patient compliance. Spironolactone is a poorly water-soluble antihypertensive drug with variable oral bioavailability due to extensive first-pass metabolism. The incorporation of β-Cyclodextrin and Tween 80 can improve drug solubility and dissolution. The present study focused on the development of mucoadhesive buccal films using HPMC polymer by solvent casting technique.

Materials

Spironolactone was used as the active pharmaceutical ingredient. HPMC E15 was used as film forming polymer, PEG 400 as plasticizer, Tween 80 as surfactant and β-Cyclodextrin as solubility enhancer. All chemicals and reagents used were of analytical grade.

Methodology

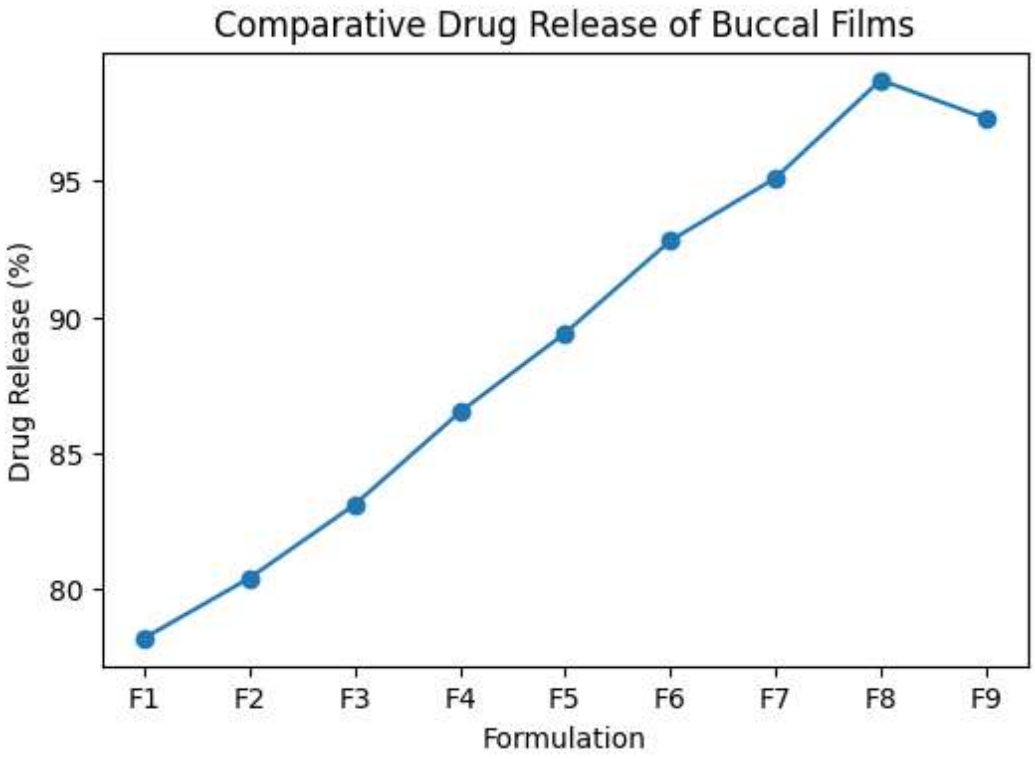
Buccal films were prepared by solvent casting method. Required quantities of HPMC were dissolved in distilled water with continuous stirring. PEG 400 and Tween 80 were incorporated followed by addition of β-Cyclodextrin inclusion complex containing Spironolactone. The solution was casted into petri plates and dried at room temperature for 24 hours. Films were cut into suitable dimensions and evaluated.

Formulation Table

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
Spironolactone (mg)	25	25	25	25	25	25	25	25	25
HPMC E15 (mg)	200	220	240	260	280	300	320	340	360
PEG 400 (mL)	0.2	0.2	0.3	0.3	0.4	0.4	0.5	0.5	0.6
Tween 80 (mL)	0.1	0.1	0.2	0.2	0.3	0.3	0.4	0.4	0.5
β-CD (mg)	50	60	70	80	90	100	110	120	130

Evaluation Parameters

Batch	Thickness(mm)	Folding Endurance	Surface pH	Drug Content(%)	Drug Release(%)
F1	0.18	210	6.4	92.1	78.2
F2	0.19	225	6.5	93.4	80.4
F3	0.2	240	6.6	94.8	83.1
F4	0.22	255	6.7	95.2	86.5
F5	0.23	268	6.7	96.3	89.4
F6	0.24	275	6.8	97.1	92.8
F7	0.25	288	6.8	97.8	95.1
F8	0.26	295	6.9	99.2	98.7
F9	0.27	290	6.8	98.5	97.3



FTIR Study

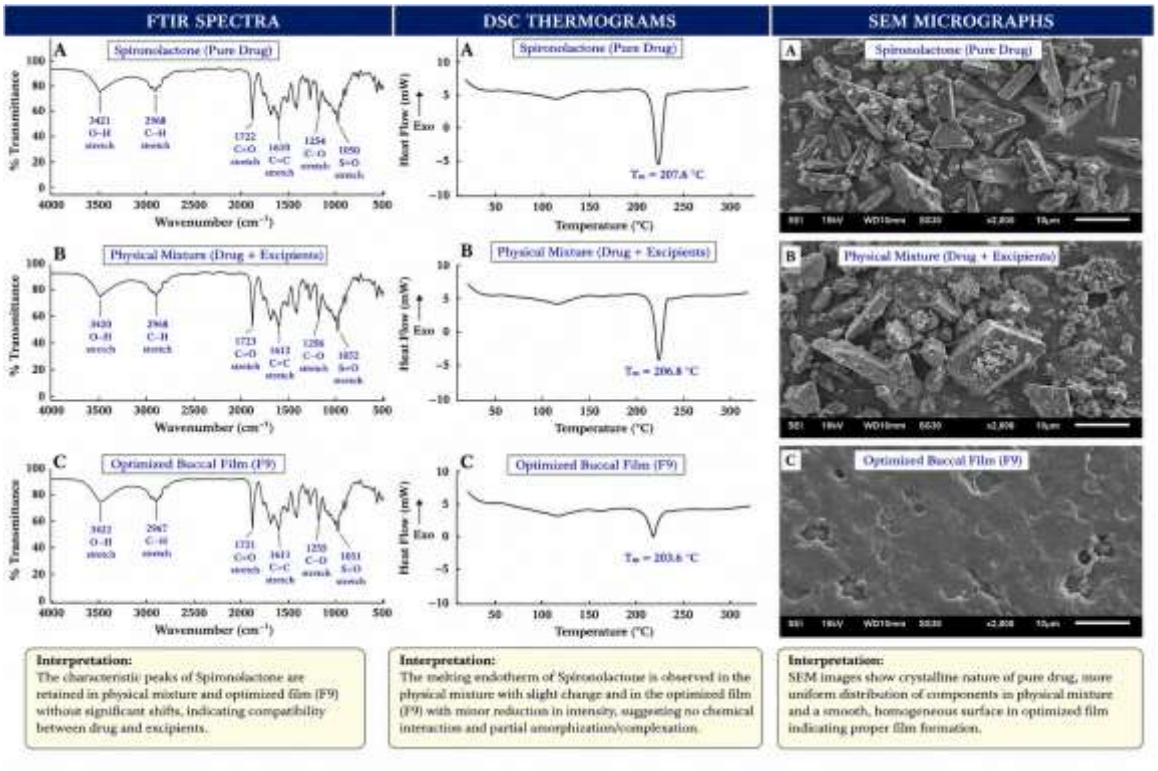
FTIR spectra showed characteristic peaks of Spironolactone without significant shifts, indicating compatibility between drug and excipients.

DSC Study

DSC thermograms demonstrated retention of characteristic melting endotherm suggesting absence of major interaction.

SEM Analysis

SEM images revealed smooth surface morphology and uniform drug distribution throughout the polymeric matrix.



Swelling Index

Optimized formulation exhibited satisfactory swelling behavior essential for prolonged buccal residence.

Ex-vivo Permeation Study

F8 demonstrated enhanced permeation through buccal mucosa due to improved solubility and polymer hydration.

Release Kinetics

Drug release followed Higuchi diffusion kinetics with non-Fickian transport mechanism.

Stability Study

Optimized formulation remained stable under accelerated conditions (40°C/75% RH) for three months.

Statistical Analysis

One-way ANOVA showed significant differences among formulations ($p < 0.05$).

Conclusion

The present study successfully developed mucoadhesive buccal films of Spironolactone using HPMC by solvent casting technique. Use of β-Cyclodextrin and Tween 80 significantly improved solubility and drug release characteristics. Among all formulations, F8 showed optimum thickness, folding endurance, drug content uniformity and maximum drug release of 98.7%, making it the optimized formulation. The developed buccal films demonstrated potential for enhancing bioavailability, reducing first-pass metabolism and improving therapeutic efficacy of Spironolactone.

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