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Development of Lornoxicam-Loaded Mucoadhesive Buccal Films Using Biopolymer Blends for Sustained Anti-Inflammatory Effect

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Abstract: The current investigation aimed to formulate and assess LRN-loaded mucoadhesive buccal films utilising biopolymer blends for sustained anti-inflammatory effect. LRN was selected as a potent non-steroidal anti-inflammatory drug, while chitosan and pullulan were used as functional biopolymers. Chitosan served as the mucoadhesive and release-controlling polymer, and pullulan acted as the primary film-forming polymer. Glycerol was utilised as plasticizer, and the films were prepared by solvent casting technique. Seven formulations, LBF1 to LBF7, were developed by varying chitosan and pullulan concentrations. The films that were developed underwent a thorough evaluation, focusing on various parameters such as appearance, thickness, weight variation, folding endurance, surface pH, moisture content, and swelling index, mucoadhesive residence time, drug content, content uniformity, in vitro drug release, release kinetics as well as stability. All formulations demonstrated acceptable physicochemical properties. Drug content varied from 96.72 ± 1.18% to 99.08 ± 1.02%. LBF5 was selected as the optimized formulation due to good flexibility, suitable surface pH, controlled swelling, adequate mucoadhesion and sustained drug release of 86.72 ± 3.84% at 8 h. Stability studies confirmed acceptable stability of the optimized formulation.

Keywords: LRN; Mucoadhesive buccal film; Chitosan; Pullulan; Biopolymer blend; Sustained release; Solvent casting.

INTRODUCTION

Inflammatory pain is commonly managed with non-steroidal anti-inflammatory drugs (NSAIDs), which reduce prostaglandin synthesis through cyclooxygenase inhibition. Repeated oral NSAID administration can be associated with gastrointestinal irritation and other systemic adverse effects, creating interest in alternative dosage forms that control drug release and reduce direct gastric exposure [1–4].

Lornoxicam is an oxicam-class NSAID with analgesic and anti-inflammatory activity. Its relatively low dose is favourable for incorporation into a thin buccal dosage form, while its limited aqueous solubility makes polymer hydration and drug dispersion important formulation considerations [5–8].

The buccal route allows a dosage form to remain in contact with the inner cheek and can support local or systemic drug delivery depending on drug permeability and formulation design. Mucoadhesive films are thinner than buccal tablets and can provide accurate placement, prolonged residence, and controlled release from a hydrated polymeric matrix [9–12].

Chitosan is a cationic, biodegradable polymer with established mucoadhesive behaviour, whereas pullulan is a hydrophilic film-forming polysaccharide that can improve film smoothness and handling. Blending the two polymers can balance adhesion, flexibility, swelling, and release. Glycerol is incorporated to reduce brittleness and improve folding endurance [13–16].

Previous buccal-film studies demonstrate the importance of polymer ratio, hydration, film thickness, and mucoadhesion in controlling drug release [17–20]. The present study therefore developed seven lornoxicam-loaded chitosan–pullulan buccal films and evaluated their physicochemical, mucoadhesive, release, and stability characteristics.

MATERIALS AND METHODS

Chemicals

LRN was obtained from Gift sample from Unichem Laboratories Ltd., Mumbai, Maharashtra, India. Chitosan was obtained from Otto Chemie Pvt. Ltd., Mumbai, Maharashtra, India. Pullulan was obtained from Otto Chemie Pvt. Ltd., Mumbai, Maharashtra, India. Glycerol was obtained from Merck Life Science Private Limited, India. Glacial acetic acid was obtained from S D Fine-Chem Limited, Mumbai, Maharashtra, India.

Preformulation and analytical studies

Lornoxicam was evaluated for appearance, melting behaviour, solubility, UV absorption at 376 nm, and FTIR compatibility.

Formulation design

Seven formulations, LBF1–LBF7, were prepared with 80 mg lornoxicam per 10 mL casting solution while chitosan and pullulan concentrations were varied. Glycerol was maintained as the plasticizer in a 1% acetic acid–water casting vehicle.

Table 1: Formulation composition of lornoxicam-loaded mucoadhesive buccal films

Formulation	LRN (mg)	Chitosan (% w/v)	Pullulan (% w/v)	Glycerol (% v/v)	1% acetic acid–water vehicle q.s.
LBF1	80	0.75	3.00	1.00	10 mL
LBF2	80	1.00	3.00	1.00	10 mL
LBF3	80	1.25	3.00	1.00	10 mL
LBF4	80	1.00	3.50	1.00	10 mL
LBF5	80	1.25	3.50	1.00	10 mL
LBF6	80	1.50	3.50	1.00	10 mL
LBF7	80	1.25	4.00	1.00	10 mL

Preparation method

Chitosan was dispersed in 1% acetic acid and pullulan was separately dissolved in purified water. The two polymer phases were combined, followed by addition of a uniform lornoxicam dispersion and glycerol. The final casting solution was deaerated, poured on a level surface, dried at 40 ± 2°C, peeled, and cut into 2 × 2 cm films.

FTIR compatibility study

FTIR spectra of pure lornoxicam and the drug-polymer physical mixture were compared to assess preservation of characteristic functional-group bands.

Evaluation

Films were evaluated for appearance, thickness, weight variation, folding endurance, surface pH, moisture content, swelling, mucoadhesive residence time, drug content, and content uniformity.

In vitro drug release

In vitro release was monitored over 8 h using the medium and analytical conditions specified.

Stability study

Optimized LBF5 was stored at 40 ± 2°C/75 ± 5% RH for three months and reassessed for the principal film and release attributes.

RESULTS AND DISCUSSION

Preformulation and calibration of LRN

Lornoxicam showed poor aqueous solubility. The calibration curve of LRN showed linearity in the concentration range of 2–12 µg/mL. Absorbance increased proportionally with concentration, indicating compliance with Beer–Lambert's law. The R^2 value of 0.9997 confirmed excellent linearity of the analytical method.

Table 2: Solubility profile of lornoxicam

Solvent	Observation	Solubility inference
Purified water	Undissolved drug particles observed	Practically insoluble
Phosphate buffer pH 6.8	Partial dissolution with slight turbidity	Sparingly soluble
0.1 N HCl	Poor dissolution	Slightly soluble
Methanol	Clear solution	Soluble
Dilute alkaline medium	Clear solution	Soluble

FTIR compatibility

Characteristic FTIR bands that remained identifiable in the physical mixture. The observed minor shifts were consistent with physical incorporation into the polymer matrix rather than formation of a new chemical species

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

Functional group	Pure LRN (cm^{-1})	Physical mixture (cm^{-1})
O–H stretching	3390	3368
Aromatic C–H stretching	3081	–
Aliphatic C–H stretching	2927	2925
Amide C=O stretching	1651	1658
Aromatic C=C stretching	1594, 1508	1598, 1512

C–H bending	1413	1415
S=O stretching	1301, 1247	1310, 1241
C–N stretching	1147	1153
C–O stretching	1057	1079
Aromatic C–H out-of-plane bending	825	750
C–Cl stretching	617	622

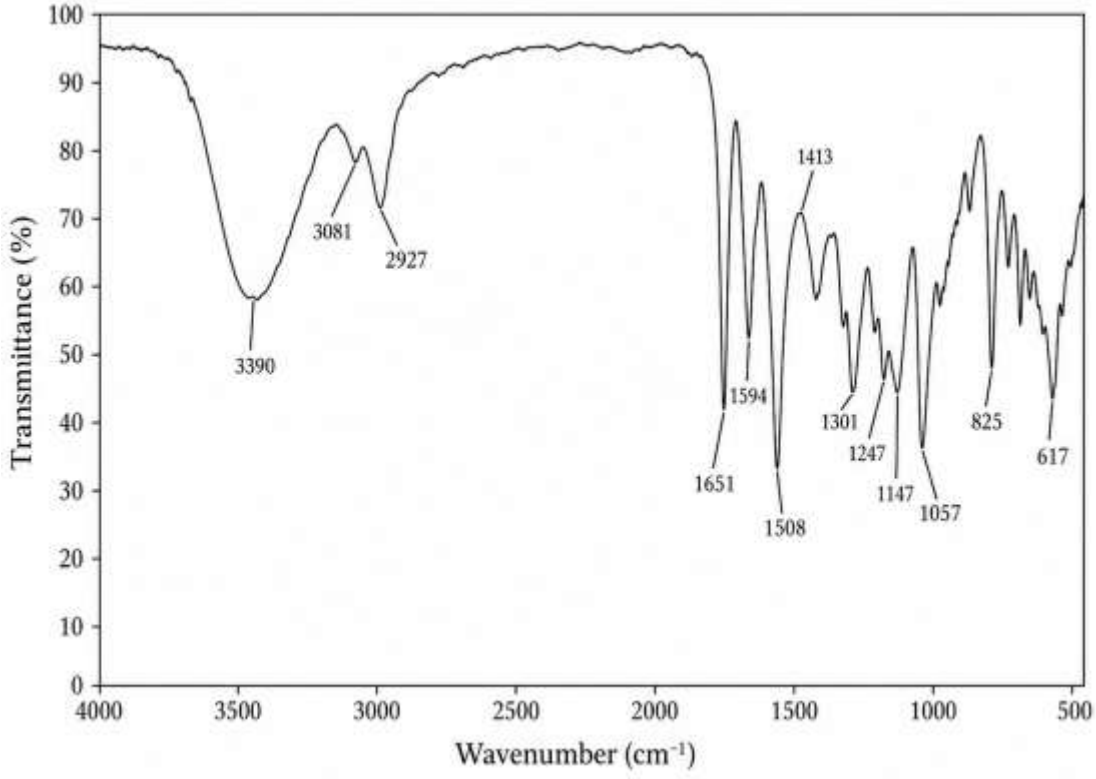

Fig 1: FTIR spectrum of pure lornoxicam.

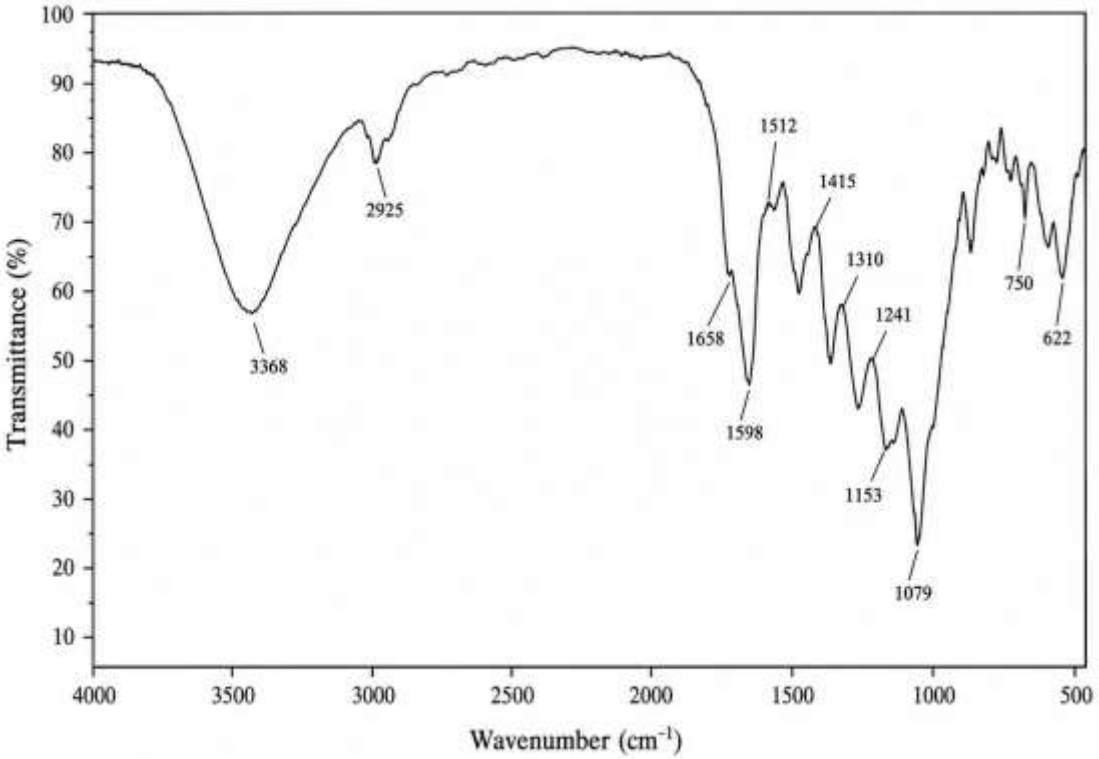

Fig 2: FTIR spectrum of the lornoxicam physical mixture.

Film characteristics and mucoadhesion

All batches formed smooth pale-yellow films. Increasing polymer concentration increased thickness, weight, folding endurance, moisture content, swelling, and mucoadhesive residence time. Drug content remained within the reported acceptable range. LBF5 provided a balanced combination of flexibility, surface pH, swelling, and residence.

Table 4: Physical appearance of lornoxicam buccal films

Formulation	Appearance
LBF1	Thin, smooth, pale yellow, flexible film
LBF2	Smooth, pale yellow, flexible film
LBF3	Smooth, uniform, slightly thicker film
LBF4	Smooth, translucent, flexible film
LBF5	Smooth, uniform, flexible and peelable film
LBF6	Thick, smooth, slightly less flexible film
LBF7	Smooth, slightly thick and flexible film

Table 5: Physicochemical properties of lornoxicam buccal films

Formulation	Thickness (mm)	Average weight (mg)	Folding endurance	Surface pH	Moisture content (%)
LBF1	0.132 ± 0.006	52.6 ± 2.0	162 ± 8	6.48 ± 0.04	3.56 ± 0.21
LBF2	0.147 ± 0.007	58.4 ± 2.2	185 ± 9	6.42 ± 0.04	3.84 ± 0.24
LBF3	0.164 ± 0.008	64.2 ± 2.5	204 ± 8	6.36 ± 0.05	4.18 ± 0.26

LBF4	0.173 ± 0.008	68.6 ± 2.6	218 ± 10	6.47 ± 0.04	4.32 ± 0.28
LBF5	0.189 ± 0.009	74.8 ± 2.8	246 ± 11	6.40 ± 0.04	4.76 ± 0.31
LBF6	0.217 ± 0.011	82.4 ± 3.1	226 ± 10	6.33 ± 0.05	5.28 ± 0.34
LBF7	0.225 ± 0.010	86.6 ± 3.2	238 ± 12	6.44 ± 0.04	5.42 ± 0.36

Table 6: Swelling, mucoadhesive residence, drug content, and content uniformity

F code	Swelling index at 60 min (%)	Mucoadhesive residence time (min)	Drug content (%)	Content uniformity (%)
LBF1	54.8 ± 2.6	52 ± 4	96.72 ± 1.18	96.58 ± 0.74
LBF2	68.2 ± 3.1	74 ± 5	97.38 ± 1.14	97.24 ± 0.70
LBF3	82.4 ± 3.6	96 ± 6	98.12 ± 1.10	98.04 ± 0.66
LBF4	78.6 ± 3.4	92 ± 6	98.46 ± 1.08	98.36 ± 0.62
LBF5	96.8 ± 4.2	128 ± 8	99.08 ± 1.02	99.02 ± 0.58
LBF6	114.2 ± 4.8	154 ± 9	98.64 ± 1.16	98.48 ± 0.68
LBF7	106.4 ± 4.5	142 ± 8	98.52 ± 1.12	98.40 ± 0.64

In vitro drug release and optimized formulation

All formulations provided sustained release over 8 h. LBF1 released drug more rapidly because of its lower matrix density, whereas higher chitosan content progressively retarded release. LBF5 released 86.72 ± 3.84% at 8 h and was selected as the optimized formulation because it balanced mechanical strength, mucoadhesion, swelling, drug content, and sustained release.

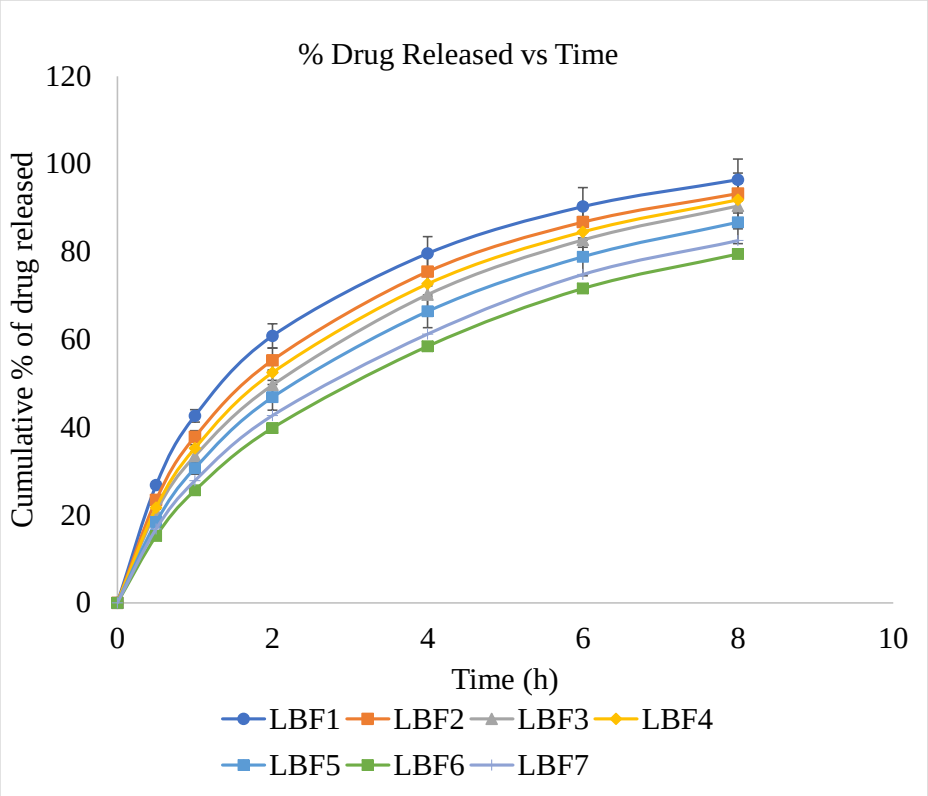

Fig 3: In vitro drug-release profiles of LBF1–LBF7.

Stability

LBF5 showed no major change in appearance, surface pH, folding endurance, drug content, or release during three months of accelerated storage.

CONCLUSION

Lornoxicam-loaded mucoadhesive buccal films were successfully prepared using chitosan and pullulan. Polymer concentration influenced film thickness, flexibility, swelling, mucoadhesive residence, and release. LBF5 provided the best overall balance and released 86.72 ± 3.84% lornoxicam at 8 h while maintaining acceptable physical and mucoadhesive properties. The optimized formulation remained stable during the short accelerated study.

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