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Formulation and Characterization of Sustained Release Matrix Tablets of Diclofenac Sodium Using Ziziphusmauritiana Lam. Mucilage as a Novel Natural Polymer

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Abstract:
The present study was aimed at formulating and characterizing sustained release matrix tablets of Diclofenac sodium, a widely used non-steroidal anti-inflammatory drug (NSAID), employing mucilage extracted from Ziziphusmauritiana Lam. (Ber) as a novel natural polymer matrix former. Nine formulations (F1–F9) were prepared using dry granulation and wet granulation techniques with varying concentrations of Ziziphus mucilage (12–72 mg) and guar gum as matrix-forming materials. The mucilage was isolated from fresh and dried berries by aqueous extraction and alcohol precipitation and was evaluated for physicochemical properties including swelling index, viscosity, ash values, moisture content, and solubility. Preformulation and post-compression parameters—angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio, hardness, friability, weight variation, thickness, and content uniformity—were assessed for all batches. In vitro drug release studies were conducted in 0.1 N HCl (pH 1.2) for 2 hours followed by phosphate buffer (pH 6.8) for 10 hours using USP Type-I basket apparatus. DSC and HPTLC studies confirmed compatibility between Diclofenac sodium and the excipients. The optimized formulation F9 (12 mg mucilage, wet granulation) exhibited a maximum cumulative drug release of 87.11% over 12 hours, comparable to the marketed formulation Voveran SR 100 (88.01%). A direct inverse relationship between mucilage concentration and drug release rate was established. Results indicate that Ziziphusmauritiana Lam. mucilage is a promising, economical, and eco-friendly natural polymer for sustained release drug delivery systems.

Keywords: Diclofenac sodium; Sustained release; Matrix tablet; Ziziphusmauritiana; Natural mucilage; Swelling index; Drug release

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1. INTRODUCTION

Oral sustained release drug delivery systems have attracted considerable interest over the last few decades owing to their ability to maintain therapeutic drug plasma concentrations over extended periods (8–12 hours), reduce dosing frequency, improve patient compliance, and minimize adverse effects arising from peak plasma fluctuations [1]. Sustained release formulations (SRFs) attempt to mimic zero-order drug release by releasing the drug in a slow, first-order fashion, providing a uniform drug effect with a lesser total dose compared to conventional immediate-release dosage forms [2].

Among various drug release technologies, hydrophilic matrix systems have emerged as one of the most versatile and commercially successful approaches. In these systems, swellable polymers form hydrogel matrices that control drug release through a combination of swelling, diffusion, and erosion mechanisms. The primary rate-limiting ingredients are hydrophilic polymers that swell on contact with aqueous media, forming a gel layer on the tablet surface through which drug diffuses. The degree of hydration, which governs viscosity of the resulting solution, depends on the chemical uniformity, purity, molecular weight, and ionic nature of the polymer [3].

Natural gums and mucilages have gained renewed attention as matrix-forming excipients in tablet formulations due to their several advantages over synthetic polymers: low cost, natural origin, biocompatibility, environmental friendliness, renewable sourcing, freedom from significant side effects, and widespread local availability—particularly valuable in developing countries [4,5]. Ziziphusmauritiana Lam. (family Rhamnaceae), commonly known as Ber or Indian jujube, is a widely cultivated plant whose fruits possess rich pharmacological properties including antioxidant, anti-inflammatory, and nutritive activities. The mucilage present in its fruits has been characterized as a negatively charged polysaccharide hydrocolloid with pseudoplastic rheological behavior, similar to guar gum and xanthan gum [6,7].

Diclofenac sodium (2-[(2,6-dichlorophenyl)amino]benzeneacetic acid, sodium salt) is a potent NSAID with anti-inflammatory, analgesic, and antipyretic activities. Its short biological half-life of 1.2–2 hours necessitates frequent dosing of the conventional tablet (thrice daily), making it an ideal candidate for sustained release formulation. A sustained release matrix system would reduce dosing frequency, decrease gastrointestinal side effects, and improve therapeutic outcomes in chronic pain management [8].

The present investigation was undertaken to isolate and characterize mucilage from Ziziphusmauritiana Lam. and to explore its potential as a natural hydrophilic matrix former for sustained release tablets of Diclofenac sodium, comparing its performance with guar gum and the marketed sustained release formulation.

2. MATERIALS AND METHODS

2.1 Materials

Diclofenac sodium was used as the model drug. Ziziphusmauritiana Lam. berries were collected from the Malwa region, Madhya Pradesh, India, and authenticated by a botanist. Guar gum, lactose, PVP K30, starch, magnesium stearate, and talc were of pharmaceutical grade. All chemicals and reagents used were of analytical grade. The marketed formulation Voveran SR 100 (Novartis, Mumbai, Batch No. 122007AD) was procured from the local market.

2.2 Extraction and Isolation of Ziziphus Mucilage

Mucilage was isolated from both fresh and dried ripe berries. Fresh berries were incubated for 9 days to maximize mucilage content. The pulp was mixed with water in a ratio of 1:7 at 60°C, and the mucilage solution was precipitated by adding 90% ethanol (mucilage:ethanol ratio 1:3) at 5°C. The precipitate was collected by filtration, washed with acetone, and dried at room temperature. The dried mucilage powder was passed through a 60-mesh sieve and stored in an airtight container. The percentage yield was calculated for both fresh and dried berry sources [9].

2.3 Physicochemical Characterization of Mucilage

The isolated mucilage was characterized for organoleptic properties (color, odor, taste), solubility in various solvents, pH (1% w/v solution), moisture content, ash values (total, water-soluble, and acid-insoluble ash), true density,

viscosity at different temperatures and pH values using a Brookfield viscometer, and chemical identification tests (Molisch's test for carbohydrates, ferric chloride test for tannins, barium chloride test for sulfates). Swelling index was determined in 0.1 N HCl, distilled water, and phosphate buffer pH 6.8 by the British Pharmacopoeia method [10]. Preformulation study of the mucilage was carried out including angle of repose, bulk density, tapped density, Carr's compressibility index, and Hausner's ratio.

2.4 Drug-Excipient Compatibility Studies

DSC analysis was performed to assess compatibility between Diclofenac sodium and Ziziphus mucilage. HPTLC was performed to confirm the absence of chemical interaction between the drug and mucilage, evaluating the Rf value and area under the curve (AUC) of drug in the presence of mucilage and other excipients.

2.5 Formulation of Sustained Release Matrix Tablets

Nine formulations (F1–F9) of Diclofenac sodium matrix tablets (100 mg drug per tablet, total weight 250 mg) were prepared by varying the concentration of Ziziphus mucilage (12–72 mg) and granulation technique. Formulations F1 and F3 were prepared by dry granulation using PVP K30 as binder, while F2 and F4–F9 were prepared by wet granulation using 5% starch slurry as binder. All ingredients were passed through a 60-mesh sieve. Drug, lactose, and mucilage (or guar gum for F1, F2) were mixed geometrically for 10–15 minutes. Granules were prepared, dried, and lubricated with talc and magnesium stearate before compression into tablets using 8 mm punches on a single-punch tablet press.

Table 1: Composition of Various Formulations (mg/tablet)

Ingredient	F1 (DG)	F2 (WG)	F3 (DG)	F4 (WG)	F5 (WG)	F6 (WG)	F7 (WG)	F8 (WG)	F9 (WG)
Diclofenac sodium	100	100	100	100	100	100	100	100	100
Ziziphus mucilage	–	–	72	72	60	48	36	24	12
Guar gum	72	72	–	–	–	–	–	–	–
Lactose	63.6	63.6	63.6	63.6	75.6	87.6	99.6	111.6	123.6
Starch slurry (5%)	–	7.2	–	7.2	7.2	7.2	7.2	7.2	7.2
PVP K30	7.2	–	7.2	–	–	–	–	–	–
Magnesium stearate	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Talc	4.8	4.8	4.8	4.8	4.8	4.8	4.8	4.8	4.8

DG: Dry granulation; WG: Wet granulation

2.6 Evaluation of Granules and Tablets

Pre-compression parameters (angle of repose, bulk density, tapped density, Carr's compressibility index, Hausner's ratio) and post-compression parameters (thickness, average weight, hardness using Monsanto hardness tester, friability using Roche friabilator at 25 rpm for 4 minutes, weight variation, and drug content by UV spectrophotometry at 274 nm) were evaluated for all formulations according to standard pharmacopoeial methods.

Swelling index was determined by placing one tablet in a Petri dish containing phosphate buffer pH 6.8 and weighing every 2 hours up to 12 hours. Swelling index (SI) was calculated as: $SI = [(Mt – Mo)/Mo] \times 100$, where Mt = weight at time t and Mo = initial tablet weight.

2.7 In Vitro Drug Release Studies

Dissolution studies were performed using USP Type-I basket apparatus. Tablets were subjected to 0.1 N HCl (pH 1.2) for 2 hours to simulate gastric conditions, followed by phosphate buffer (pH 6.8) for 10 hours at 37 ± 0.5°C, 50 rpm. A 5 mL sample was withdrawn at 1-hour intervals and replaced with fresh medium to maintain sink conditions. Samples were analyzed by UV spectrophotometry using a calibration curve established in respective media. Six tablets per batch were tested. The optimized formulation F9 was compared with the marketed formulation Voveran SR 100 for % cumulative drug release.

3. RESULTS AND DISCUSSION

3.1 Mucilage Extraction and Characterization

Ziziphus mucilage was successfully isolated from fresh berries with a yield of 13% w/w, significantly higher than from dried berries (4.94% w/w by alcohol precipitation; 4.21% w/w by acetone precipitation). Fresh ripe berries at 9 days maturity yielded the maximum mucilage content (11.37 ± 0.19% dry weight), confirming that optimal mucilage levels are achieved at full ripeness [9]. The mucilage appeared as a slightly brown, amorphous, tasteless, and odorless powder. It was practically insoluble in non-polar solvents (ethanol, acetone, ether, chloroform) but soluble in warm water, consistent with its polysaccharide nature.

Key physicochemical parameters of the isolated mucilage are summarized in Table 2. The pH of a 1% w/v solution was 5.8, confirming its weakly acidic nature, suitable for oral use. Moisture content (2.4%), ash values (total 0.68%, water-soluble 0.35%, acid-insoluble 0.21%), and chemical identity tests (positive Molisch's test, negative tannin and sulfate tests) were within acceptable limits. The soluble dietary fiber content of 89.76 g/100 g (Table 3) was notably higher than that reported for Ocimumcanum mucilage [11], indicating high purity.

Table 2: Physicochemical Characterization of Ziziphusmauritiana Mucilage

Parameter	Result
Physical state	Amorphous powder
Color	Slightly brown
Odor / Taste	No characteristic odor / Tasteless
pH (1% w/v solution)	5.8
Moisture content (%)	2.4
Total ash (%)	0.68
Water-soluble ash (%)	0.35
Acid-insoluble ash (%)	0.21
True density	1.31
Carbohydrate test (Molisch's)	Positive
Tannin test ($FeCl_3$)	Negative
Sulphate test ($BaCl_2$)	Negative
Yield from fresh berry (% w/w)	13.0
Yield from dried berry – EtOH precipitation (% w/w)	4.94

Table 3: Chemical Composition of Ziziphusmauritiana Mucilage (g/100 g)

Component	Content (mean ± SD)
Fat	0.12 ± 0.05
Protein	0.27 ± 0.03
Ash	1.03 ± 0.09
Moisture	2.8 ± 0.02
Carbohydrate	8.82 ± 0.07
Soluble dietary fiber	89.76 ± 0.03

Viscosity of the mucilage (Table 4) was significantly higher at pH 7.2 (38.66 cps) than at pH 1.2 (5.2 cps), confirming its behavior as a negatively charged polysaccharide whose viscosity increases with pH. Temperature inversely affected viscosity (11.33 cps at 37°C vs. 6.66 cps at 65°C), consistent with pseudoplastic behavior reported for related hydrocolloids [6]. The swelling index was highest in phosphate buffer pH 6.8 (reaching 90 at 24 h) compared to

distilled water (60) and 0.1 N HCl (40), suggesting preferential swelling in intestinal fluid—advantageous for sustained release in the GI tract.

Table 4: Viscosity of Ziziphus Mucilage under Different Conditions

Condition	Viscosity (cps)
37°C	11.33
65°C	6.66
Overnight standing (distilled water)	14.36
At pH 1.2	5.20
At pH 7.2	38.66

3.2 Compatibility Studies

DSC thermograms showed no significant shift in the characteristic endothermic peak of Diclofenac sodium in the presence of Ziziphus mucilage, confirming absence of thermal interaction. HPTLC analysis showed no variation in Rf values or AUC of the drug in the presence of mucilage and other excipients, confirming physicochemical compatibility of all formulation components.

3.3 Preformulation Parameters of Granules

The preformulation study of the isolated mucilage showed an angle of repose of 32° ± 0.14 and a Carr's index of 36 ± 0.57, indicating poor flowability—necessitating granulation to improve powder flow before compression. After granulation, all nine formulations (F1–F9) showed acceptable flow properties with angles of repose between 21° and 25° (Table 5), Carr's compressibility indices between 26–35%, and Hausner's ratios between 1.10 and 1.17, confirming satisfactory flow characteristics of the prepared granules.

Table 5: Preformulation Parameters of Granules (F1–F9)

Batch	Angle of Repose (°)	Bulk Density (g/mL)	Tapped Density (g/mL)	% Compressibility	Hausner's Ratio
F1	21±0.14	0.50±0.053	0.582±0.006	27±0.57	1.10±0.031
F2	22±0.33	0.49±0.152	0.576±0.010	28±0.76	1.15±0.041
F3	24±0.35	0.50±0.044	0.580±0.018	35±1.23	1.16±0.021
F4	25±0.46	0.50±0.342	0.551±0.082	28±1.89	1.15±0.012
F5	24±0.56	0.50±0.442	0.586±0.030	26±2.42	1.17±0.016
F6	22±0.39	0.50±0.326	0.579±0.034	28±1.39	1.15±0.024
F7	23±0.34	0.50±0.023	0.581±0.081	27±1.54	1.16±0.031
F8	22±1.12	0.50±1.230	0.578±1.297	28±2.01	1.15±0.014
F9	21±0.31	0.50±0.780	0.581±0.814	27±1.26	1.16±0.017

3.4 Post-Compression Parameters

All formulations demonstrated satisfactory post-compression parameters (Table 6). Tablet hardness ranged from 7.7 to 8.9 kg/cm², indicating adequate mechanical strength for handling and transportation. Friability values were below 1% for all batches (0.20–0.60%), meeting the pharmacopoeial requirement. Weight variation and content uniformity (95.67–99.01%) were within acceptable limits (90–110%), confirming uniform drug distribution. Thickness ranged from 4.1 to 4.8 mm with negligible variation.

Table 6: Post-Compression Parameters of Matrix Tablets (F1–F9)

Batch	Thickness (mm)	Avg. Weight (mg)	Hardness (kg/cm²)	Friability (%)	Content Uniformity (%)
F1	4.6±0.01	251±0.01	8.9±0.2	0.20	96.27±0.654
F2	4.6±0.07	249±0.45	8.3±0.32	0.21	97.65±0.576
F3	4.8±0.02	250.2±0.2	8.0±0.56	0.30	99.01±0.634
F4	4.6±0.05	251±0.51	8.6±1.4	0.32	95.67±0.234
F5	4.5±0.01	249.5±0.7	8.4±0.63	0.31	97.45±0.276
F6	4.5±0.05	250.6±0.2	8.1±0.78	0.28	98.45±0.134
F7	4.1±0.20	254.8±0.2	8.0±0.2	0.21	97.60±0.463
F8	4.6±0.40	253.7±0.2	7.8±0.1	0.32	96.00±0.865
F9	4.3±0.05	252.8±0.2	7.7±0.1	0.60	97.34±0.768

3.5 Swelling Index

The swelling behavior of matrix tablets in 0.1 N HCl and phosphate buffer pH 6.8 is presented in Table 7. Formulations containing higher concentrations of Ziziphus mucilage (F3, F4) exhibited greater swelling, with F4 showing the maximum swelling index of 102.25 in phosphate buffer pH 6.8. Conversely, F9 (lowest mucilage, 12 mg) showed the minimum swelling index of 15.6. This concentration-dependent swelling is consistent with the gel-forming behavior of hydrophilic polysaccharides: at higher concentrations, the denser hydrogel network impedes drug diffusion, resulting in slower release rates. Formulations F1 and F2 (guar gum) demonstrated swelling indices of 82.77 and 83.33, respectively, in phosphate buffer pH 6.8, comparable to mucilage-based formulations.

Table 7: Swelling Index of Matrix Tablet Formulations

Formulation	0.1 N HCl	Phosphate Buffer pH 6.8
F1	77.46	82.77
F2	76.18	83.33
F3	74.79	61.09
F4	63.01	102.25
F5	45.91	63.47
F6	33.33	41.63
F7	13.80	23.98
F8	12.32	19.91
F9	8.90	15.60

3.6 In Vitro Drug Release

The cumulative percentage drug release profiles of all formulations over 12 hours are presented in Table 8. A clear inverse relationship between mucilage concentration and drug release rate was observed across all formulations. Formulations with higher mucilage concentrations (F3, F4) released drug more slowly due to the formation of a denser, more viscous gel barrier upon hydration, which retarded drug diffusion through the matrix. F4 (72 mg mucilage, wet granulation) released only 83.51% drug at 12 hours, while F9 (12 mg mucilage) released 87.11% at 12 hours, the highest among mucilage-based formulations.

Table 8: Cumulative % Drug Release from Formulations F1–F9

Time (h)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	0.86	0.78	0.87	0.80	0.72	0.81	0.82	0.84	0.86
2	1.94	1.04	1.22	1.40	1.58	1.74	1.76	1.78	1.94
3	5.66	5.07	5.16	5.25	5.34	5.52	5.57	5.61	5.66
4	12.46	5.26	5.26	9.76	9.31	11.56	11.78	12.23	12.46
5	22.22	9.71	15.92	11.42	15.92	17.72	19.07	21.32	22.22
6	23.30	13.22	17.72	13.22	17.72	19.52	21.32	23.12	23.30
7	26.27	15.61	20.11	16.37	20.87	22.22	24.47	25.37	26.27
8	76.31	34.91	25.91	31.31	49.31	67.31	69.11	74.51	76.31
9	77.57	52.91	56.51	49.31	67.31	85.31	76.31	76.49	77.57
10	80.63	56.51	60.11	72.71	74.51	74.51	79.91	79.91	80.63
11	85.31	61.91	65.51	79.91	81.71	79.91	83.51	83.51	85.31
12	87.11	67.30	79.91	83.51	85.31	83.51	85.31	86.21	87.11

Comparison of the optimized formulation F9 with the marketed formulation Voveran SR 100 (Table 9) revealed comparable drug release profiles throughout the 12-hour period. F9 released 87.11% compared to 88.01% for Voveran SR 100 at 12 hours, with similar release kinetics across all time points. These results establish the feasibility of Ziziphus mucilage as an effective natural alternative to synthetic polymers in sustained release matrix tablets.

Table 9: Comparative Drug Release – Optimized Formulation (F9) vs. Marketed Formulation

Time (h)	F9 (% CDR)	Voveran SR 100 (% CDR)
1	0.86	0.61
2	1.94	1.68
3	5.66	5.21
4	12.46	13.86
5	22.22	17.73
6	23.30	21.33
7	26.27	25.83
8	76.31	40.32
9	77.57	59.58
10	80.63	83.70
11	85.31	86.40
12	87.11	88.02

CDR: Cumulative Drug Release

4. CONCLUSION

The present study demonstrates that mucilage isolated from Ziziphusmauritiana Lam. berries is a promising natural hydrophilic polymer for the formulation of sustained release matrix tablets of Diclofenac sodium. The mucilage was successfully isolated with a high yield of 13% w/w from fresh ripe berries and was physicochemically characterized as a carbohydrate-rich, weakly acidic, pseudoplastic hydrocolloid with a high soluble dietary fiber content. DSC and HPTLC studies confirmed complete compatibility with Diclofenac sodium and other excipients.

All nine formulations exhibited acceptable preformulation and post-compression parameters. A clear concentration-dependent inverse relationship between Ziziphus mucilage content and drug release rate was established: higher mucilage concentrations produced greater swelling and slower drug release due to a denser gel network. The optimized formulation F9 (12 mg mucilage, wet granulation) achieved 87.11% cumulative drug release over 12 hours, closely matching the marketed formulation Voveran SR 100 (88.01%), validating the sustained release performance of the system.

The use of Ziziphusmauritiana mucilage as a natural, biodegradable, economical, and environment-friendly matrix former represents a viable alternative to synthetic polymers. The mucilage extraction process is simple, cost-effective, and scalable, making it particularly suitable for pharmaceutical applications in developing countries where the plant is abundantly available. Future studies on stability, in vivo pharmacokinetics, and scale-up are warranted to fully establish the clinical potential of this formulation.

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