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DESIGN AND EVALUATION OF SUSTAINED-RELEASE VILDAGLIPTIN TABLETS USING NATURAL PLANT MUCILAGES AS FUNCTIONAL POLYMERS

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ABSTRACT

Background: Natural plant-derived mucilages are gaining attention as biodegradable and biocompatible alternatives to synthetic polymers in sustained-release drug delivery systems. This study focuses on the development of prolonged-release matrix tablets of Vildagliptin using mucilages from *Mimosa pudica* seeds and *Tinospora sinensis* stems for improved glycemic control in type II diabetes mellitus. **Methodology:** Mucilages were extracted by aqueous extraction and evaluated for physicochemical properties. The swelling index ranged from 250–280%, with a near-neutral pH (6.5–7.0). Matrix tablets were prepared by direct compression and assessed for hardness (5.2–6.1 kg/cm²), friability (<1%), weight variation, and drug content (98.2–101.4%). In vitro drug release studies were conducted for 12 hours. Drug–polymer compatibility was analyzed using FTIR spectroscopy, and release kinetics were evaluated using mathematical models. **Results and Discussion:** FTIR analysis confirmed the absence of drug–polymer interactions. The optimized formulation showed 96.8% cumulative drug release over 12 hours, indicating effective sustained-release performance. The release followed the Korsmeyer–Peppas model ($R^2 = 0.97$) with anomalous (non-Fickian) transport, suggesting a combination of diffusion and polymer erosion mechanisms. The combination of the two mucilages demonstrated superior release control compared to either polymer alone. **Conclusion:** *Mimosa pudica* and *Tinospora sinensis* mucilages exhibit strong potential as natural matrix-forming agents for sustained-release formulations of Vildagliptin, providing a sustainable, cost-effective alternative to synthetic polymers.

INTRODUCTION

Diabetes mellitus is a long-lasting metabolic disorder characterized by high blood sugar levels that are not controlled by insulin and/or a lack of insulin production. Such a patient's effective glycaemic control is an important measure—alongside others—that can help reduce diabetes-related complications, such as cardiovascular disease, neuropathy, and nephropathy [1]. While oral hypoglycaemic agents have been the mainstay of treatment for diabetes, traditional immediate-release (IR) formulations often result in rapid absorption and elimination,

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leading to fluctuations in plasma drug concentration. These fluctuations may hinder the treatment from being effective, make patients more vulnerable to hypoglycemia, and require frequent dosing, thus keeping the patient from getting accustomed to the treatment [2,3]. Sustained-release drug delivery systems have been introduced to diminish these drawbacks and to ensure the drug release is going on in a controlled manner over long periods. In this way, sustained-release formulations offer constant plasma concentrations, fewer daily doses, and reduced side effects, ultimately leading to better patient acceptance [4]. Vildagliptin, one of the Dipeptidyl Peptidase-4 (DPP-4) inhibitors most commonly used for type 2 diabetes, has a short biological half-life (~3 hours), necessitating 3 or more daily doses to maintain its effectiveness [5,6]. This factor makes Vildagliptin a prime candidate for the sustained-release (SR) formulation methods. Amongst the excipients used in drug delivery, natural polymers are gaining researchers' favor due to their eco-friendly characteristics and low cost. Besides ranking first among drug delivery systems based on their properties, mucilages are naturally able to provide good swelling, rapid absorption, and controlled drug release throughout the entire period. Particularly, *Mimosa pudica* mucilage exhibits strong gel-forming and adhesive properties, whereas *Tinospora sinensis* mucilage demonstrates high viscosity and significant swelling capacity. These physicochemical characteristics make them promising natural matrix-forming agents for sustained-release drug delivery applications [7,8]. Natural polymers, on the other hand, have their own hurdles to overcome, such as batch-to-batch variation, susceptibility to bacterial and fungal growth, and moisture sensitivity, which, in combination, can result in an unrepeatable formulation. Mother Nature and her products do not always yield the same results in laboratory environments. Therefore, a cautious evaluation of their benefits and drawbacks is necessary. The present study discusses the preparation of Vildagliptin sustained-release tablets using the mucilage of Mimosa and Tinospora as matrix-forming agents. It compares their efficacy in controlling drug release with that of conventional synthetic excipients to determine the feasibility of natural mucilage as an eco-friendly substitute in controlled drug delivery systems [9-12].

MATERIAL AND METHODS

Material

Vildagliptin was obtained from Venkata Narayana Active Ingredients Pvt. Ltd., Chennai, India, as a gift sample. The plant materials were taxonomically authenticated by the Botanical Survey of India, Western Regional Centre, Pune, India. Voucher specimens were deposited and assigned specimen numbers BSI/WRC/IDEN./2021/111 PPT 01 for *Mimosa pudica* L. and PPT 02 for *Tinospora sinensis* (Lour.) Merr. They were extracted in-house using standardized aqueous methods. Microcrystalline cellulose was used as a capacity batting and binder, lactose monohydrate (Merck, India) as a diluent, magnesium stearate as a lubricant, and talc as a glidant. All other reagents and solvents (ethanol, hydrochloric acid, phosphate buffer salts) were of analytical grade.

EXTRACTION AND CHARACTERIZATION OF MUCILAGE

Extraction of Mucilage

Mucilage was extracted by an aqueous extraction method. The collected plant materials were thoroughly washed to remove adhering impurities and air-dried. The seeds of *Mimosa pudica* and stems of *Tinospora sinensis* were soaked in distilled water for 24 hours to ensure complete hydration. The hydrated materials were subsequently heated at 60–70 °C for 2 hours to facilitate mucilage release. This temperature range was selected as it enhances extraction efficiency without causing thermal degradation of polysaccharides, which are generally stable below 80 °C. The extracted mucilage was filtered and dried for further evaluation [13].

The mixture was then filtered using a muslin cloth to separate the coarse residues from the resulting liquid. The same liquid was centrifuged (Centrifuge (Model: Remi R-8C, Remi Elektrotechnik Ltd., India)) to remove insoluble matter, and the clear supernatant was mixed with 95% ethanol in equal parts, thus precipitating mucilage. The precipitate was washed with ethanol several times. The material was first dried at 40 °C in a hot-air oven until its weight remained constant, then ground into a powder and sealed in airtight containers for future use [14-16].

Percentage Yield Calculation: The percentage yield of mucilage was found as:

Mimosa pudica mucilage: 11.82% w/w

Tinospora sinensis mucilage: 7.46% w/w

Physicochemical Characterization of Mucilage

The physicochemical parameters of the extracted mucilage were evaluated for various applications to determine whether it is a suitable natural polymer for sustained-release tablet formulation.

Solubility: The mucilage solubility test was performed in water, ethanol, and phosphate buffer (pH 6.8) by adding known amounts of mucilage to each solvent, stirring, and observing the dispersion or dissolution behavior.

pH: A 1% w/v water mucilage dispersion was made, and pH was determined with a calibrated digital pH meter to check if it is compatible with the body's natural acid-base conditions.

Viscosity: The viscosity of the mucilage solution was determined using a Brookfield viscometer at varying shear rates. This analysis helped evaluate its gelling and thickening potential for sustained-release matrix formation.

Swelling Index: The Swelling Index was determined by measuring the weight of a pre-weighed mucilage sample placed in a graduated cylinder containing distilled water. The test measured volume expansion between two time points to determine the swelling index, which shows how much water the sample absorbed and its ability to control drug release.

Fourier Transform Infrared Spectroscopy (FTIR): FTIR was conducted using a Shimadzu IRTracer-100 FTIR spectrometer (Japan). Samples were prepared by the KBr pellet method and scanned over 4000–400 cm^{-1} at a resolution of 4 cm^{-1} to confirm functional groups and assess drug–polymer compatibility.

Statistical Analysis: All physicochemical parameters (pH, viscosity, swelling index, and moisture content) were analyzed using one-way ANOVA followed by Tukey's post-hoc test to compare natural mucilage (Mimosa and Tinospora) with synthetic polymers (HPMC and Sodium Alginate(SA)). A p-value < 0.05 was considered statistically significant. Data were reported as mean ± SD (n = 3) [17-19].

Formulation of Sustained-Release Tablets

Sustained-release tablets of Vildagliptin (50 mg) were formulated using natural mucilage obtained from *Mimosa pudica* and *Tinospora sinensis* as matrix-forming polymers to modify drug release. A 3^2 factorial design was employed to investigate the effects of polymer type and concentration on drug-release behavior. The formulations (F1–F9) were prepared with varying concentrations of the natural polymers (50 mg and 100 mg), used either individually or in combination to study their influence on sustained drug release. All formulations maintained a total tablet weight of 250 mg, with a constant drug content of 50 mg per tablet. Microcrystalline cellulose (MCC) was used as a diluent to improve compressibility. Magnesium stearate (4 mg) & talc (8mg) were incorporated as lubricants and glidants, respectively, to enhance powder flow and tablet quality. The detailed composition of each formulation is presented in Table 1 [20].

Table 1: Formulation design of sustained-release Vildagliptin tablets (F1–F9) [21,22].

Formulation Components (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F-Control (HPMC)	F-Control (SA)
Vildagliptin	50	50	50	50	50	50	50	50	50	50	50
HPMC	--	--	--	--	--	--	--	--	--	100	--
SA	--	--	--	--	--	--	--	--	--	--	100
T. Mucilage	--	50	100	--	50	100	--	50	100	--	--
M. Mucilage	--	--	--	50	50	50	100	100	100	--	--
B. Mucilage	--	50	100	50	100	--	100	--	50	--	--
MCC	188	138	88	138	88	138	88	138	88	88	88
Mg. Stearate	4	4	4	4	4	4	4	4	4	4	4
Talc	8	8	8	8	8	8	8	8	8	8	8
Total	250	250	250	250	250	250	250	250	250	250	250

Total tablet weight = 250 mg. All values are in mg/tablet. The factorial design (F1–F9) allowed systematic variation of polymer type and concentration to optimize sustained-release behavior.

Tablet Preparation Method

The tablets were prepared by the direct compression method. All ingredients except magnesium stearate and talc were accurately weighed & passed through a 60-mesh sieve. The drug, polymers, and MCC were uniformly blended for 10 min using the polybag method. Talc and magnesium stearate were then added and mixed for an additional 2–3 min. The final blend was compressed using a rotary tablet compression machine fitted with 8 mm flat-faced punches. The compression force was maintained at 6–8 kN to obtain tablets with a hardness of 4–7 kg/cm^2 [23].

EVALUATION OF FORMULATED TABLETS

The prepared sustained-release (SR) Vildagliptin tablets underwent complete pre- and post-compression testing to confirm their quality, effectiveness, and compliance with Pharmacopoeial standards. The powder flow properties of each formulation's powder blend were tested before compression to ensure proper die filling and to prevent issues with weight distribution and inadequate compressibility.

1. Angle of repose is defined as the maximum angle at which a heap of materials rests stably. In the calculation, use the fixed funnel method. The angle of repose for both areas was determined to assess the powder's flowability. The angle was calculated with the help of the formula**:**

$$\boldsymbol{\theta = \tan^{-1}\left(\frac{h}{r}\right)}$$

Height h is the cone height of the powders, and r is the radius of the base. Values below 30° indicate excellent flow, while values above 40° suggest poor flow.

2. Bulk Density & Tapped Density: The two density measurements, bulk density and tapped density, require different methods of measurement, which start from the initial bulk volume and proceed to measure the volume after multiple tap tests.

3. The first test method measures powder compressibility through Carr's index percentage, while the second method obtains results through the Hausner ratio measurement.

$$\textbf{Carr's Index} = \left(\boldsymbol{Tapped\ Density} - \frac{\boldsymbol{BulkDensity}}{\boldsymbol{TappedDenisty}}\right) \times \mathbf{100}$$

Values <15% indicate good flow, whereas >25% suggest poor flowability.

Hausner Ratio was calculated as:

$$\boldsymbol{Hausner\ Ratio} = \frac{\boldsymbol{Tapped\ Density}}{\boldsymbol{Bulk\ Density}}$$

A value <1.25 indicates good flow [23-25].

The tablet development process started with initial tablet creation. The tablets underwent various tests that examined their physical properties and functional performance.

1. The team used a Monsanto or Pfizer hardness tester to measure the hardness of materials, which showed their mechanical strength. The hardness was maintained between 4 and 7 kg/cm² to prevent tablet breakage and ensure the required drug release.

2. The thickness measurement process used a digital Vernier caliper to obtain the thickness measurement. For weight variation, 20 tablets were weighed from each batch, and the results were compared with the Pharmacopoeial limit (±5% for tablets ≤250 mg).

3. The friability test was performed on the Roche friabilator at a speed of 25 rpm for 4 minutes. The percentage of weight loss was determined using the formula:

$$\boldsymbol{Friability} = \frac{\boldsymbol{Initial\ Weight - Final\ Weight}}{\textbf{Initial Weight}} \times \mathbf{100}$$

The acceptability limit was <1% weight loss.

4. **Swelling Index:** The tablets were subjected to a phosphate buffer solution with a pH of 6.8 at a temperature of 37°C, and their weights were measured at specific time intervals that were predetermined. The swelling index value was calculated as follows:

$$\boldsymbol{Swelling\ Index} = \frac{\boldsymbol{Final\ Weight - Initial\ Weight}}{\textbf{Initial Weight}} \times \mathbf{100}$$

The more swelling, the better, as it directly indicates gel formation for sustained release.

5. **Drug Content Uniformity**: The testing included 10 tablets, which were crushed into powder and used to extract their drug content through proper solvent extraction methods. The Vildagliptin content was measured by UV-Vis spectrophotometry, which confirmed that the drug concentration remained within 5% of the product label.

6. **In-Vitro Drug Release Study**: The dissolution study was performed using a USP Type II (paddle) dissolution apparatus at 37 ± 0.5°C with a stirring speed of 50 rpm. A total dissolution volume of 900 mL was used throughout the study. The drug release was evaluated under bio-relevant conditions using 0.1N HCl (pH 1.2) for the initial 2 hours (simulating gastric conditions), followed by phosphate buffer (pH 6.8) for the remainder of the period (simulating intestinal conditions).

Vildagliptin is a highly water-soluble drug, and the selected dissolution volume was sufficient to maintain sink conditions throughout the 12-hour study. The maximum drug concentration achieved during dissolution remained well below one-third of its saturation solubility, thereby ensuring maintenance of sink conditions and accurate evaluation of release kinetics (Table 2). Samples were withdrawn at predetermined time intervals,

filtered, and analyzed using UV-Visible spectrophotometry at 210 nm.

Table 2: Linearity Data for Vildagliptin at 210 nm

Sr. No.	Conc. (µg/mL)	Absorbance at 210 nm
1	2	0.11
2	4	0.22
3	6	0.34
4	8	0.45
5	10	0.56
6	12	0.67

Analytical Method Validation

The UV-Visible spectrophotometric method used for drug estimation at 210 nm was validated for linearity in the concentration range of X–Y µg/mL in both 0.1N HCl (pH 1.2) and phosphate buffer (pH 6.8). The calibration curves showed good linearity with correlation coefficients (R^2) greater than 0.99 (Figure 1). The limit of detection (LOD) and limit of quantification (LOQ) were calculated from the standard deviations of the calibration curve intercept and slope, confirming the method's adequate sensitivity for dissolution analysis.

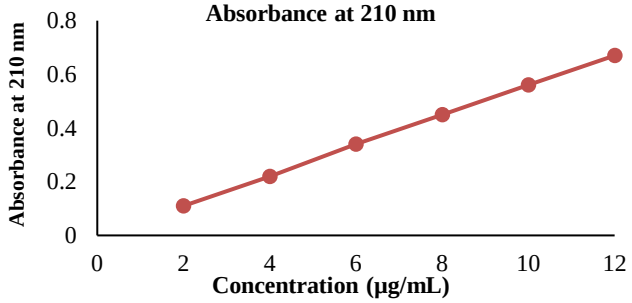


Figure 1: Calibration curve of Vildagliptin at 210 nm showing a linear relationship between concentration (2–12 µg/mL) and absorbance.

Linearity: The method showed good linearity in the concentration range of 2–12 µg/mL at 210 nm, with correlation coefficients (R^2)> 0.99 in the dissolution media.

LOD and LOQ: The LOD and LOQ were calculated according to ICH Q2(R1) guidelines using the standard deviation of the intercept and slope of the calibration curve, confirming the sensitivity and suitability of the method for dissolution analysis.

7. **Kinetic Modeling & Release Mechanism**: Through the application of a suitable mathematical model, the data were elegantly resolved.

a) Zero-Order Model This model indicates a release of the drug at a constant rate over time.

b) First-Order Model This model suggests a release of the drug that is reliant on the remaining concentration.

c) Higuchi Model This model depicts the release as being due to the diffusion of the drug through the polymer matrix.

d) Korsmeyer-Peppas Model

$$kt^n = \frac{Mt}{M\infty}$$

"n" value determines the drug release mechanism

- n = 0.45 (Fickian diffusion)
- 0.45 < n < 0.89 (Non-Fickian diffusion)
- n > 0.89 (Super case-II transport)[26-28].

Accelerated Stability Study

The optimized formulations (F3 and F6) were subjected to accelerated stability testing in accordance with ICH guidelines at 40 ± 2°C and 75 ± 5% RH for 3 months. Tablets were packed in airtight containers and evaluated at 0, 1, and 3 months for physical appearance, hardness, drug content, and in vitro drug release.

No significant changes were observed in tablet integrity, hardness, or dissolution profile during the study period. Drug content remained within acceptable limits (±5%), and no evidence of degradation or excessive moisture-induced hardening was observed. These findings indicate that the mucilage-based sustained-release tablets possess adequate stability under accelerated storage conditions.

RESULT AND DISCUSSION

Characterization of Mucilage

The physicochemical characteristics of mucilage from Mimosa pudica and Tinospora sinensis were studied, and the two were compared with synthetic polymers commonly used in sustained-release formulations.

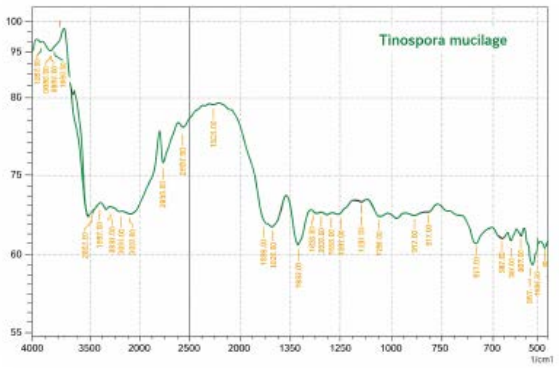
Physicochemical Properties:

The physicochemical properties of both *Mimosa pudica* and *Tinospora sinensis* mucilage were checked and compared not only against synthetic polymers of hydroxypropyl methylcellulose (HPMC) and sodium alginate (SA) but also ascertained for their possible use in sustained-release drug delivery systems [29]. The comparative results are presented in Table 3.

Table 3: Comparative Physicochemical Properties of Natural Mucilage and Synthetic Polymers

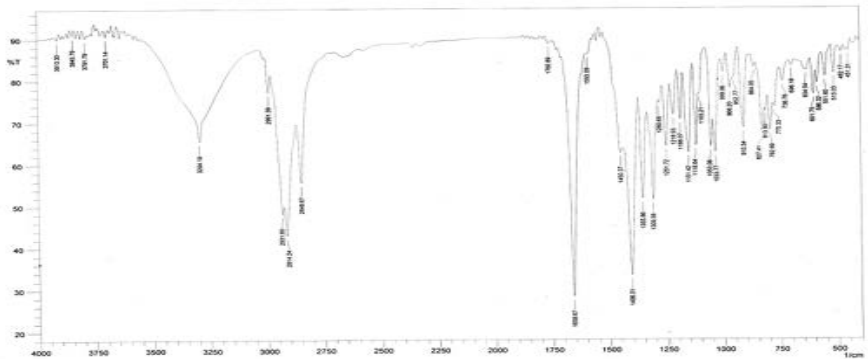
Parameter	*Mimosa* Mucilage	*Tinospora* Mucilage	HPMC (Synthetic)	Sodium Alginate (Synthetic)
Solubility	Swells in water	Swells in water	Soluble in water	Soluble in water
pH (1% w/v)	6.5 ± 0.2	6.8 ± 0.3	7.0 ± 0.1	6.9 ± 0.2
Viscosity (cP)	120 ± 5	150 ± 6	180 ± 4	160 ± 5
Swelling Index (%)	250 ± 10	280 ± 12	220 ± 8	230 ± 9
Moisture Content (%)	8.5 ± 0.5	9.2 ± 0.4	6.0 ± 0.3	7.0 ± 0.3

FTIR

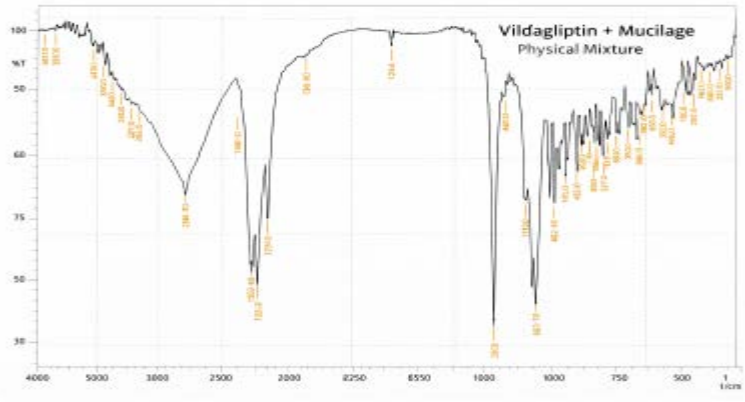


IR spectra of *T. sinensis* Mucilage

IR Spectra of *Mimosa pudica* Mucilage



IR spectra of Pure Vildagliptin



IR spectra of Vildagliptin + Mucilages

Figure 2: FTIR Spectra of Pure Vildagliptin, Individual Mucilages, and Drug-Polymer Mixtures

Both mucilages exhibited desirable swelling behavior and near-neutral pH. *Tinospora sinensis* mucilage showed higher viscosity and a higher swelling index than *Mimosa pudica* mucilage, indicating greater potential for forming a sustained-release matrix. Moisture content was slightly higher in natural mucilages, potentially affecting their flowability and

compressibility. FTIR spectra of pure Vildagliptin, Mimosa mucilage, Tinospora mucilage, and their physical mixtures were analyzed (Figure 2). Vildagliptin exhibited characteristic peaks at 3290 cm^{-1} (N–H stretching), 2940 cm^{-1} (C–H stretching), 1640 cm^{-1} (C=O stretching), and 1065 cm^{-1} (C–N stretching). Both mucilages showed broad –OH stretching bands around 3380–3420 cm^{-1} and C–O–C stretching vibrations between 1020–1100 cm^{-1}, confirming their polysaccharide nature. In the physical mixtures, the characteristic peaks of Vildagliptin were retained without disappearance. Minor shifts (within ±5–8 cm^{-1}) were observed in the –OH and C=O regions, which may be attributed to weak hydrogen bonding interactions between the hydroxyl groups of mucilage polysaccharides and functional groups of Vildagliptin. However, the absence of significant peak broadening, new peak formation, or major frequency shifts indicates that no chemical interaction occurred, confirming drug–polymer compatibility. These findings suggest that any observed interaction is likely physical and may contribute to matrix formation without affecting drug stability.

Evaluation of Powder Blend

Flow properties of pre-compression blends (Table 4) revealed that formulations F1–F4 exhibited good flow with Carr's index <15% and Hausner's ratio < 1.20. The hygroscopic and fibrous nature of mucilage was the reason for higher mucilage concentrations (F6–F9), leading to lower flow (Carr's index ~19%). This implies that incorporating flow enhancers would be necessary if higher mucilage loads are used in industry.

FLOW PROPERTY RESULTS

Table 4: Flow Properties of Powder Blends Used for Tablet Compression

Formulation	Angle of Repose (°)	BD (g/cm³)	TD (g/cm³)	Carr's Index (%)	Hausner's Ratio	Flow Property
F1	28.5 ± 0.4	0.45 ± 0.02	0.52 ± 0.01	13.46	1.16	Good
F2	29.2 ± 0.3	0.44 ± 0.01	0.51 ± 0.01	13.73	1.16	Good
F3	30.4 ± 0.5	0.43 ± 0.02	0.51 ± 0.02	15.69	1.19	Fair to good
F4	27.8 ± 0.6	0.46 ± 0.01	0.53 ± 0.01	13.21	1.15	Good
F5	31.0 ± 0.4	0.42 ± 0.02	0.50 ± 0.01	16.00	1.19	Fair to good
F6	33.5 ± 0.5	0.40 ± 0.01	0.49 ± 0.01	18.37	1.22	Fair
F7	32.2 ± 0.6	0.41 ± 0.01	0.50 ± 0.02	18.00	1.22	Fair
F8	34.1 ± 0.4	0.39 ± 0.01	0.48 ± 0.01	18.75	1.23	Fair
F9	35.4 ± 0.5	0.38 ± 0.02	0.47 ± 0.01	19.15	1.24	Passable

Formulations F1–F4 exhibited good flow properties (Carr's Index <15%, Hausner's Ratio <1.20), indicating suitability for direct compression. However, formulations F6–F9, containing higher mucilage concentrations, showed comparatively reduced flowability (Carr's Index 18–19% and Hausner's Ratio 1.22–1.24). This decrease in flow may be attributed to the hydrophilic and fibrous nature of mucilage, which increases interparticle cohesion and moisture affinity, thereby enhancing resistance to flow. For improved industrial scalability, optimization strategies such as increasing glidant concentration can be employed. Dry granulation (roller compaction) techniques are used to improve particle-size uniformity and reduce cohesiveness. These approaches would enhance flow behavior while maintaining the sustained-release characteristics of the mucilage-based matrix system. 0.1N HCl (pH 1.2)

TABLET EVALUATION RESULTS

Post-compression assessment: Post-compression assessments have demonstrated consistent properties and good mechanical quality across batches. The detailed evaluation results are presented in Table 5.

Table 5: Evaluation of Physical Parameters and Drug Content in Compressed Tablets

Formulation	Weight Variation (mg)	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	Drug Content (%)
F1	249.2 ± 1.5	3.42 ± 0.05	5.5 ± 0.2	0.52	98.6 ± 0.7
F2	248.8 ± 1.7	3.44 ± 0.04	5.4 ± 0.3	0.50	99.2 ± 0.5
F3	250.3 ± 1.6	3.46 ± 0.06	5.6 ± 0.2	0.54	97.8 ± 0.6
F4	249.7 ± 1.4	3.41 ± 0.05	5.3 ± 0.3	0.48	99.0 ± 0.8
F5	251.2 ± 1.8	3.45 ± 0.04	5.2 ± 0.4	0.55	98.4 ± 0.6
F6	250.1 ± 1.5	3.47 ± 0.05	5.1 ± 0.3	0.57	98.0 ± 0.7
F7	248.9 ± 1.6	3.43 ± 0.04	5.0 ± 0.3	0.59	97.5 ± 0.8
F8	250.5 ± 1.7	3.46 ± 0.06	5.3 ± 0.2	0.56	98.2 ± 0.6
F9	251.0 ± 1.6	3.48 ± 0.05	5.1 ± 0.4	0.58	97.9 ± 0.5

All tablets met pharmacopoeial specifications. The variations in weight and friability did not exceed the permissible limits (<1%), and hardness ranged from 5.0 to 5.6 kg/cm², thus confirming the good mechanical strength of the tablets. The uniformity of drug content across the batches was also evaluated and confirmed, indicating good blend mixing and homogeneity.

In-Vitro Drug Release Study: All formulations were subjected to in vitro drug release studies in phosphate buffer (pH 6.8) for 12 hours. Drug release experiments were performed in triplicate, and results were expressed as mean ± SD (Table 6, Figure 3). The initial drug release at 1 hour ranged between 8.5–11.0%, indicating effective retardation by the mucilage matrices and absence of dose dumping. At 12 hours, cumulative drug release ranged from 92.3 ± 1.2% (F7) to 99.0 ± 0.8% (F3). Formulations containing higher concentrations of Tinospora mucilage (F3 and F6) demonstrated comparatively better control over drug release, which may be attributed to its higher swelling index and viscosity, resulting in the formation of a stronger gel barrier.

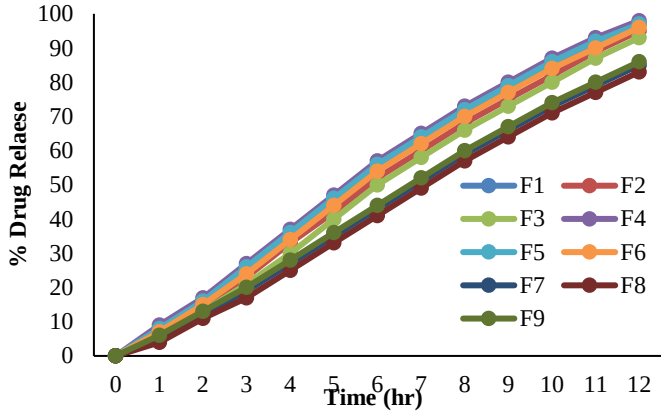


Figure 3: Comparative In Vitro Drug Release Profiles of Vildagliptin Tablets (F1–F9)

Table 6: In vitro drug release (%) of vildagliptin tablets at different time intervals

Time (h)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	10.2	9.5	11.0	8.9	9.2	10.5	8.5	9.8	9.0
4	35.4	32.8	37.2	30.5	33.1	34.8	29.9	31.5	32.2
8	68.9	65.5	71.1	62.2	66.5	67.8	60.8	63.9	64.5
12	98.5	96.2	99.0	94.8	95.9	97.5	92.3	94.1	95.2

Drug Release Kinetics

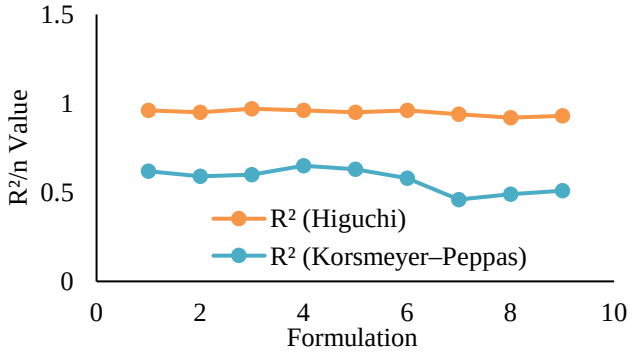


Figure 4: Drug release kinetics modeling of vildagliptin formulations

The release kinetics of Vildagliptin tablets were studied by applying the Zero-order, First-order, Higuchi, and Korsmeyer–Peppas models (Figure 4). The regression coefficient (R^2) values indicated that most formulations best fit the Korsmeyer–Peppas model (R^2 = 0.95–0.98), suggesting a non-Fickian (anomalous) transport mechanism involving diffusion and polymer relaxation. Formulations F3 and F6 were observed to fit the Zero-order model very well (R^2 > 0.98), indicating nearly constant drug release over 12 hours. The release exponent (n) values (0.61–0.72) confirmed anomalous transport once again, suggesting a balance between diffusion and erosion. Such results demonstrate that combinations of Mimosa and Tinospora mucilages are more effective at aiding and regulating drug release than the individual use of mucilage.

The Korsmeyer–Peppas release exponent (n) values ranging from 0.61 to 0.72 indicate anomalous (non-Fickian) transport, suggesting that drug release is governed by a combination of diffusion and polymer relaxation/erosion mechanisms. A direct correlation can be established between the swelling behavior of the mucilages and the observed release kinetics. Tinospora mucilage exhibited a higher swelling index (≈280%) compared to Mimosa mucilage (≈250%), indicating greater water uptake and gel layer formation. The enhanced swelling of Tinospora mucilage likely results in a thicker, more viscous gel barrier around the tablet matrix, thereby increasing the diffusion path length and contributing to greater release retardation. In contrast, Mimosa mucilage, with relatively lower swelling capacity, forms a comparatively less dense gel structure, permitting slightly faster drug diffusion. The difference in swelling indices thus directly influences the extent of polymer relaxation and matrix integrity, explaining the variation in n-values within the anomalous diffusion range. These findings confirm that swelling behavior plays a critical role in modulating sustained drug release from mucilage-based matrix systems.

Table 7: Accelerated Stability Study of Optimized Formulations (40 ± 2°C / 75 ± 5% RH)

Parameter	F3 Initial	F3 1 Month	F3 3 Months	F6 Initial	F6 1 Month	F6 3 Months
Physical Appearance	No change	No change	No change	No change	No change	No change
Hardness (kg/cm²)	5.6 ± 0.2	5.8 ± 0.3	6.0 ± 0.3	5.1 ± 0.3	5.3 ± 0.2	5.6 ± 0.3
Friability (%)	0.54	0.58	0.62	0.57	0.61	0.65
Drug Content (%)	97.8 ± 0.6	97.2 ± 0.8	96.5 ± 0.9	98.0 ± 0.7	97.4 ± 0.9	96.8 ± 1.0
% Drug Release at 12 h	98%	96%	95%	95%	94%	93%

The optimized formulations (F3 and F6) were subjected to accelerated stability testing at 40 ± 2°C / 75 ± 5% RH for 3 months, in accordance with ICH guidelines. No visible changes in tablet appearance were observed during the study period. A gradual increase in hardness was noted, possibly due to minor moisture-induced polymer densification; however, friability remained below 1%, indicating acceptable mechanical integrity. Drug content remained within pharmacopeial limits (95–105%) throughout the study (Table 7). The dissolution profiles after 3 months showed only minimal variation (<5% difference at 12 h) compared to initial values, confirming that the sustained-release characteristics of the mucilage-based matrix system were maintained under accelerated conditions.

Discussion

The outcome of this research confirms that the combination of *Mimosa pudica* and *Tinospora sinensis* mucilage is a potential natural polymer for the manufacturing of sustained-release tablets (SR). Their physical and chemical properties, namely, swelling capacity, viscosity, and near-neutral pH, are well-suited for use in the formulation of matrix-based drug delivery systems. In particular, natural polymers with very high swelling indices are known to induce gel layer formation, which is a key factor in controlling drug diffusion [14,29]. The swelling index of Tinospora mucilage is slightly higher than that of Mimosa, indicating a denser gel barrier that may prolong drug release. The pH of both mucilages being near-neutral (6.5-6.8) concurs with the earlier finding, and thus they can be safely used for oral administration without the risk of causing gastrointestinal irritation. The moisture content, although it was only slightly higher than that of synthetic polymers, is characteristic of plant-derived gums [20,21]. The hygroscopic nature of such materials can make them more prone to microbial contamination and moisture-induced instability, underscoring the need for proper formulation, packaging, and storage conditions to minimize these risks. The absence of significant interactions between the drug and the polymer was confirmed by FTIR, which showed no major peak shifts. The findings thus corroborate earlier compatibility studies on plant mucilages, which indicated their inertness and safety when combined with active pharmaceutical ingredients [7,32].

The flowability of powder blends is an important property for the direct compression method of tablet production. Formulations with lower mucilage concentrations exhibited better flowability, primarily due to the diluting effect of microcrystalline cellulose and the addition of glidants such as talc [4,33]. All blends met pharmacopoeial flow standards despite slight variations. Post-compression tests showed that the tablets made with natural mucilages had hardness, friability, and uniformity values within acceptable limits, indicating that the incorporation of mucilage did not adversely affect mechanical strength [9,34]. Very importantly, the tablets exhibited prolonged drug release, especially at higher mucilage concentrations, with the gradual release lasting for 12 hours. This release profile was similar to that of commonly used synthetic polymers such as HPMC and sodium alginate, indicating the potential use of these mucilages as economical and biocompatible alternatives. It is worth noting that commercial SR tablets of vildagliptin and other antidiabetics often use HPMC-based matrices; the natural mucilages tested here exhibited similar, and in some cases more gradual, release patterns. Drug release kinetics complied with the Korsmeyer–Peppas model, with n-values between 0.61 and 0.72, thereby confirming anomalous (non-Fickian) transport [36]. This means that both diffusion and polymer relaxation were mechanisms of drug release, which is commonly reported for hydrophilic matrix systems. Keeping it short, the flowability of powder blends is an important property for the direct compression method of tablet production. The Higuchi model demonstrated strong correlations ($R^2 > 0.95$), further supporting diffusion-controlled release as the primary mechanism. Other SR systems composed of natural polymers, including guar gum and locust bean gum, have also exhibited similar kinetic behavior [10,37]. To assess the potential clinical relevance of the developed formulations, the optimized batches (F3 and F6) were compared with reported dissolution profiles of commercially available sustained-release Vildagliptin formulations described in the literature. Marketed

sustained-release tablets typically aim for controlled drug release over 12–24 hours to maintain glycemic control and reduce dosing frequency. The optimized formulation F6 demonstrated sustained drug release over 12 hours, with controlled-release kinetics comparable to reported sustained-release profiles, indicating its potential suitability for once-daily or modified dosing regimens. The release pattern exhibited minimal burst effect and gradual drug diffusion, which is desirable for maintaining steady plasma drug levels. Although a direct experimental comparison with a marketed product was not performed in the present study, the observed release behavior aligns with the therapeutic objective of sustained glycemic management, suggesting promising clinical applicability of the mucilage-based matrix system.

CONCLUSION

The use of mucilage from Mimosa and Tinospora as a natural polymeric matrix allowed the study to produce and evaluate sustained-release Vildagliptin tablets with promising results as a substitute for synthetic polymers. Mucilage was extracted from both plants using a standardized method, ensuring its quality for pharmaceutical use. Characterization studies showed that the mucilage exhibited suitable physicochemical properties, as evidenced by specific viscosity, swelling index, and solubility values, thereby enabling controlled drug release. The tablets produced delivered the drug steadily through 12 hours while showing excellent physical properties that included weight, hardness, and drug content. The in vitro drug-release tests showed that formulations with higher mucilage content released their drugs more slowly via a non-Fickian diffusion mechanism. The use of natural polymers provides a system that exhibits both biodegradable and biocompatible properties while reducing the need for synthetic excipients, creating more affordable and environmentally friendly sustained drug delivery systems.

The formulated sustained-release tablets of Vildagliptin showed acceptable physical properties, including weight uniformity, hardness, friability, and drug content, and successfully sustained drug release for up to 12 hours. In vitro release studies indicated that higher mucilage concentrations effectively controlled drug release through a non-Fickian diffusion mechanism. The optimized formulations (F3 and F6) remained stable under accelerated conditions (40 ± 2°C / 75 ± 5% RH) for three months in accordance with the International Council for Harmonization, with no significant changes in appearance, drug content, or dissolution profile. These findings suggest that mucilage from *Mimosa pudica* and *Tinospora sinensis* can serve as cost-effective, biodegradable, and sustainable alternatives to synthetic polymers in sustained-release formulations.

FINANCIAL ASSISTANCE

NIL

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTION

Poonam Taru was responsible for conceptualization, methodology, and study design, formal analysis, and preparation of the original draft of the manuscript. E. Bhavya contributed to methodology and study design, carried out the investigation, and participated in reviewing and editing the manuscript. T. S. Shanmugrajan was involved in methodology and study design and contributed to writing, reviewing, and editing of the manuscript.

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