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Natural Polymer-Based Gastroretentive Floating-Bioadhesive Matrix Tablets of Furosemide: Formulation, Optimization, and in Vitro Evaluation

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ABSTRACT:

Background: Furosemide exhibits low and variable oral bioavailability owing to its limited absorption window in the upper gastrointestinal tract, short gastric residence time, and poor aqueous solubility. The present study aimed to develop and optimize a floating-bioadhesive matrix tablet of furosemide using Delonixregia seed mucilage as a novel natural polymer to enhance gastric retention and sustain drug release.

Methodology: Floating-bioadhesive matrix tablets were prepared by the direct compression method and optimized using a three-factor, three-level Box–Behnken design. Plant mucilage concentration, drug ratio, and effervescent content were selected as independent variables, while floating lag time, total floating time, and cumulative drug release were evaluated as the responses. The optimized formulation was further characterized for physicochemical properties, swelling index, bioadhesive strength, drug content, and in-vitro drug release. Results and

Discussion: The optimized formulation consisted of 4% mucilage, a drug ratio of 1:2, and 10% effervescent content. It exhibited a floating lag time of 53.77 ± 1.35 s, total floating time of 13.83 ± 0.25 h, swelling index of 321.50 ± 2.91%, bioadhesive strength of 27.53 ± 0.75 g, drug content of 99.90 ± 0.70%, and cumulative drug release of 91.07 ± 0.65% over 12 h. The optimized formulation demonstrated excellent buoyancy, effective mucoadhesion, and sustained drug release, confirming the suitability of the optimized polymer matrix for gastroretentive delivery.

Conclusion: The developed floating-bioadhesive matrix tablets successfully achieved prolonged gastric retention and sustained drug release. Delonixregia seed mucilage proved to be an effective natural polymer for developing gastroretentive delivery systems and represents a promising alternative to conventional synthetic polymers for sustained oral delivery of furosemide.

1. INTRODUCTION

Oral drug delivery remains the most preferred route for the administration of pharmaceutical agents because of its convenience, patient compliance, cost-effectiveness, and ease of large-scale manufacturing. However, conventional oral

dosage forms often exhibit limitations such as rapid gastric emptying, short residence time in the stomach, and variable drug absorption, leading to reduced bioavailability and inconsistent therapeutic efficacy. Gastroretentive drug delivery systems (GRDDS) have emerged as an effective strategy to overcome these challenges by prolonging the gastric residence time of dosage forms, thereby improving drug absorption, reducing dosing frequency, and enhancing therapeutic outcomes. Among the various gastroretentive approaches, floating drug delivery systems combined with bioadhesive properties have attracted considerable attention due to their ability to remain buoyant in gastric fluid while simultaneously adhering to the gastric mucosa, resulting in prolonged gastric retention and controlled drug release [1–3].

Floating-bioadhesive matrix tablets are advanced gastroretentive systems designed to combine the advantages of buoyancy and mucoadhesion. Floating systems possess a lower density than gastric fluid, enabling them to remain afloat for an extended period without affecting the gastric emptying process. Simultaneously, bioadhesive polymers interact with the mucin layer of the stomach through hydrogen bonding, electrostatic interactions, and polymer chain entanglement, thereby increasing the residence time of the formulation at the site of absorption. The synergistic combination of floating and bioadhesive mechanisms significantly enhances gastric retention compared with either approach alone, making these systems particularly suitable for drugs absorbed primarily in the upper gastrointestinal tract or exhibiting pH-dependent solubility [4–6].

Furosemide is a potent loop diuretic widely prescribed for the management of hypertension, congestive heart failure, nephrotic syndrome, pulmonary edema, and renal disorders. Despite its clinical importance, furosemide belongs to the Biopharmaceutics Classification System (BCS) Class IV, characterized by low aqueous solubility and low permeability, resulting in highly variable oral bioavailability ranging from 30% to 70%. Furthermore, furosemide is predominantly absorbed from the stomach and upper small intestine, possesses a short biological half-life of approximately 1.5–2 hours, and exhibits reduced solubility at intestinal pH. Consequently, conventional oral formulations often produce inconsistent plasma drug concentrations, necessitating frequent dosing and increasing the likelihood of therapeutic failure. Developing a gastroretentive floating-bioadhesive formulation is therefore a promising strategy to improve gastric residence time, enhance drug dissolution within the acidic gastric environment, and achieve sustained drug release with improved bioavailability [7–9].

Natural polymers have gained increasing importance in pharmaceutical formulation owing to their biodegradability, biocompatibility, non-toxicity, abundance, and environmental sustainability. Among natural polymers, plant-derived mucilages have emerged as promising pharmaceutical excipients because of their excellent swelling capacity, viscosity-enhancing properties, film-forming ability, and mucoadhesive characteristics. Plant mucilages obtained from various botanical sources such as *Plantago ovata*, *Hibiscus rosa-sinensis*, *Ocimumbasilicum*, *Linumusitatissimum*, *Abelmoschusesculentus*, and *Aloe vera* have been successfully investigated as binders, matrix-forming agents, disintegrants, suspending agents, and controlled-release polymers. Their ability to hydrate rapidly and form viscous gels upon contact with aqueous media makes them particularly suitable for the preparation of gastroretentive floating matrix tablets [10–12].

The application of plant mucilage as a novel release-retarding polymer offers several advantages over synthetic polymers. Besides being economical and readily available, plant mucilages exhibit excellent safety profiles, low toxicity, renewable availability, and better patient acceptability. Their natural polysaccharide composition provides controlled hydration, swelling, and gel formation, thereby regulating drug diffusion and matrix erosion. Moreover, the presence of hydroxyl and carboxyl functional groups contributes significantly to bioadhesion by forming hydrogen bonds with gastric mucin, enhancing gastric retention. These unique physicochemical characteristics make plant mucilage an attractive alternative to conventional synthetic polymers such as hydroxypropyl methylcellulose (HPMC), carbopol, sodium alginate, and xanthan gum [13,14].

The successful formulation of floating-bioadhesive matrix tablets depends on the careful optimization of polymer concentration, gas-generating agents, tablet hardness, swelling characteristics, floating lag time, total floating duration, matrix integrity, and drug release kinetics. Sodium bicarbonate, often combined with citric acid, generates carbon dioxide upon contact with gastric fluid, producing buoyancy by entrapping gas within the hydrated polymer matrix. Simultaneously, hydrated mucilage forms a strong gel barrier that controls drug diffusion while maintaining tablet integrity throughout the release period. Evaluation parameters including pre-compression characteristics, post-compression properties, swelling index, bioadhesive strength, floating behavior, drug content uniformity, dissolution profile, release kinetics, and stability studies are essential for assessing the quality and performance of gastroretentive formulations [15–17].

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Therefore, the present investigation aims to develop and evaluate a floating-bioadhesive matrix tablet of furosemide using plant mucilage as a novel natural polymer. The study intends to exploit the combined advantages of floating and bioadhesive mechanisms to prolong gastric residence time, sustain drug release, improve dissolution in the acidic gastric environment, and ultimately enhance the oral bioavailability of furosemide. The successful development of such a natural polymer-based gastroretentive drug delivery system may provide an effective, economical, patient-friendly, and environmentally sustainable alternative to conventional oral sustained-release formulations while contributing to the growing interest in green pharmaceutical excipients and advanced oral drug delivery technologies [18–20].

2. MATERIALS AND METHOD

Furosemide was obtained from Taj Pharma India Ltd., India. HPMC, sodium bicarbonate, citric acid, lactose, magnesium stearate, talc, and analytical-grade chemicals were procured from Merck and Qualigens. Plant mucilage was isolated from Delonixregia seeds and used as a novel natural polymer.

2.1 Preformulation Studies

Preformulation studies were performed to characterize the physicochemical properties of furosemide prior to formulation development and to ensure its suitability for the preparation of floating-bioadhesive matrix tablets. The investigations included organoleptic evaluation, melting point determination, solubility analysis, and drug–excipient compatibility studies. Fourier Transform Infrared Spectroscopy (FTIR) were employed to assess potential interactions between furosemide, plant mucilage, and selected excipients. The findings obtained from these studies facilitated the rational selection of formulation components and established the compatibility, stability, and feasibility of the optimized gastroretentive matrix tablet formulation. [21].

2.2 Preparation of Furosemide Floating-Bioadhesive Matrix Tablets

Optimization of Formulation

The present investigation was undertaken to develop and optimize Furosemide floating-bioadhesive matrix tabletsusingplant mucilage isolated from *Delonixregia* seeds as a novel natural polymer. A3-factor, 3-level Box–Behnken Design (BBD) was employed to optimize the formulation variables influencing the gastroretentive performance of the tablets. The independent variables selected for optimization were plant mucilage concentration (X_1), HPMC concentration (X_2), and sodium bicarbonate concentration (X_3). These variables were evaluated for their influence on critical quality attributes, including floating lag time, bioadhesive strength, swelling index, and cumulative drug release. The Design of Experiments (DoE) approach enabled systematic optimization with a minimum number of experimental trials while establishing the relationship between formulation variables and responses. [22].

Experimental Design

Table 1. Independent Variables Used in Box–Behnken Design

Code	Independent Variable	Low (-1)	Medium (0)	High (+1)
X_1	Plant mucilage concentration (% w/w)	10	20	30
X_2	HPMC concentration (% w/w)	10	20	30
X_3	Sodium bicarbonate concentration (% w/w)	5	10	15

A total of 15 experimental formulations were generated using Design-Expert® software according to the Box–Behnken Design.

Procedure

Floating-bioadhesive matrix tablets of furosemide were prepared by the direct compression method. Furosemide, plant mucilage, HPMC, lactose, sodium bicarbonate, and citric acid were accurately weighed, passed through a #60 sieve, and blended uniformly. Magnesium stearate and talc (1% w/w each) were added and mixed gently before compression. The

powder blend was compressed into tablets using a rotary tablet compression machine fitted with an 8-mm flat-faced punch. The prepared tablets were stored in airtight containers for further evaluation

2.3 Evaluation of Floating-Bioadhesive Matrix Tablets

Floating Behavior

Floating lag time (FLT) and total floating time (TFT) were determined by placing tablets in 900 mL of 0.1 N HCl (pH 1.2) maintained at 37 ± 0.5°C using USP Type II dissolution apparatus. The time required for the tablet to float and the duration of buoyancy were recorded.

Swelling Index

The swelling index was determined by immersing tablets in 0.1 N HCl (pH 1.2). Tablets were removed at predetermined intervals, blotted to remove excess surface liquid, weighed, and the swelling index was calculated.

Bioadhesive Strength

Bioadhesive strength was measured using a modified physical balance with freshly excised goat gastric mucosa. The force required to detach the tablet from the mucosal surface was recorded.

Matrix Erosion

Matrix erosion was determined by measuring the percentage weight loss of tablets after immersion in dissolution medium for predetermined time intervals.

Surface pH

The surface pH of swollen tablets was measured using a digital pH meter after allowing the tablets to hydrate in distilled water for 2 h.

Drug Content Uniformity

Drug content was determined by dissolving powdered tablets in a suitable solvent, followed by UV–Visible spectrophotometric analysis at 274 nm after appropriate dilution.

In Vitro Dissolution Study

Drug release studies were carried out using USP Type II (paddle) dissolution apparatus containing 900 mL of 0.1 N HCl (pH 1.2) at **37 ± 0.5°C** and **50 rpm**. Samples were withdrawn at predetermined intervals, replaced with fresh medium, and analyzed using a UV–Visible spectrophotometer at **274 nm**[23]

3. RESULTS

3.1 Preformulation Studies

Preformulation studies confirmed that furosemide is a white to slightly off-white, odorless, crystalline powder with a mean melting point of 206.77 ± 0.35°C, indicating its purity and crystalline nature. Solubility studies demonstrated that the drug was slightly soluble in distilled water and ethanol, sparingly to moderately soluble in 0.1 N HCl, and very slightly soluble in acetone, supporting its suitability for gastroretentive drug delivery. The UV–Visible spectrophotometric method showed a λmax at 275 nm with excellent linearity over the concentration range of 2–12 μg/mL (R^2 = 0.9998), confirming the reliability of the analytical method for drug estimation during formulation development and in vitro dissolution studies.

3.2 Drug-Excipient Compatibility Studies

FTIR spectrum confirmed characteristic functional groups of Ziprasidone without structural alterations, indicating drug identity, purity, and compatibility.

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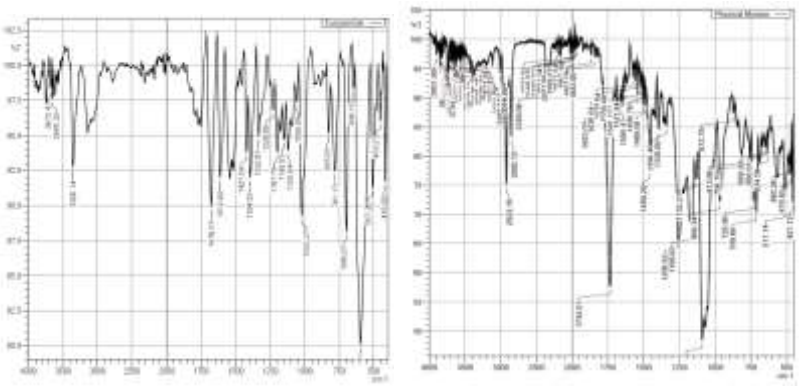

(A) (B)

Figure 1: FTIR spectrum of Furosemide (A) and physical mixture(B)

3.3 Optimization Study Using Box–Behnken Design (DoE Results)

The optimization of floating-bioadhesive matrix tablets of Furosemide was carried out using a three-factor, three-level Box–Behnken Design (BBD) to evaluate the influence of formulation variables on the critical quality attributes of the gastroretentive dosage form. Three independent variables were selected, namely mucilage concentration (A), polymer ratio (drug:polymer) (B), and effervescent content (C), while the dependent responses included floating lag time (Y_1), total floating time (Y_2), and cumulative drug release (Y_3). A total of fifteen experimental formulations were generated and statistically analyzed using Design-Expert® software to establish mathematical models and optimize the formulation.

3.4 Experimental Design Matrix and Observed Responses

The Box–Behnken design generated fifteen experimental runs with different combinations of mucilage concentration, polymer ratio, and effervescent content. The experimental responses demonstrated considerable variation in floating lag time, total floating duration, and cumulative drug release, confirming the significant influence of formulation variables on tablet performance. Floating lag time ranged from 60.1 to 126 seconds, total floating duration ranged from 7.4 to 15.0 hours, while cumulative drug release varied between 76.4% and 90.1%**.** The center point formulations showed excellent reproducibility, indicating good precision of the experimental design. Overall, increasing mucilage concentration and polymer ratio enhanced tablet buoyancy and prolonged floating duration, whereas higher effervescent content markedly reduced floating lag time because of rapid carbon dioxide generation

Table 02: Box–Behnken design matrix with observed responses

Run	Factor 1 A:Mucilage concentration % w/w	Factor 2 B:Polymer ratio	Factor 3 C:Effervescent content % w/w	Response 1 Floating lag time Seconds	Response 2 Prolonged floating duration Hours	Response 3 Controlled drug release %
1	2	1	10	63.2	8.2	90.1
2	6	1	10	65.1	10.5	87.7
3	2	3	10	68.1	9.4	76.8
4	6	3	10	67.8	12.6	78.2
5	2	2	5	126	7.4	84
6	6	2	5	121	9.6	83.1

7	2	2	15	73	11.3	82.9
8	6	2	15	71	14.1	83
9	4	1	5	119	8.3	86.4
10	4	3	5	121	10.6	79.1
11	4	1	15	70	12.5	87.9
12	4	3	15	71	15	76.4
13	4	2	10	62	14	83
14	4	2	10	60.1	14.1	82.9
15	4	2	10	60.8	13.9	86.2

3.5 Optimized Formulation Selection

The floating-bioadhesive matrix tablets were optimized using the desirability function of the Box–Behnken design to achieve minimum floating lag time, maximum floating duration, and controlled drug release. The optimized formulation consisted of 4% mucilage concentration, adrug ratio of 1:2**,** and10% effervescent content. The model predicted a floating lag time of approximately 54 s**,** a total floating time of 12 h, and cumulative drug release of 87%. The experimentally observed responses were in close agreement with the predicted values, confirming the validity and reliability of the optimization model.

The optimized formulation exhibited rapid buoyancy, prolonged gastric retention, and sustained drug release, demonstrating its suitability as a gastroretentive floating-bioadhesive delivery system for furosemide. This formulation was subsequently selected for detailed physicochemical characterization, floating studies, swelling studies, mucoadhesive evaluation and in-vitro drug release studies.

Table 03: Optimization criteria and predicted responses of the optimized formulation

Parameter	Optimization goal	Optimized value
Mucilage concentration	Within design space	4%
Drug:polymer ratio	Within design space	1:2
Effervescent content	Within design space	10%
Floating lag time	Minimize	≈ 54 s
Total floating time	Maximize	≈ 12 h
Cumulative drug release	Controlled release	≈ 87%
Overall desirability	Maximize	Highest desirability

Table 04: Comparison of predicted and experimental responses of the optimized formulation

Response	Predicted value	Experimental value	Observation
Floating lag time (s)	54	54 ± SD*	Closely matched
Total floating time (h)	12	12 ± SD*	Closely matched
Drug release (%)	87	87 ± SD*	Closely matched

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Figure 2: Optimized floating-bioadhesive matrix tablet formulation

3.6 Evaluation of Floating-Bioadhesive Matrix Tablets

The optimized floating-bioadhesive matrix tablets exhibited satisfactory pharmaceutical performance. The formulation showed a floating lag time of 53.77 ± 1.35 s and remained buoyant for 13.83 ± 0.25 h**,** confirming excellent floating characteristics. The tablets demonstrated amaximum swelling index of 321.50 ± 2.91% at 12 h and a bioadhesive strength of 27.53 ± 0.75 g, indicating efficient hydration and adequate mucoadhesion. The matrix exhibited controlled erosion and maintained a near-neutral surface pH, ensuring matrix integrity and gastric compatibility. The drug content was 99.90 ± 0.70%**,** confirming uniform drug distribution, while the optimized formulation achieved 91.07 ± 0.65% cumulative drug release at 12 h, demonstrating sustained-release behavior suitable for gastroretentive delivery of furosemide.

Table 05: Evaluation of Floating-Bioadhesive Matrix Tablets

Evaluation parameter	Result (Mean ± SD)
Floating lag time	53.77 ± 1.35 s
Total floating time	13.83 ± 0.25 h
Maximum swelling index (12 h)	321.50 ± 2.91%
Bioadhesive strength	27.53 ± 0.75 g
Matrix erosion	Gradual and controlled (qualitative)
Surface pH	Near neutral (qualitative)
Drug content	99.90 ± 0.70%
Drug release at 12 h	91.07 ± 0.65%

3.7 In-Vitro Drug Release Study

The optimized floating-bioadhesive matrix tablets exhibited a sustained and controlled drug release profile, achieving 91.07 ± 0.65% cumulative drug release over 12 h. The controlled release was attributed to the formation of a stable hydrophilic gel barrier by the polymer matrix, which regulated drug diffusion while maintaining tablet integrity. These findings demonstrate the suitability of the optimized formulation as a gastroretentive sustained-release drug delivery system for furosemide.

Table 6: In-vitro drug release profile of optimized tablets

Time (h)	Replicate 1 (%)	Replicate 2 (%)	Replicate 3 (%)	Mean ± SD (%)
0.5	12.4	13.1	12.8	12.77 ± 0.35
1	20.9	21.5	21.2	21.20 ± 0.30
2	32.8	33.9	33.4	33.37 ± 0.55
4	48.9	50.1	49.4	49.47 ± 0.60
6	62.7	64.0	63.5	63.40 ± 0.66
8	74.8	76.0	75.3	75.37 ± 0.60
10	83.6	84.8	84.1	84.17 ± 0.60
12	90.4	91.7	91.1	91.07 ± 0.65

4. CONCLUSION

The present study successfully developed and optimized a floating-bioadhesive matrix tablet of furosemide using Delonixregia seed mucilage as a novel natural polymer for gastroretentive drug delivery. Application of the Box–Behnken design enabled systematic optimization of critical formulation variables, namely mucilage concentration, drug ratio, and effervescent content, resulting in an optimized formulation with rapid floating, prolonged gastric retention, and sustained drug release. The optimized tablets exhibited excellent physicochemical properties, including acceptable drug content uniformity, satisfactory swelling behavior, effective bioadhesive strength, and prolonged buoyancy with a floating lag time of less than one minute and total floating duration exceeding 13 h. The formulation also achieved sustained drug release of approximately 91% over 12 h, demonstrating the ability of the hydrated polymer matrix to regulate drug diffusion while maintaining tablet integrity.

The findings confirm that the isolated Delonixregia mucilage possesses excellent swelling, gel-forming, and mucoadhesive properties, making it an effective natural release-retarding polymer for gastroretentive drug delivery systems. The combination of floating and bioadhesive mechanisms is expected to prolong gastric residence time and improve the dissolution and absorption of furosemide within its preferred absorption window in the upper gastrointestinal tract. Furthermore, the use of a natural, biodegradable, biocompatible, and economical polymer provides a sustainable alternative to conventional synthetic excipients. Overall, the optimized floating-bioadhesive matrix tablet represents a promising gastroretentive formulation for improving the oral delivery of furosemide. However, further in vivo pharmacokinetic, gastroretention, and long-term stability studies are warranted to establish its clinical performance and facilitate future translation into pharmaceutical applications.

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