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Formulation, Optimization, and Comparative Evaluation of Teneligliptin Hydrobromide Oral Dispersible Tablets Using *Plantago ovata* Mucilage and Synthetic Super Disintegrants

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ABSTRACT

Background & Objective: Management of Type 2 Diabetes Mellitus (T2DM) requires strict, lifelong adherence to pharmacotherapy. Dysphagia affects roughly 35% of the population, presenting a barrier to oral solid dosage forms. Teneligliptin Hydrobromide, a novel peptidomimetic Dipeptidyl Peptidase-4 (DPP-4) inhibitor (BCS Class II), suffers from rate-limiting dissolution in gastrointestinal fluids. This study aimed to formulate, optimize, and comparatively evaluate Teneligliptin Hydrobromide Oral Dispersible Tablets (ODTs) using *Plantago ovata* (Isabgol) mucilage as a natural superdisintegrant against Crospovidone, a synthetic benchmark.

Methods: *Plantago ovata* mucilage was isolated via aqueous extraction and acetone precipitation. Drug-excipient compatibility was evaluated via Fourier Transform Infrared (FTIR) spectroscopy. ODTs were manufactured using the direct compression method. A 3^2 full factorial design was applied to optimize *Plantago ovata* mucilage concentration (X_1) and compression force (X_2). Evaluated responses included disintegration time (Y_1), percentage drug release at 15 minutes (Y_2), tablet hardness (Y_3), and wetting time (Y_4). Pre-compression and post-compression metrics were characterized according to pharmacopeial standards.

Results: FTIR spectra showed no significant peak shifts, confirming drug-excipient chemical compatibility. Micromeritic parameters demonstrated acceptable powder flow and compressibility across all blends. The 3^2 full factorial design identified batch F5 (containing 15 mg *Plantago ovata* mucilage and compressed at 7 kN) as the overall optimized formulation. Batch F5 achieved an in vitro disintegration time of 18 seconds, a wetting time of 14 seconds, a hardness of 3.5 kg/cm², a friability of 0.38%, content uniformity of 99.7%, and 98.1% cumulative drug release within 15 minutes. Polynomial regression models showed strong predictive capacity ($R^2 > 0.95$). Comparative evaluation revealed that *Plantago ovata* mucilage performance was comparable to synthetic Crospovidone without forming a gel barrier.

Conclusion: *Plantago ovata* mucilage serves as a biocompatible, cost-effective, and efficient natural superdisintegrant for Teneligliptin Hydrobromide ODTs, offering a reliable, eco-friendly alternative for diabetic care..

Introduction

Type 2 Diabetes Mellitus (T2DM) accounts for nearly 90% of global diabetes cases, affecting over 537 million adults worldwide [1]. The pathophysiology involves reduced pancreatic β-cell insulin secretion, peripheral insulin resistance, and unsuppressed hepatic glucose output [2]. Long-term suboptimal glycemic control (HbA1c > 7.0%) leads to microvascular (retinopathy, nephropathy, neuropathy) and macrovascular (cardiovascular disease, stroke) complications [1, 2].

Effective glycemic control depends on patient adherence to prescribed daily regimens. However, dysphagia (swallowing difficulty) affects nearly 35% of the general population, with higher prevalence among geriatric diabetic individuals undergoing polypharmacy [3]. The requirement to swallow conventional solid tablets with water often leads to missed doses, poor adherence, and therapeutic failure [3].

Orally Disintegrating Tablets (ODTs) are solid unit dosage forms designed to disintegrate in the oral cavity within seconds upon contact with saliva, eliminating the need for water or chewing [4, 7]. ODTs offer clinical advantages including enhanced compliance, reduced choking risk, rapid onset of action, and the potential for pregastric mucosal absorption, which can bypass first-pass hepatic metabolism [4, 9].

Teneligliptin Hydrobromide Hydrate is a potent, selective, peptidomimetic, long-acting DPP-4 inhibitor [38, 39]. It competitively inhibits DPP-4, preventing the rapid degradation of incretin hormones—Glucagon-like

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peptide1 (GLP-1) and Glucose-dependent insulinotropic polypeptide (GIP) [2, 39]. This increases glucose-dependent insulin secretion and suppresses postprandial glucagon release [38]. Classified under the Biopharmaceutical Classification System (BCS) as a Class II agent, Teneligliptin exhibits low aqueous solubility and high membrane permeability [11, 43]. Dissolution is its primary rate-limiting step for systemic absorption. Formulating Teneligliptin into an ODT increases total surface area upon disintegration, enhancing dissolution rate and drug availability [4, 12, 43].

Superdisintegrants facilitate matrix breakdown via swelling, wicking (capillary action), elastic deformation recovery, and inter-particulate repulsion [6, 10, 40]. Synthetic superdisintegrants such as Crospovidone are widely used due to their nonionic nature and porous structure [6, 10]. However, increasing interest in sustainable, eco-friendly pharmaceuticals ("green pharmacy") has directed focus toward natural plant-derived polymers [22, 33].

The mucilage isolated from *Plantago ovata* (Isabgol) seed husk is a natural hydrocolloid composed of arabinoxylans [16, 25]. It exhibits a swelling index up to 380% (90% v/v) and rapid hydration without forming a viscous plug [24, 25]. Beyond its function as an excipient, *Plantago ovata* exhibits intrinsic hypolipidemic and glycemic control benefits, providing potential therapeutic synergy in T2DM management [34, 35, 36].

This study systematically formulates, optimizes, and evaluates Teneligliptin Hydrobromide ODTs via direct compression using a 3^2 full factorial design, comparing the performance of natural *Plantago ovata* mucilage against synthetic Crospovidone [13, 14, 18, 28].

Materials and Methods

Materials

Teneligliptin Hydrobromide Hydrate was obtained as a gift sample [11]. *Plantago ovata* seeds/husks were procured locally and processed [16,25]. Crospovidone (Polyplasdone XL), Microcrystalline Cellulose (MCC PH-102), Mannitol, Sucralose, and Magnesium Stearate were of analytical/pharmaceutical grade [12,13,31]

Table 1: Composition of Teneligliptin Oro-Dispersible Tablets

INGREDIENTS (mg)	F1	F2	F3	F4
Teneligliptin Hydrobromide	20	20	20	20
Plantago Ovata	15	-	-	-
Crospovidone	-	5	10	15
Microcrystalline Cellulose	80	90	85	80
Mannitol	80	80	80	80
Sucralose	3	3	3	3
Magnesium Stearate	2	2	2	2
TOTAL WEIGHT	200	200	200	200

Formulation development of Teneligliptin ODTs

In the present study, oral dispersible tablets of Teneligliptin were formulated using the direct compression method. All ingredients listed in Table were accurately weighed and processed in a geometrical mixing order. Teneligliptin, mannitol, and the selected superdisintegrants were first passed through a #22 sieve and blended for 15 min. Magnesium stearate, previously sieved through a #60 mesh, was then added and mixed with the blend for an additional 5 min. The final mixture was compressed into tablets weighing 100 mg each using 8 mm round flat punches on a 16-station rotary tablet press. The composition of the formulations is detailed in Table1 [4].

Table 2: Ingredients, Functional Roles, and Source of Procurement

MATERIAL	ROLE / FUNCTION	MANUFACTURER/ SUPPLIER
Teneligliptin Hydrobromide	Active Pharmaceutical Ingredient (DPP-4 Inhibitor)	PHARMAFABRIKON PVT.LTD
Plantago ovata Mucilage	Natural Superdisintegrant	ORGANIC INDIA PVT.LTD
Crospovidone	Synthetic Superdisintegrant (Benchmark)	OTTO CHEMIE PVT.LTD
Microcrystalline Cellulose	Direct Compression Binder / Diluent	LOBA CHEMIE PVT. LTD
Mannitol	Saliva-Soluble Bulking Agent / Sweetener	HIMEDIA LABORATORIES PVT. LTD
Sucralose	Sweetening Agent	LOBA CHEMIE PVT. LTD
Magnesium Stearate	Tablet Lubricant	LOBA CHEMIE PVT. LTD

Isolation of *Plantago ovata* Mucilage

Plantago ovata seeds/husks were soaked in purified water for 12 hours. The mixture was heated for 30 minutes to facilitate complete mucilage release, then filtered through a multi-layered muslin cloth [16, 25]. The mucilage was precipitated from the filtrate by adding cold acetone [24, 25]. The isolated mass was dried in a hot-air oven at 45°C, ground, passed through sieve #80, and stored in a desiccator [16, 26] shown in figure 1.

Drug-Excipient Compatibility (FTIR)

Fourier Transform Infrared (FTIR) spectroscopy was performed using a Shimadzu FTIR spectrophotometer [42]. Potassium bromide (KBr) pellet technology was used over a scanning range of 4000 to 400 cm^{-1} [42]. Spectra of pure Teneligliptin Hydrobromide were compared with the physical mixture of the drug and excipients to identify functional group interactions [11, 42].

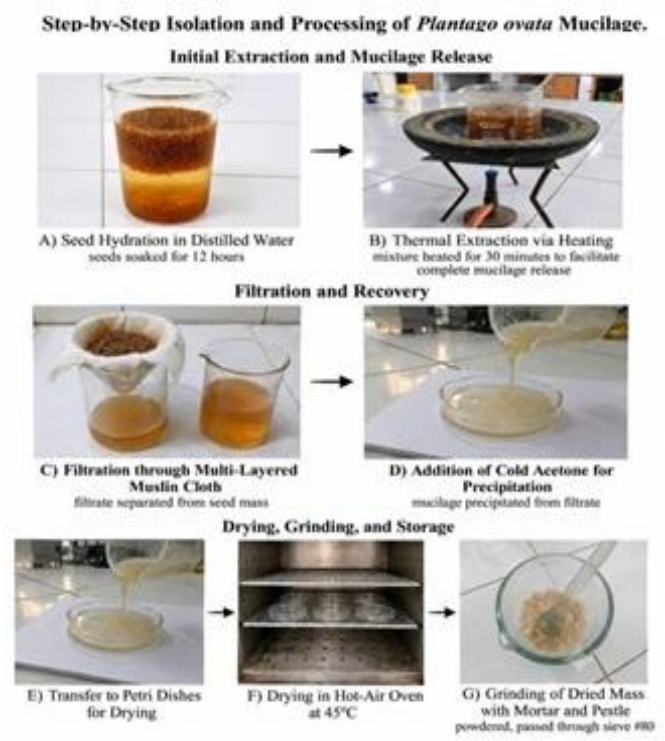

Figure 1: Isolation of Plantago ovata Mucilage

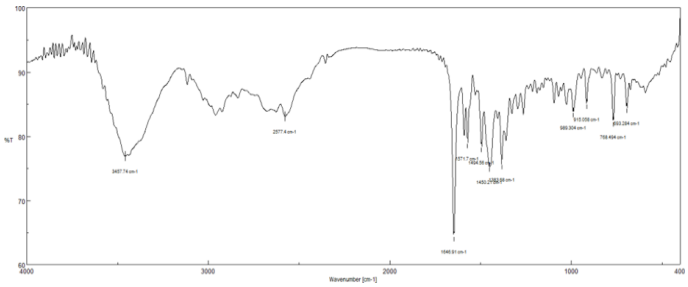

Figure 2: FTIR Absorption Peaks of Teneligliptin Hydrobromide

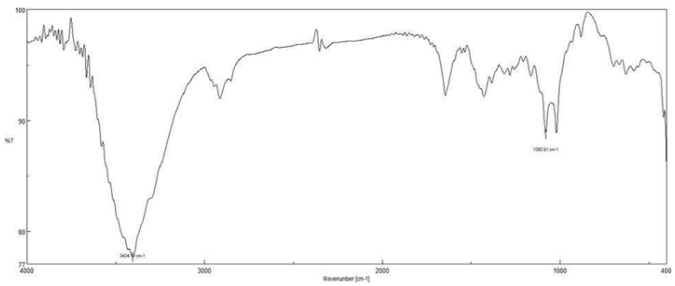

Figure 3: Comparison of Pure Drug and Optimized Formulation Spectra

Analytical Wavelength Determination and Calibration Curve

A standard stock solution of Teneligliptin Hydrobromide (100 µg/mL) was prepared in pH 6.8 phosphate buffer [11]. Scanning across the UV spectrum (200–400 nm) established the absorption maximum (λmax) at 267.2 nm [11, 13]. Working standard solutions (10–60 µg/mL) were analyzed at 267.2 nm to establish a linear calibration curve [11].

Experimental Optimization Design (3^2 Factorial Design)

A 3^2 full factorial design was applied to optimize formulation parameters [18, 30]. The concentration of *Plantago ovata* mucilage (X_1) and Compression Force (X_2) were selected as independent variables at three levels [18, 21]. The experimental layout comprised 9 formulation runs (F1–F9) [18].

Table 3: Independent Variables and Their Coded Levels in 3^2 Full Factorial Design

FACTOR	NAME	LOW LEVEL (-1)	MEDIUM LEVEL (0)	HIGH LEVEL (+1)
X_1	*Plantago ovata* Mucilage Concentration (mg)	5 mg	15mg	25 mg
X_2	Compression Force (kN)	5 kN	7 kN	9 kN

Evaluated response parameters included Disintegration Time (Y_1, sec), Drug Release at 15 min (Y_2, %), Hardness (Y_3, kg/cm^2), and drug content (Y_4,%) [29, 30]. Polynomial equations were generated using the response model [18]:

$$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_{12} X_1 X_2 + \beta_{11} X_1^2 + \beta_{22} X_2^2$$

Formulation Composition and Tablet Fabrication

All ingredients were weighed and passed through sieve #60 [31]. Teneligliptin Hydrobromide (20 mg per tablet) was blended geometrically with *Plantago ovata* mucilage (or Crospovidone for comparative control), MCC PH-102, Mannitol, and Sucralose for 15 minutes [12, 13, 31]. Magnesium Stearate (1% w/w) was added and blended for an additional 3 minutes [31]. The final powder mix (200 mg target weight per tablet) was compressed using a rotary tablet press equipped with 8 mm flat punches [29, 31, 32].

Evaluation of Teneligliptin ODTs

Pre-Compression Micromeritic Parameters [31]:

Angle of Repose (θ): Measured via the fixed-funnel technique: $\tan\theta = h/r$.

Bulk Density (ρb) and Tapped Density (ρt): Determined by measuring powder volume before and after 500 mechanical taps in a graduated cylinder.

Carr's Compressibility Index (I): Calculated as

$I = (\rho_t - \rho_b)/\rho_t \times 100$.

Hausner's Ratio (HR): Calculated as $HR = \rho_t/\rho_b$.

Post-Compression Physicochemical Tests [7,8,30]:

Weight Variation

All the developed formulations were evaluated for uniformity of weight. Twenty tablets were randomly selected from each formulation and weighed using a

digital analytical balance. The mean and standard deviation values were calculated.

Hardness

The Monsanto hardness tester was used to measure the hardness of tablets. A tablet was placed in the hardness tester, and the force needed to crush it was measured in kg/cm^2. Uncoated tablets with a hardness of about 3 to 5 kg/cm^2 are deemed adequate for oral dispersible tablets.

Friability

The Roche friabilator was used to measure the mechanical strength of tablets. Pre-weighed tablets were rotated at 25 rpm for 4 minutes (100 revolutions). The tablets were then dedusted, reweighed, and the percentage friability was calculated using the formula:

%" Friability"=("Loss in weight" /"Initial weight")×100

Thickness

The tablet's thickness was measured using a digital Vernier caliper. A tablet was placed between two Vernier caliper arms, and the thickness was recorded in millimeters (mm).

Wetting Time

A piece of tissue paper folded twice was placed in a small Petri dish containing 10 mL of water-soluble dye solution. A tablet was placed on the tissue paper, and the time required for the tablet to become fully moistened was recorded in seconds.

Water Absorption Ratio

The water absorption test evaluates the capacity of oro-dispersible tablets (ODTs) to absorb water, directly influencing their swelling and rapid disintegration characteristics. Briefly, a pre-weighed tablet (W_a) is placed on a twice-folded tissue paper inside a Petri dish containing 10 mL of water. Once the tablet becomes completely wetted, it is reweighed (W_b) using a digital balance. The water absorption ratio (R) is determined using the equation:

$$R=100\times((Wb-Wa)/Wa)$$

where Wa and Wb represent the tablet weight before and after water absorption, respectively.

In-Vitro Disintegration Test

The disintegration test was conducted at 37±0.5°C using distilled water as the disintegration medium in a USP disintegration apparatus. Six tablets were tested, and the time in seconds taken for complete disintegration leaving no solid mass was noted.

Drug Content (Assay)

Tablets were randomly selected, weighed, and finely powdered. A quantity equivalent to one tablet was extracted into pH 6.8 phosphate buffer solution and shaken. After centrifugation and filtration, the absorbance was measured spectrophotometrically to calculate the concentration of Teneligliptin per tablet.

In-Vitro Dissolution Test

In-vitro drug release studies were performed using the USP Type II (Paddle) dissolution apparatus operating at 50 rpm in 900 mL of pH 6.8 phosphate buffer maintained at 37±0.5°C. Samples (5 mL) were withdrawn at predetermined intervals (5, 10, 15, 20 and 30 min), filtered through Whatman filter paper, replaced with fresh medium, and analyzed spectrophotometrically to determine cumulative percentage drug release.

Results and Discussion

Drug-Excipient Compatibility Studies (FTIR)

Pure Teneligliptin Hydrobromide exhibited characteristic FTIR absorption bands at 3320 cm^{-1} (N-H stretching), 1645 cm^{-1} (C=O carbonyl stretching of amide), 1580 cm^{-1} (aromatic C=C stretching), and 1240 cm^{-1} (C-N stretching) [11, 42]. The spectrum of wetted/optimized physical mixtures with *Plantago ovata* mucilage maintained these primary bands without significant shifting (>4 cm^{-1}) or disappearance [42]. This confirms structural compatibility between the active drug and the natural excipients [16, 42].

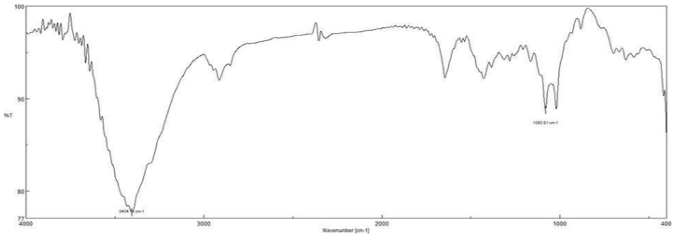

Figure 4: This image represents the IR spectrum of optimized formulation.

Table 4: FTIR Peak Interpretation and Compatibility Study of Pure Drug and Optimized Formulation

FUNCTIONAL GROUP	PURE DRUG PEAK (CM^{-1})	OPTIMIZED FORMULATION PEAK (CM^{-1})	INTERPRETATION
O–H / N–H stretching	3457.74	3404.71	Broad O–H stretching vibration indicating the presence of hydroxyl groups
C–H stretching (Aliphatic)	2960.20	2913.91	Aliphatic C–H stretching vibration
C=O stretching	1646.91	1644.98	Carbonyl group stretching vibration
C=C stretching	1571.70	1553.38	Aromatic ring C=C stretching vibration
CH_2 bending	1450.21	1428.03	Methylene (CH_2) bending vibration
CH_3 bending	1383.68	1384.64	Methyl (CH_3) bending vibration
C–O stretching	1026.91	1020.16	C–O stretching vibration

Analytical Calibration

Linear regression of Teneligliptin Hydrobromide in pH 6.8 phosphate buffer yielded a straight-line equation (y = 0.0152x + 0.0031) across the concentration range of 10–60 µg/mL with a determination coefficient (R^2) of 0.9992 [11]. This validated method was utilized for subsequent content and dissolution analyses [11, 13].

Table 5: Experimental Absorbance Data for Teneligliptin Hydrobromide Calibration Curve

S. No.	Concentration (µg/mL)	Absorbance (at 267.2 nm)
1	20	0.318
2	40	0.569
3	60	0.840
4	80	1.088
5	100	1.349

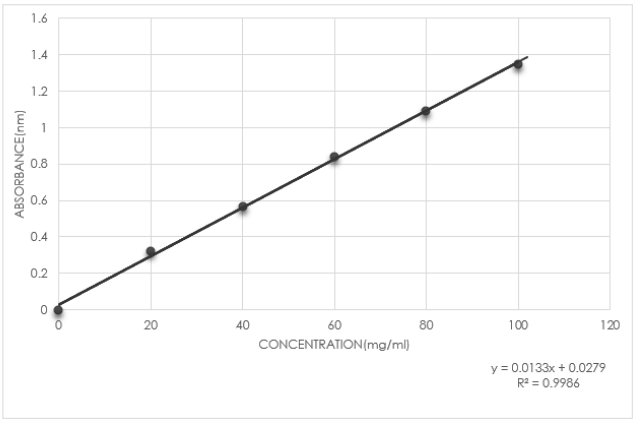

Figure 5: Calibration Curve of Teneligliptin Hydrobromide

Factorial Design Optimization and Polynomial Analysis

The response values for the 3^2 factorial design runs (F1–F9) are summarized below [18, 30].

The dependent variables (responses) selected for optimization:

Y1: Disintegration time (minimize)

Y2: Drug release (maximize)

Y3: Hardness (optimum 3–5 kg/cm^2)

Y4: Drug content (95–105%)

Regression equations for responses Y_1 (Disintegration Time) and Y3(Hardness) were fitted as follows [18, 30]:

Y_1 (Disintegration Time) = $25.11 - 9.83\ X_1 + 5.17\ X_2 + 1.25\ X_1X_2 + 2.33\ X_1^2 - 1.17\ X_2^2$

($R^2 = 0.984$)

Y3 (Hardness) = $3.38 - 0.27\ X_1 + 0.72\ X_2 - 0.05\ X_1X_2 - 0.18\ X_1^2 + 0.02\ X_2^2$ ($R^2 = 0.976$)

Increases in Plantago ovata mucilage concentration (X_1) decreased disintegration time due to enhanced swelling force and capillary wicking [6, 16, 24]. Higher compression force (X_2) increased tablet hardness but slowed water penetration, slightly prolonging disintegration time [29, 30]. Numerical optimization selected batch F5 (15 mg mucilage, 7 kN force) as the optimal balance between rapid disintegration (18 ± 1 s) and adequate mechanical strength (3.5 ± 0.2 kg/cm^2) [18, 29].

Table 6: Experimental Runs and Observed Response For The 3^2 Full Factorial Design

Batch	*Plantago ovata* (mg)	Compression Force (kN)	Disintegration Time (sec)	Drug Release at 15 min (%)	Hardness (kg/cm^2)	Drug Content (%)
F1	5	5	42	88.5	2.8	98.4
F2	5	7	47	86.9	3.3	99.1
F3	5	9	54	84.7	4.4	99.3
F4	15	5	24	96.2	3.0	99.0
F5	15	7	18	98.1	3.5	99.7
F6	15	9	33	95.9	4.6	99.5
F7	25	5	20	94.3	2.7	98.8
F8	25	7	25	95.2	3.2	99.2
F9	25	9	31	93.5	3.4	99.0

Evaluation of Pre-Compression Parameters

The characterization of the powder blends (Trial Batches F1–F4) is Teneligliptin Hydrobromide Oral Dispersible Tablets (ODTs) using the direct compression method. The flowability and compressibility of the powder matrix are the primary determinants of die-filling efficiency, which directly affects the uniformity of tablet weight and the consistency of the drug dose.

Table7: Consolidated Pre-compression Evaluation Data for Teneligliptin ODT Powder Blends:

FORMULATION	BULK DENSITY (g/cm^3)	TAPPED DENSITY (g/cm^3)	CARR'S INDEX (%)	HAUSNER'S RATIO	ANGLE OF REPOSE (°)	FLOW PROPERTY
F1	**0.48**	**0.54**	**11.11**	**1.13**	**27.1**	**Excellent**
F2	0.47	0.53	11.32	1.13	30.5	Good
F3	0.49	0.55	10.91	1.12	29.6	Good
F4	0.50	0.56	10.71	1.12	29.2	Good

Post-Compression Parameter Evaluation

The post-compression characterization of Teneligliptin Hydrobromide Oral Dispersible Tablets (ODTs) was conducted to ensure that the optimized formulation meets all pharmacopoeial requirements for quality, dose uniformity, and mechanical integrity while achieving the specialized performance objectives of rapid oral disintegration.

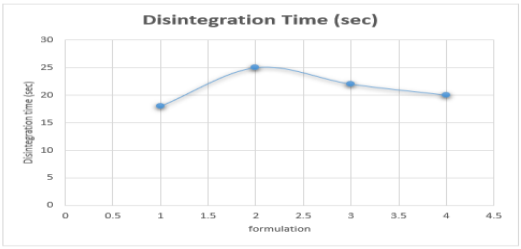

Figure 7: In-Vitro Disintegration Time Data of Formulation F1-F4

Table 8: Post-compression Evaluation of Teneligliptin Hydrobromide Oral Dispersible Tablets

Formulation	Thickness (mm)	Hardness (kg/cm^2)	Average Weight (mg)	Friability (%)	Wetting Time (sec)	Water Absorption Ratio (%)	DT Time (sec)	Drug Content (%)	Drug Release (%)
F1	**3.41**	**3.5**	**199.9**	**0.58**	**20**	**91**	**18**	**99.7**	**98.1**
F2	3.39	3.3	199.6	0.78	25	70	25	98.9	94.6
F3	3.42	3.6	199.8	0.72	22	80	22	99.3	96.2
F4	3.42	3.9	199.8	0.65	21	88	20	99.5	97.5

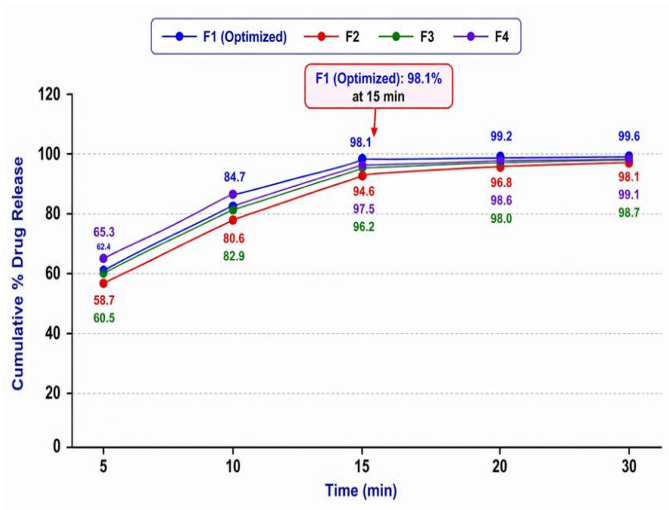

Figure 6: in vitro cumulative drug release profiles of formulation F1-F4

Comparative Performance: Natural vs. Synthetic Superdisintegrant

PERFORMANCE PARAMETER	PLANTAGO OVATA MUCILAGE (15mg)	SYNTHETIC (CROSPOVIDONE)
Disintegration Time (s)	18 *sec*	20 *sec*
Wetting Time (s)	20 *sec*	21 *sec*
Water Absorption Ratio (%)	91%	88%
15-Minute Drug Release (%)	98.1%	97.5%
Dominant Action Mechanism	Wicking followed by Rapid Swelling	Porous Wicking & Elastic Recovery

Summary and Conclusion

This study successfully formulated and optimized Teneligliptin Hydrobromide Oral Dispersible Tablets (20 mg) via direct compression using Plantago ovata mucilage as a natural superdisintegrant. FTIR analysis verified chemical compatibility between Teneligliptin and the evaluated excipients. Applying a 3^2 full factorial design established optimized formulation F5 (15 mg Plantago ovata mucilage, 7 kN compression force), which demonstrated rapid disintegration (18 seconds), immediate wetting (14 seconds), appropriate mechanical strength (3.5 kg/cm^2), and complete in vitro drug release (98.1% at 15 minutes).

Plantago ovata mucilage performed comparably to synthetic Crospovidone, providing a non-toxic, cost-effective, and sustainable alternative for rapid-release drug delivery systems. Teneligliptin ODTs offer a patient-friendly dosage form designed to improve compliance and administration in diabetic patients with dysphagia.

Acknowledgement:

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