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Formulation and Evaluation of Buccal Thin Films of Ondansetron Using Biodegradable Natural Polymers (Chitosan-Gelatin) for Rapid Onset of Action

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Abstract: The present investigation was designed to develop and assess buccal thin films of Ondansetron HCl using biodegradable natural polymers for rapid onset of antiemetic action. Ondansetron HCl was chosen as the model drug because of its established clinical relevance in nausea and vomiting, where administration of conventional oral dosage forms can be problematic. Buccal thin films were produced by the solvent casting technique with chitosan as a mucoadhesive polymer and gelatin as a biodegradable film-forming polymer, with glycerol as plasticizer. Six formulations, OBF1 to OBF6, were developed by varying chitosan and gelatin concentrations. The films were subsequently assessed for appearance, thickness, weight variation, folding endurance, surface pH, moisture content, swelling index, drug content, content uniformity, mucoadhesive residence time, hydration time and in vitro drug release. All formulations showed acceptable physical and pharmaceutical characteristics. Among them, OBF4 provided the most suitable balance of flexibility, surface pH, swelling, mucoadhesion, drug content and rapid release, with 95.36% drug release within 15 min. Stability testing indicated acceptable stability of the optimized formulation.

Keywords: Ondansetron HCl; Buccal thin film; Chitosan; Gelatin; Biodegradable polymer; Solvent casting; Rapid drug release.

INTRODUCTION

Nausea and vomiting occur in several clinical settings, including chemotherapy, radiotherapy, surgery, anaesthesia, and acute illness. During active nausea, swallowing and retaining a conventional tablet can be difficult, creating a practical need for dosage forms that can be administered without water and release drug rapidly in the oral cavity [1–4].

Ondansetron is a selective 5-hydroxytryptamine type-3 receptor antagonist used for prevention and treatment of nausea and vomiting in appropriate clinical settings. Rapid drug availability and convenient administration are desirable during acute symptoms, making ondansetron a suitable model for an oral-mucosal film platform [5–8].

Buccal films are thin polymeric systems placed against the inner cheek. They can hydrate quickly, remain in contact with the mucosal surface for a defined period, and release drug into saliva or toward the mucosa. Their performance depends on film thickness, mechanical strength, swelling, surface pH, mucoadhesion, disintegration, and drug release [9–12].

Chitosan is a biodegradable cationic polymer with mucoadhesive properties, while gelatin is a hydrophilic protein polymer with good film-forming and flexibility characteristics. Their combination can provide a film matrix that remains manageable during handling but hydrates rapidly after administration. Glycerol is used to improve flexibility [13–16].

Previous oral-film and buccal-film studies support the use of natural polymer blends for rapid or mucosal drug delivery [17–20]. The present investigation therefore formulated six ondansetron buccal thin films with chitosan and gelatin and evaluated their physicochemical properties, swelling, mucoadhesive residence, disintegration, drug content, in vitro release, and stability.

MATERIALS AND METHODS

Chemicals

Ondansetron HCl was obtained from Gift sample from Dr. Reddy's Laboratories, Hyderabad. Chitosan was obtained from Aura Biotechnologies Pvt. Ltd., Chennai. Gelatin was obtained from Sigma-Aldrich, Hyderabad. Glycerol was obtained from Vincitore Chemicals, Pune. Acetic acid was obtained from Elim Chemicals, Hyderabad.

Preformulation and analytical studies

Ondansetron hydrochloride was evaluated for appearance, melting behaviour, solubility, UV absorption at 310 nm, and FTIR compatibility. Calibration data were used for analysis.

Formulation design

Six formulations, OBF1–OBF6, were prepared with 40 mg ondansetron in a 10 mL casting solution while chitosan and gelatin concentrations were varied. Glycerol and 1% acetic acid were used as plasticizer and chitosan-solubilising vehicle, respectively.

Table 1: Formulation composition of ondansetron buccal thin films

Formulation	OND (mg)	Chitosan (% w/v)	Gelatin (% w/v)	Glycerol (% v/v)	Acetic acid (% v/v)	Purified water q.s.
OBF1	40	1.00	0.50	0.20	1.00	10 mL
OBF2	40	1.00	0.75	0.20	1.00	10 mL
OBF3	40	1.25	0.50	0.20	1.00	10 mL
OBF4	40	1.25	0.75	0.20	1.00	10 mL
OBF5	40	1.50	0.50	0.20	1.00	10 mL
OBF6	40	1.50	0.75	0.20	1.00	10 mL

Preparation method

Chitosan was hydrated in 1% acetic acid, while gelatin was dissolved separately in warm purified water at approximately 40–45°C. The cooled gelatin phase was added to the chitosan solution, ondansetron was incorporated, and glycerol was added. The homogeneous casting solution was deaerated, poured onto a level casting surface, dried at 40 ± 2°C, peeled, and cut to the required film size.

FTIR compatibility study

FTIR spectra of pure ondansetron and the chitosan–gelatin physical mixture were compared for retention and shifting of the principal drug bands.

Evaluation

Films were assessed for appearance, thickness, average weight, folding endurance, surface pH, moisture content, swelling index, drug content, content uniformity, mucoadhesive residence time, and disintegration time.

In vitro drug release

In vitro release was monitored over the short test period reported in the thesis using phosphate-buffer conditions and UV quantification at 310 nm.

Stability study

The optimized OBF4 formulation was stored under accelerated conditions for three months. The major film and release characteristics were assessed.

RESULTS AND DISCUSSION

Preformulation and FTIR compatibility

Ondansetron was soluble in the tested aqueous media and showed characteristic FTIR bands that remained present in the physical mixture. Minor shifts and broadening were attributed to polymer overlap and physical interactions within the film matrix.

Table 2: Solubility profile of ondansetron

Solvent	Observation	Solubility inference
Purified water	Clear solution formed	Soluble
Phosphate buffer pH 6.8	Clear solution formed	Soluble
Methanol	Clear solution formed rapidly	Freely soluble
0.1 N HCl	Clear solution formed	Freely soluble

Table 3: Comparative FTIR peak assignments of ondansetron and physical mixture

Functional group	Pure Ondansetron (cm^{-1})	Ondansetron + Chitosan + Gelatin (cm^{-1})
N–H stretching	3392	3340
Aliphatic C–H stretching	2956	2930
C=O stretching	1614	1652
Amide II N–H bending	–	1542
Aromatic C=C stretching	1591	–
CH2 bending	1465	1450
C–N stretching	1386	1378
C–N stretching and amide III region	1171	1245
C–O–C stretching	–	1150
C–O stretching	1032	1035
Aromatic C–H out-of-plane bending	820	821

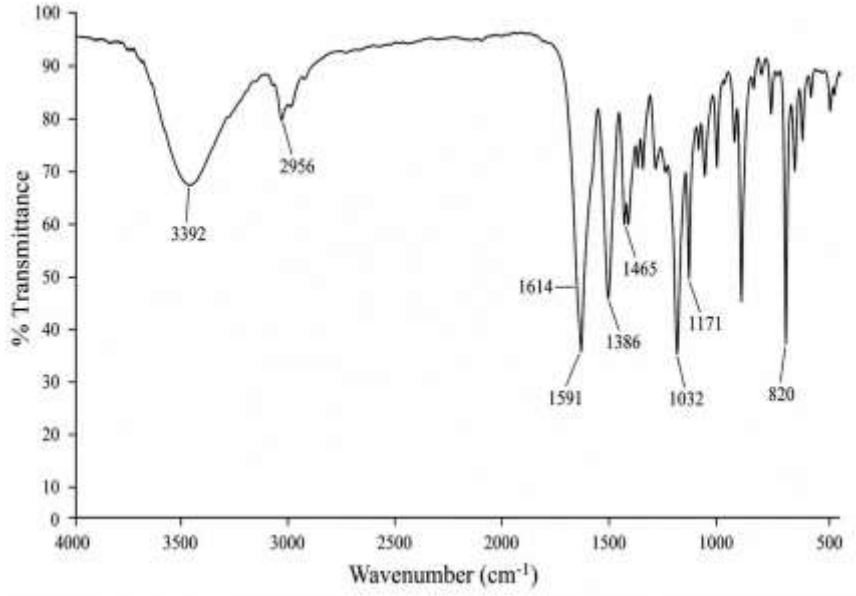

Fig 1: FTIR spectrum of pure ondansetron.

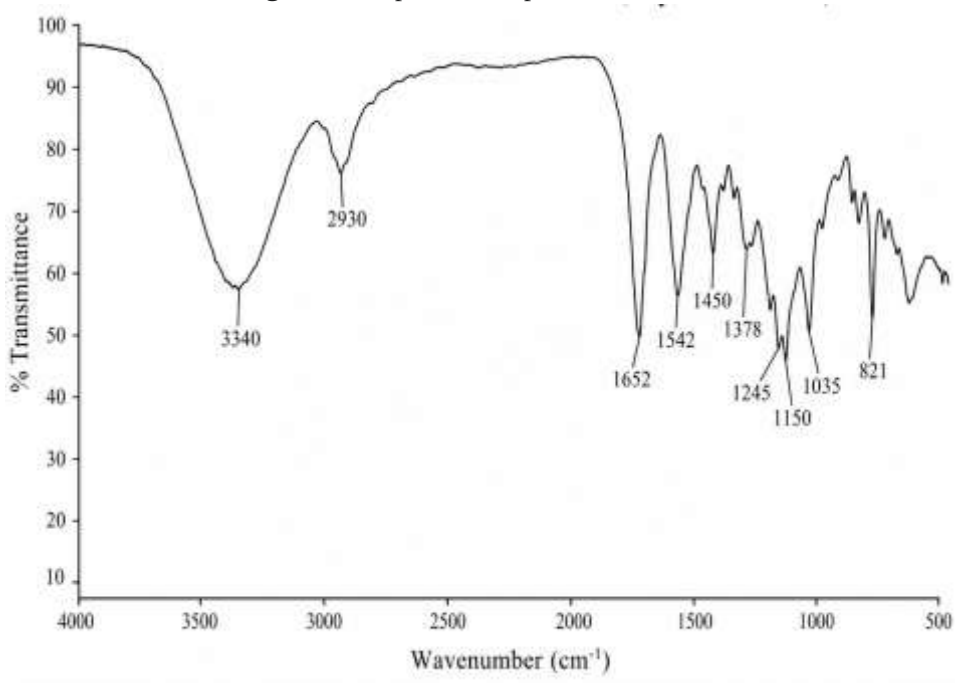

Fig 2: FTIR spectrum of the ondansetron–polymer physical mixture.

Film characteristics

All formulations produced smooth, flexible, translucent films without visible cracks or drug crystallization. Increasing the polymer concentration increased thickness, weight, folding endurance, moisture content, swelling, residence time, and disintegration time. Drug content remained uniform across the batches.

Table 4: Physical appearance of ondansetron buccal films

Formulation	Appearance
OBF1	Smooth, thin, flexible, translucent film
OBF2	Smooth, flexible, translucent film
OBF3	Smooth, slightly thicker, translucent film

OBF4	Smooth, uniform, flexible, translucent film
OBF5	Slightly thick, smooth, flexible film
OBF6	Thick, smooth, slightly less flexible film

Table 5: Physicochemical properties of ondansetron buccal films

Formulation	Thickness (mm)	Average weight (mg)	Folding endurance	Surface pH	Moisture content (%)
OBF1	0.106 ± 0.006	48.6 ± 1.8	168 ± 6	6.42 ± 0.04	3.84 ± 0.22
OBF2	0.118 ± 0.007	53.2 ± 2.1	186 ± 9	6.48 ± 0.05	4.12 ± 0.26
OBF3	0.132 ± 0.009	57.8 ± 2.4	204 ± 10	6.51 ± 0.04	4.46 ± 0.28
OBF4	0.146 ± 0.008	62.4 ± 2.2	232 ± 11	6.56 ± 0.03	4.78 ± 0.31
OBF5	0.161 ± 0.009	68.6 ± 2.6	218 ± 8	6.60 ± 0.05	5.24 ± 0.34
OBF6	0.176 ± 0.010	73.8 ± 2.9	205 ± 9	6.64 ± 0.04	5.68 ± 0.37

Table 6: Swelling, drug content, residence, and disintegration characteristics

Formulation	Swelling index at 5 min (%)	Drug content (%)	Content uniformity (%)	Residence time (min)	Disintegration time (sec)
OBF1	42.6 ± 2.8	97.18 ± 1.24	97.32 ± 0.72	18.4 ± 1.2	34 ± 3
OBF2	48.4 ± 3.1	98.06 ± 1.18	98.04 ± 0.68	22.6 ± 1.5	42 ± 2
OBF3	56.8 ± 3.4	98.42 ± 1.15	98.38 ± 0.61	28.8 ± 1.8	49 ± 5
OBF4	64.2 ± 3.7	99.12 ± 1.08	99.08 ± 0.54	34.2 ± 2.1	58 ± 4
OBF5	72.6 ± 4.1	98.64 ± 1.21	98.56 ± 0.66	41.6 ± 2.4	72 ± 5
OBF6	81.4 ± 4.6	98.28 ± 1.26	98.31 ± 0.69	48.8 ± 2.7	86 ± 6

In vitro drug release and optimized formulation

All formulations released ondansetron rapidly. OBF4 provided the most suitable balance between flexibility, swelling, mucoadhesive residence, disintegration, and rapid release, reaching 95.36 ± 3.42% release within 15 min. It was therefore selected as the optimized formulation.

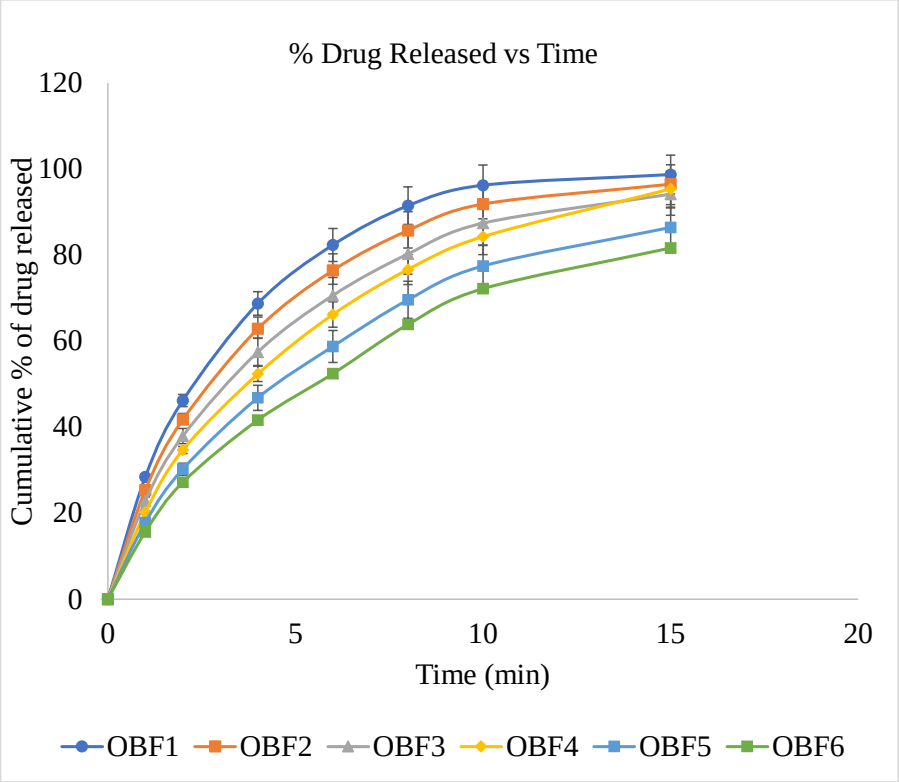

Fig 3: In vitro drug-release profiles of ondansetron buccal films.

Stability

OBF4 showed no major deterioration in appearance, surface pH, folding endurance, drug content, or release during three months of accelerated storage.

CONCLUSION

Ondansetron buccal thin films were successfully developed using a chitosan–gelatin biodegradable polymer blend. The polymer ratio affected film hydration, mechanical properties, mucoadhesive residence, disintegration, and drug release. OBF4 showed the most balanced performance and released 95.36 ± 3.42% ondansetron within 15 min while maintaining acceptable film characteristics. The optimized formulation remained stable during the short accelerated study. The work demonstrates formulation feasibility for rapid buccal ondansetron delivery.

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