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Research Article

Formulation and Characterization of Mucoadhesive Drug Delivery Systems for Cefixime and Lamotrigine

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ABSTRACT

Mucoadhesive drug delivery systems were developed for Cefixime and Lamotrigine to enhance oral bioavailability, improve absorption, and achieve sustained release. Natural polymers from Hibiscus rosa-sinensis leaves and Abelmoschus esculentus (Okra) fruits were used as mucoadhesive agents, and tablets were prepared via the direct compression method. The formulations were evaluated for physicochemical properties, swelling behavior, mucoadhesive strength, and in vitro drug release. Okra gum exhibited stronger adhesion than Hibiscus gum, leading to superior mucoadhesive performance. Optimized formulations (C3 for Cefixime and L3 for Lamotrigine) provided controlled drug release over 12 hours, following zero-order kinetics with a non-Fickian diffusion mechanism. FTIR analysis confirmed compatibility between drugs and polymers, and stability studies showed no significant changes over 90 days. These results indicate that mucoadhesive tablets formulated with natural polymers can effectively sustain drug release, reduce dosing frequency, and enhance patient compliance.

INTRODUCTION

Fast dissolving oral films (FDOFs) represent an innovative delivery platform that rapidly disintegrates in the mouth without water, enhancing patient compliance—especially among those with swallowing difficulties—and enabling rapid absorption that bypasses first-pass metabolism.

Selegiline (a selective irreversible MAO-B inhibitor) and lazabemide (a reversible MAO-B inhibitor) both offer neuroprotective benefits in Parkinson's disease but are limited by low oral bioavailability, rapid metabolism, and dosing challenges. Transforming them into fast dissolving oral films offers several advantages: improved

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bioavailability, reduced gastrointestinal degradation, and patient-friendly administration.

Previous studies have demonstrated the feasibility of formulating selegiline as mouth-dissolving films to bypass first-pass loss and enhance therapeutic onset. Fast dissolving film technology has been widely adopted for delivering poorly soluble or rapidly metabolized drugs, leveraging various polymers for optimal film formation, disintegration, and drug release.

This study aims to develop, characterize, and validate fast dissolving oral films containing selegiline and lazabemide for enhanced neuroprotective delivery. Parameters such as mechanical strength, film uniformity, disintegration time, drug release profile, and stability under ICH conditions are evaluated, following ICH Q2(R1) analytical validation guidelines.

MATERIALS AND METHODS

Materials

Cefixime and Lamotrigine were used as active pharmaceutical ingredients (APIs). Natural mucoadhesive polymers such as okra mucilage and hibiscus mucilage were extracted and purified for formulation development. Other excipients like lactose monohydrate, magnesium stearate, talc, and PVP K30 were procured from standard suppliers. Analytical-grade solvents and reagents, including ethanol, sodium hydroxide, and phosphate buffer (pH 6.8), were utilized throughout the study.

Instrumentation

All instruments employed in the study were calibrated prior to analysis. The UV-visible spectrophotometer provided sharp absorption peaks, while other analytical devices such as

hardness tester, friabilator, and dissolution apparatus functioned within operational standards. This ensured accuracy and reproducibility of experimental data.

RESULTS AND DISCUSSION

Extraction and Evaluation of Polymers

Okra gum (cold extraction) and hibiscus mucilage (hot aqueous extraction) were obtained in good yield.

Assessment of Mucoadhesive Property

- **Thumb Test**

The thumb test confirmed a concentration-dependent mucoadhesion for both extracts. Okra gum showed a clear increase in adhesion from 0.5% (+) to 1.5% (+++), while Hibiscus *rosasinensis* demonstrated only up to (++) even at the highest concentration. This indicates that Okra provided superior bioadhesive strength at equivalent concentrations.

- **Gum (Ring) Test**

Similar results were noted in the gum test, where Okra extract exhibited maximum mucoadhesion (+++) at 1.5%, while Hibiscus gum remained moderate (++) . These findings suggest that Okra polysaccharides contribute to stronger binding at the mucosal interface.

- **Shear Stress Method**

Adhesiveness increased with concentration and time for both extracts. At 30 minutes, Okra (1.5%) exhibited 83 g of force compared to 79 g for Hibiscus (1.5%). Overall, Okra gum consistently showed better resistance to shear detachment, confirming its superior mucoadhesive capacity.



- **Robinson's Test**

Tensile strength also increased with time and concentration. Okra (1.5%) reached a maximum of 12 units at 30 minutes, whereas Hibiscus (1.5%) attained 11 units. Although both were effective, Okra provided slightly higher binding strength.

- **Wilhelmy Plate Method**

Surface tension measurements confirmed better wettability and adhesion for Okra extracts. At 30 minutes, Okra (1.5%) recorded 4.3 dynes/cm compared to 3.9 dynes/cm for Hibiscus. The progressive increase suggested enhanced interfacial adhesion with Okra polysaccharides.

- **Falling Sphere Test**

Coated seeds with Okra extract took longer to pass through the mucus solution compared to Hibiscus-coated seeds. At 1.5% concentration, Okra delayed passage up to 18 minutes versus 17 minutes for Hibiscus, reinforcing its better mucoadhesive nature.

Overall, across all test methods, Okra extract demonstrated relatively stronger mucoadhesion compared to Hibiscus *rosasinensis*, making it a more promising polymer for mucoadhesive tablet formulations.

Pre-Compression Evaluation of Powder Blends

The micromeritic properties of Cefixime blends showed angles of repose below 25°, Carr's index values under 20%, and Hausner's ratios close to 1.1. These findings indicate good flowability and compressibility, within Indian Pharmacopoeia limits. Similarly, Lamotrigine blends exhibited comparable results, with angles of repose less than 25° and Carr's index values ranging from 17–20%, signifying acceptable flow behavior. All parameters were within pharmacopoeial limits,

ensuring that the blends were suitable for direct compression into mucoadhesive tablets.

Pre-formulation Studies

UV spectroscopy confirmed λ_{max} of Cefixime at 287 nm and Lamotrigine at 254 nm, aligning with reference standards. Calibration curves in pH 6.8 buffer and 0.1 N HCl exhibited excellent linearity ($R^2 > 0.99$), fulfilling Beer–Lambert's law. Melting point studies confirmed purity of the drugs, with observed values falling within pharmacopoeial ranges. Solubility analysis indicated that both drugs were sufficiently soluble in acidic and buffer media. Powder flow parameters including Carr's index (<15%) and Hausner ratio (<1.25) indicated acceptable flow behavior.

Identification of Cefixime and Lamotrigine by FTIR

FTIR spectroscopy was employed to confirm the identity of Cefixime and Lamotrigine. Cefixime exhibited sharp absorption peaks corresponding to hydroxyl, amine, carbonyl, and aromatic functional groups. Similarly, Lamotrigine showed characteristic bands for hydroxyl, amine, carbonyl, aromatic C–C, and C–Cl stretching vibrations. The presence of these distinct peaks confirmed the authenticity of both drugs, in agreement with reference spectra.

Formulation and Development of Mucoadhesive Tablets

Cefixime Mucoadhesive Tablets

Cefixime (200 mg) tablets were successfully developed using direct compression with Okra and Hibiscus gums as natural mucoadhesive agents. Formulations with Okra (C1–C3) contained increasing gum concentrations (95–145 mg), while Hibiscus-based formulations (C4–C6) contained



105–155 mg. Excipients like PVP K30, MCC, talc, and magnesium stearate ensured uniform blending and good compressibility. The blends showed acceptable flow properties, and tablets were within pharmacopoeial limits for weight variation and hardness.

Table1. Composition of Mucoadhesive Tablets of Cefixime (mg/tablet)

Ingredients	C1	C2	C3	C4	C5	C6
Cefixime	200	200	200	200	200	200
Okra gum	95	120	145	–	–	–
Hibiscus gum	–	–	–	105	130	155
PVP K30	28	25	26	27	25	26
MCC	32	30	30	31	30	30
Talc	1	1	1	1	1	1
Magnesium stearate	68	44	22	68	42	18

Lamotrigine Mucoadhesive Tablets

Lamotrigine (50 mg) mucoadhesive tablets were also prepared by direct compression. Okra-based formulations (L1–L3) contained 28–68 mg of gum, while Hibiscus-based formulations (L4–L6) used 32–72 mg. Similar excipients and process steps ensured uniformity. All formulations produced intact tablets with acceptable physicochemical characteristics, suitable for mucoadhesive evaluation.

Table2. Composition of Mucoadhesive Tablets of Lamotrigine (mg/tablet)

Ingredients	L1	L2	L3	L4	L5	L6
Lamotrigine	50	50	50	50	50	50
Okra gum	28	48	68	–	–	–
Hibiscus gum	–	–	–	32	52	72
PVP K30	14	15	15	14	15	15
MCC	21	20	20	21	20	20
Talc	1	1	1	1	1	1
Magnesium stearate	48	28	12	48	28	12

EVALUATION OF FORMULATED TABLETS

Physicochemical properties:

Both Cefixime (C1–C6) and Lamotrigine (L1–L6) tablets showed uniform thickness (C: 4.1–4.7 mm; L: 2.5–3.4 mm), weight (C: 426.2–426.9 mg; L: 165.7–166.8 mg), and acceptable hardness (C: 4.3–5.5 kg/cm²; L: 3.8–4.7 kg/cm²). Friability for all formulations was below 1%, indicating good mechanical strength. Drug content ranged within pharmacopoeial limits (C: 97.8–99.6%; L: 97.3–99.6%), confirming uniform distribution. Surface pH values were near neutral (C: 7.22–7.44; L: 7.08–7.22), suggesting suitability for buccal application without mucosal irritation.

Mucoadhesive properties:

Mucoadhesive strength and force increased with gum concentration. C6 (Hibiscus gum) showed the highest adhesion (43.49 g; 4.26 N) among Cefixime tablets, while L6 had the strongest Lamotrigine adhesion (43.12 g; 4.20 N). Both drug tablets exhibited reliable adhesion, indicating prolonged residence at the buccal site.

Swelling studies:

Swelling indices increased over 12 hours for both drugs (C: 21–84%; L: 23–81%). Higher gum content enhanced hydration and gel formation, which is favorable for controlled and sustained drug release.

Drug–Excipient Compatibility by FTIR

The FTIR spectra of Cefixime and its excipient blend demonstrated no significant shifts or disappearance of major peaks when compared with the pure drug. This indicated absence of chemical interactions and ensured compatibility with selected natural polymers. Likewise, Lamotrigine combined with excipients showed retention of all major functional group bands, with no additional peaks observed. These results



confirmed that both drug-polymer systems were stable and suitable for formulation.

In-vitro drug release:

All formulations released more than 88% of drug within 12 hours. Tablets with higher gum

concentration (C3, C6, L3, L6) showed slower, controlled release due to gel-forming properties. Release kinetics followed zero-order and non-Fickian anomalous transport, indicating drug release occurred via a combination of diffusion and polymer relaxation mechanisms.

Table 3. In-vitro dissolution study of Cefixime mucoadhesive tablets

Time (hrs)	√Time	Log Time	Cumulative % Drug Release					
			C1	C2	C3	C4	C5	C6
0	0	0	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
2	1.41	0.3	26.17 ± 0.58	24.02 ± 0.71	21.26 ± 0.62	30.01 ± 0.42	28.14 ± 0.47	25.37 ± 0.64
4	2	0.6	47.92 ± 0.49	39.01 ± 0.53	34.25 ± 0.33	55.38 ± 0.18	50.92 ± 0.58	42.21 ± 0.39
8	2.82	0.9	72.33 ± 0.21	69.86 ± 0.85	65.17 ± 0.64	80.45 ± 0.55	73.26 ± 0.39	67.59 ± 0.43
10	3.16	1	91.62 ± 0.32	86.45 ± 0.41	80.88 ± 0.53	98.75 ± 0.25	93.10 ± 0.17	85.47 ± 0.66
12	3.46	1.07	98.72 ± 0.57	93.92 ± 0.45	88.21 ± 0.48	99.08 ± 0.19	98.34 ± 0.29	91.02 ± 0.51

Values are Mean ± SD; n = 3

Table 4. In-vitro dissolution study of Lamotrigine mucoadhesive tablets

Time (hrs)	√Time	Log Time	L1 (±SD)	L2 (±SD)	L3 (±SD)	L4 (±SD)	L5 (±SD)	L6 (±SD)
0	0	0	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
2	1.41	0.3	27.92 ± 0.49	25.74 ± 0.34	24.35 ± 0.79	30.06 ± 0.91	28.02 ± 0.22	26.78 ± 0.59
4	2	0.6	45.72 ± 0.12	43.11 ± 0.78	37.08 ± 0.48	51.21 ± 0.69	47.88 ± 0.33	43.22 ± 0.42
8	2.82	0.9	75.88 ± 0.89	70.72 ± 0.41	65.94 ± 0.71	80.89 ± 0.39	78.24 ± 0.19	71.45 ± 0.49
10	3.16	1	95.98 ± 0.31	91.03 ± 0.47	84.89 ± 0.23	98.12 ± 0.43	93.28 ± 0.68	87.75 ± 0.57
12	3.46	1.07	97.48 ± 0.60	—	96.02 ± 0.55	—	—	96.88 ± 0.84

Table 5. Kinetics of in-vitro drug release profile of Cefixime mucoadhesive tablets

Formulation code	Zero order R ²	First order R ²	Higuchi R ²	Korsmeyer-Peppas R ²
C1	0.981	0.927	0.961	0.991
C2	0.996	0.785	0.948	0.994
C3	0.998	0.905	0.943	0.992
C4	0.972	0.825	0.971	0.99
C5	0.976	0.887	0.968	0.989
C6	0.993	0.774	0.955	0.997



Table 6. Kinetics of *in vitro* drug release profile of Lamotrigine mucoadhesive tablets

Formulation Code	Zero Order (R ²)	First Order (R ²)	Higuchi (R ²)	Korsmeyer-Peppas Model (R ²)
L1	0.987	0.865	0.962	0.995
L2	0.989	0.893	0.952	0.997
L3	0.993	0.838	0.945	0.993
L4	0.981	0.815	0.973	0.998
L5	0.984	0.918	0.969	0.998
L6	0.986	0.823	0.967	0.997

Optimized Mucoadhesive Tablet Formulations: C3 and L3

The Cefixime (C3) and Lamotrigine (L3) mucoadhesive tablets were finalized as the optimized formulations based on physicochemical, mucoadhesive, swelling, drug release, and stability evaluations.

Physicochemical evaluation:

Both tablets exhibited uniform thickness (C3: 4.8 mm; L3: 2.8 mm), consistent weight (C3: 426.5 mg; L3: 166.0 mg), and acceptable hardness (C3: 5.6 kg/cm²; L3: 3.9 kg/cm²). Friability was below 1%, and drug content was within pharmacopoeial limits (C3: 99.5%; L3: 99.5%). Surface pH values (C3: 7.42; L3: 7.08) confirmed mucosal compatibility.

Mucoadhesive properties:

Optimized formulations showed strong adhesion and mucoadhesive force (C3: 37.59 g, 3.689 N; L3: 39.36 g, 3.864 N), ensuring prolonged retention at the buccal site. Hibiscus and Okra gums contributed significantly to the adhesive behavior.

Swelling and drug release:

C3 and L3 displayed high swelling indices (C3: 74%; L3: 70% at 12 h), supporting sustained release. *In vitro* release studies showed controlled drug release over 12 hours (C3: 88.21%; L3: 96.02%), following zero-order kinetics and non-Fickian anomalous transport, indicating combined diffusion and polymer relaxation mechanisms.

Stability studies:

Optimized formulations (C3 for Cefixime and L3 for Lamotrigine) remained physically stable, with consistent drug content, mucoadhesive strength, surface pH, and drug release profiles over 90 days at both accelerated (40°C/75% RH) and room temperature (25°C/60% RH) conditions. No significant color changes or degradation were observed, confirming formulation stability.

days under accelerated (40°C/75% RH) and room temperature (25°C/60% RH) conditions. No significant color change or degradation was observed.

Table7: Compact Stability Study of Optimized Tablets (C3 and L3)

Time (days)	Storage Condition	C3 – Cefixime	L3 – Lamotrigine
0	40°C ±2 / 75% RH	Off-white; 99.0 ±0.41%; pH 7.10 ±0.58; Strength 37.58 ±0.27 g; Force 3.705 N; % Release 93.26 ±0.57	Slight dulling; 99.6 ±0.47%; pH 7.69 ±0.34; Strength 39.62 ±0.22 g; Force 3.82 N; % Release 97.32 ±0.79



30	40°C ±2 / 75% RH	No change; 99.5 ±0.38%; pH 7.79 ±0.73; Strength 37.46 ±0.80 g; Force 3.57 N; % Release 94.73 ±0.33	No change; 99.4 ±0.38%; pH 7.32 ±0.28; Strength 39.35 ±0.51 g; Force 3.805 N; % Release 96.83 ±0.46
60	40°C ±2 / 75% RH	No change; 99.8 ±0.17%; pH 7.35 ±0.29; Strength 37.68 ±0.59 g; Force 3.81 N; % Release 93.35 ±0.49	No change; 99.3 ±0.31%; pH 7.76 ±0.66; Strength 39.27 ±0.25 g; Force 3.79 N; % Release 97.74 ±0.79
90	40°C ±2 / 75% RH	No change; 99.4 ±0.89%; pH 7.09 ±0.75; Strength 37.89 ±0.28 g; Force 3.43 N; % Release 93.51 ±0.64	No change; 99.5 ±0.28%; pH 7.38 ±0.58; Strength 39.18 ±0.29 g; Force 3.8 N; % Release 97.21 ±0.25
0	25°C ±2 / 60% RH	Off-white; 99.3 ±0.06%; pH 7.45 ±0.39; Strength 37.92 ±0.29 g; Force 3.805 N; % Release 92.87 ±0.78	Slight yellowish; 99.6 ±0.35%; pH 7.48 ±0.24; Strength 39.52 ±0.47 g; Force 3.558 N; % Release 97.35 ±0.64
30	25°C ±2 / 60% RH	No change; 99.4 ±0.61%; pH 7.35 ±0.22; Strength 37.40 ±0.07 g; Force 3.89 N; % Release 93.53 ±0.28	No change; 99.4 ±0.59%; pH 7.22 ±0.31; Strength 39.64 ±0.66 g; Force 3.685 N; % Release 96.24 ±0.18
60	25°C ±2 / 60% RH	No change; 99.6 ±0.52%; pH 7.59 ±0.79; Strength 37.09 ±0.10 g; Force 3.61 N; % Release 93.36 ±0.10	No change; 99.7 ±0.33%; pH 7.38 ±0.19; Strength 39.35 ±0.73 g; Force 3.694 N; % Release 97.09 ±0.55
90	25°C ±2 / 60% RH	No change; 99.7 ±0.38%; pH 7.67 ±0.48; Strength 37.38 ±0.06 g; Force 3.42 N; % Release 93.62 ±0.33	No change; 99.2 ±0.22%; pH 7.56 ±0.41; Strength 39.12 ±0.38 g; Force 3.661 N; % Release 97.46 ±0.27

CONCLUSION

The present study successfully developed and evaluated mucoadhesive tablets of Cefixime and Lamotrigine using natural polymers derived from *Hibiscus rosa-sinensis* leaves and *Abelmoschus esculentus* (Okra) fruits. Both polymers demonstrated excellent binding and adhesion properties, with Okra showing comparatively stronger mucoadhesive performance. The final optimized formulations, C3 for Cefixime and L3 for Lamotrigine, exhibited sustained drug release over 12 hours following zero-order kinetics with a non-Fickian mechanism, indicating controlled and predictable drug delivery. Evaluation parameters, including drug content, mucoadhesive strength, swelling index, and stability studies, were within acceptable limits, demonstrating the formulations' quality and shelf stability up to 90 days at room temperature and accelerated conditions. The mucoadhesive approach not only enhanced drug retention at the absorption site but also bypassed first-pass metabolism, improving bioavailability and supporting localized and targeted therapy.

These findings highlight the potential of natural polymer-based mucoadhesive tablets as an effective strategy for improving solubility-limited and absorption-limited drugs, while ensuring patient compliance. Future research may focus on clinical evaluation, in vivo mucoadhesion studies, and exploring additional natural polymers to further optimize and expand the applicability of this drug delivery system.

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