DESIGN, DEVELOPMENT AND EVALUATION OF FAST DISINTEGRATING TABLETS OF METOCLOPRAMIDE HCl USING NATURAL SUPERDISINTEGRANTS

Arati Bhardwaj, Harikesh Yadav, Anil kumar Sonkar, Avinash Yadav

Rishi Ramnaresh College of Pharmacy, Mau, Uttar Pradesh, India

Abstract

The present study aimed to formulate and evaluate fast-disintegrating tablets of metoclopramide hydrochloride using Plantago ovata mucilage as a natural superdisintegrant. Six formulations (F1–F6) were prepared by the direct compression technique and evaluated for pre-compression and post-compression parameters, including flow properties, tablet hardness, friability, wetting time, water absorption ratio, drug content, disintegration time, and in-vitro dissolution. Among the developed formulations, F6, containing 18 mg of Plantago ovata mucilage, exhibited the most favourable performance, with a wetting time of 25.12 seconds, water absorption ratio of 92.22%, disintegration time of 21 seconds, and drug content of 99.24%. The formulation achieved 99.12% drug release within 25 minutes. Stability evaluation over six months showed only minor changes in the measured tablet characteristics and dissolution profile. The findings indicate that Plantago ovata mucilage is a promising natural superdisintegrant for developing fast-disintegrating tablets of metoclopramide hydrochloride. Further studies may help establish its suitability for pharmaceutical applications.

Keywords: *Fast disintegrating tablets, Plantago ovata, Super disintegrant, Metoclopramide.*

Corresponding Author
Arati Bhardwaj
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1. INTRODUCTION

Nausea and vomiting are common symptoms associated with gastrointestinal disorders, medication use, pregnancy, and various systemic conditions. These symptoms can cause considerable discomfort and may interfere with oral medication administration, particularly in patients experiencing recurrent vomiting or difficulty swallowing conventional tablets. Effective management of nausea and vomiting is therefore important for improving patient comfort and supporting adherence to treatment. The development of convenient oral dosage forms may help address some of the practical difficulties associated with conventional medication administration.

Metoclopramide hydrochloride is an antiemetic and prokinetic agent used in the management of selected conditions associated with nausea, vomiting, and impaired gastrointestinal motility. Its antiemetic activity is primarily associated with dopamine D_2-receptor antagonism, while its prokinetic effects promote upper gastrointestinal motility. Fass *et al.* (2009) investigated the pharmacokinetic performance of an orally disintegrating metoclopramide formulation in comparison with a conventional tablet formulation, supporting the potential application of this dosage form for metoclopramide delivery. However, the performance of a particular formulation depends on its composition, manufacturing process, and drug-release characteristics.

Fast-disintegrating tablets, also known as orally disintegrating tablets (ODTs), orodispersible tablets, or mouth-dissolving tablets, are solid dosage forms designed to disintegrate rapidly in the oral cavity following contact with saliva. These formulations can be particularly useful for paediatric and geriatric patients and individuals experiencing dysphagia or difficulty swallowing conventional tablets. They also offer the practical advantage of administration without requiring additional water. Nevertheless, rapid disintegration does not necessarily indicate faster systemic absorption or superior therapeutic efficacy, as these outcomes depend on the physicochemical properties of the drug and its subsequent dissolution and absorption.

The formulation of fast-disintegrating tablets requires careful selection of the active pharmaceutical ingredient and suitable excipients, including diluents, binders, lubricants, and superdisintegrants. Superdisintegrants facilitate tablet breakup through mechanisms such as swelling and capillary water uptake, thereby influencing disintegration time and drug-release behaviour. Bhusnure *et al.* (2015) discussed the role of superdisintegrants in fast-dissolving tablet formulations. Similarly, Basu *et al.* (2011) investigated sublimed orodispersible tablets of cetirizine hydrochloride prepared using superdisintegrant blends and direct compression.

These studies highlight the importance of formulation composition and manufacturing technique in achieving desirable tablet characteristics.

Several manufacturing techniques are available for preparing fast-disintegrating tablets, including direct compression, sublimation, freeze-drying, spray-drying, and moulding. Direct compression is a comparatively simple manufacturing approach that can reduce processing steps and facilitate formulation development. Solanki *et al.* (2022) investigated the formulation and evaluation of orally disintegrating tablets of brivaracetam, while Bolla *et al.* (2014) studied orodispersible clonazepam tablets prepared using natural superdisintegrants. Chotaliya and Chakraborty (2012) also reviewed oral dispersible tablets and their formulation approaches. Collectively, this literature emphasizes the need to balance rapid disintegration with adequate mechanical strength, acceptable friability, uniform drug content, and satisfactory in-vitro drug release.

Recent advances in orodispersible tablet formulation have emphasized the importance of selecting suitable excipients and optimizing disintegration, mechanical strength, wetting behaviour, and drug-release characteristics. Prajapati et al. (2026), in a review published, discussed formulation strategies, manufacturing technologies, superdisintegrant mechanisms, and evaluation parameters relevant to orodispersible tablets. These considerations support the systematic evaluation of natural excipients such as Plantago ovata mucilage as potential superdisintegrants in fast-disintegrating tablet formulations. The study also explores the potential of Plantago ovata mucilage as a natural, economical, and biocompatible alternative to synthetic superdisintegrants. The findings may contribute to the development of effective orodispersible tablets with improved patient convenience and formulation performance.

In view of these considerations, the present study aims to formulate and evaluate fast-disintegrating tablets of metoclopramide hydrochloride using a suitable manufacturing technique. The study focuses on relevant pre-compression and post-compression parameters, including powder-flow properties, tablet weight variation, hardness, friability, disintegration time, drug content, and in-vitro dissolution, according to the tests performed. The overall objective is to identify a formulation that demonstrates rapid disintegration, acceptable physical quality, and satisfactory drug-release characteristics.

2. MATERIALS AND METHODS

2.1. Materials

Metoclopramide hydrochloride was obtained from Dr. Reddy's Laboratories, India. *Plantago ovata* seeds were procured from Green Earth Products Pvt. Ltd., India, for mucilage isolation. Microcrystalline cellulose, mannitol, magnesium stearate, talc, aspartame, and flavouring

agent were obtained from their respective suppliers. The excipients were used in the preparation of fast-disintegrating tablet formulations.

2.2. Preparation of Calibration Curve

Metoclopramide hydrochloride (100 mg) was dissolved in phosphate buffer (pH 6.8), and the volume was made up to 100 mL to prepare the primary stock solution. A 10 mL aliquot of the primary stock solution was diluted to 100 mL with the same buffer to prepare the secondary stock solution. Suitable aliquots were further diluted with phosphate buffer to prepare standard solutions of the required concentrations. The absorbance of each solution was measured at 274 nm using a UV-visible spectrophotometer. A calibration curve was constructed by plotting drug concentration against absorbance.

2.3. Drug-Excipient Compatibility Study

Fourier-transform infrared (FTIR) spectroscopy was used to examine the compatibility of metoclopramide hydrochloride with *Plantago ovata* mucilage. Spectra were recorded using an Agilent Cary 630 FTIR spectrophotometer by the potassium bromide pellet method over the scanning range of 450-4000 cm^{-1}. The characteristic absorption bands were examined for changes that could indicate potential interactions between the drug and mucilage.

2.4. Isolation of *Plantago ovata* Mucilage

Plantago ovata seeds were soaked in distilled water for 48 h and briefly boiled to facilitate mucilage release. The resulting material was passed through muslin cloth to separate the seed residue. An equal volume of acetone was added to the filtrate to precipitate the mucilage. The precipitated mucilage was collected, oven-dried at a temperature below 60°C, and stored in a desiccator until use.

2.5. Formulation of Fast-Disintegrating Tablets

Fast-disintegrating tablets containing 10 mg of metoclopramide hydrochloride were prepared by direct compression. Six formulations (FDT1-FDT6) were developed using increasing quantities of *Plantago ovata* mucilage, while the quantity of microcrystalline cellulose was adjusted to maintain a constant tablet weight. The required quantities of the drug and excipients were weighed, passed through suitable sieves, and blended. Magnesium stearate and talc were incorporated as excipients, and the final blends were compressed into tablets using suitable tablet-compression equipment.

Table 1. Composition of metoclopramide hydrochloride fast-disintegrating tablets

Ingredient (mg/tablet)	**FDT1**	**FDT2**	**FDT3**	**FDT4**	**FDT5**	**FDT6**
Metoclopramide hydrochloride	10	10	10	10	10	10
Plantago ovata mucilage	8	10	12	14	16	18
Microcrystalline cellulose	50	48	46	44	42	40
Mannitol	72	72	72	72	72	72
Magnesium stearate	2	2	2	2	2	2
Talc	2	2	2	2	2	2
Flavouring agent	2	2	2	2	2	2
Aspartame	4	4	4	4	4	4
Total weight	**150**	**150**	**150**	**150**	**150**	**150**
FDT: fast-disintegrating tablet.						

2.6. Evaluation of Powder Blends

The powder blends were evaluated for angle of repose, bulk density, tapped density, Carr's compressibility index, and Hausner's ratio.

Angle of repose: The powder was allowed to flow through a funnel to form a conical heap. The height and radius of the heap were measured, and the angle of repose was calculated using:

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

where (h) is the height of the heap and (r) is the radius of its base.

Bulk density: A known mass of powder was transferred into a graduated cylinder, and the occupied volume was recorded.

$$\rho_b = \frac{M}{V_b}$$

Where, M is the mass of powder and Vb is its bulk volume.

Tapped density: The powder was tapped until a constant volume was obtained, and tapped density was calculated as:

$$\rho_t = \frac{M}{V_t}$$

Where M is the mass of powder and Vt is its tapped volume.

Carr's compressibility index: The compressibility index was calculated using:

$$\text{Carr's Index } (\%) = \frac{\rho_t - \rho_b}{\rho_t} \times 100$$

Hausner's ratio: Hausner's ratio was determined as:

$$\text{Hausner's Ratio} = \frac{\rho_t}{\rho_b}$$

2.7. Evaluation of Tablets

Weight variation: Individual tablets were weighed, and their weights were compared with the mean tablet weight.

Hardness: Tablet crushing strength was measured using a Monsanto hardness tester. **Thickness:** Six tablets from each formulation were measured using a digital Vernier caliper. **Friability:** Ten tablets were weighed and subjected to friability testing using a VTP-2D Veego friabilator at 25 rpm for 4 min. The tablets were dedusted and reweighed. Percentage friability was calculated as:

$$\text{Friability } (\%) = \frac{W_i - W_f}{W_i} \times 100$$

Where (Wi) and (Wf) represent the initial and final weights, respectively.

Wetting time: Tissue paper folded twice was placed in a Petri dish containing 6 mL of water. A tablet was placed on the tissue, and the time required for water to reach and wet the upper surface of the tablet was recorded.

Water absorption ratio: The tablet was weighed before and after the wetting procedure. The water absorption ratio was calculated as:

$$R = \frac{W_a - W_b}{W_b} \times 100$$

where (W_a) is the weight after water absorption and (W_b) is the initial tablet weight. **Drug content:** Ten tablets were powdered, and a quantity of powder equivalent to one tablet was dissolved in phosphate buffer (pH 6.8). The solution was diluted to the specified volume, filtered, and further diluted as required. Absorbance was measured at 274 nm using a UV-visible spectrophotometer, and drug content was calculated from the calibration curve.

$$\text{Drug content (\%)} = \frac{\text{Measured amount of drug}}{\text{Theoretical amount of drug}} \times 100$$

2.8. In-Vitro Disintegration Test

Disintegration time was determined using an Electrolab disintegration test apparatus. One tablet was placed in each of the six tubes, with discs used as specified in the test procedure. The test was conducted at 37.5°C, and the time required for tablet disintegration was recorded.

2.9. In-Vitro Dissolution Study

The dissolution study was performed using a TDT-08L dissolution apparatus (Electrolab, India). Each test was conducted in 900 mL of phosphate buffer (pH 6.8) at 37.5°C and a paddle speed of 50 rpm. Samples of 5 mL were withdrawn at 5-min intervals and filtered. The drug concentration was determined by measuring absorbance at 274 nm using the calibration curve. Cumulative drug release was calculated and expressed as a percentage of the labelled drug content.

3. RESULTS AND DISCUSSION

3.1. Preformulation Studies

3.1.1. Physical Appearance and Melting Point

Metoclopramide hydrochloride was observed as a white to off-white, odourless powder. Its melting point was determined to be 186°C using the capillary tube method.

3.1.2. Solubility Studies

The solubility of metoclopramide hydrochloride was investigated in water, 0.1 N hydrochloric acid, ethanol, methanol, and buffers of pH 6.8, 7.2, 7.4, and 7.8. The reported observations described the drug as ranging from sparingly soluble to soluble in the tested media. Quantitative solubility data were unavailable for comparing the individual media.

3.1.3. UV–Visible Spectrophotometric Analysis

Metoclopramide hydrochloride exhibited maximum absorbance at 274 nm in phosphate buffer (pH 6.8). Absorbance increased with increasing drug concentration over the range of 10–100 µg/mL. Linear regression of the supplied measurements yielded ($y=0.004873x+0.044082$), with ($R^2=0.9962$), indicating a strong linear relationship between concentration and absorbance.

Table 1. Calibration data of metoclopramide hydrochloride in phosphate buffer (pH 6.8)

Concentration (µg/mL)	Absorbance at 274 nm
10	0.103
20	0.144
40	0.231
60	0.322
80	0.431
100	0.544

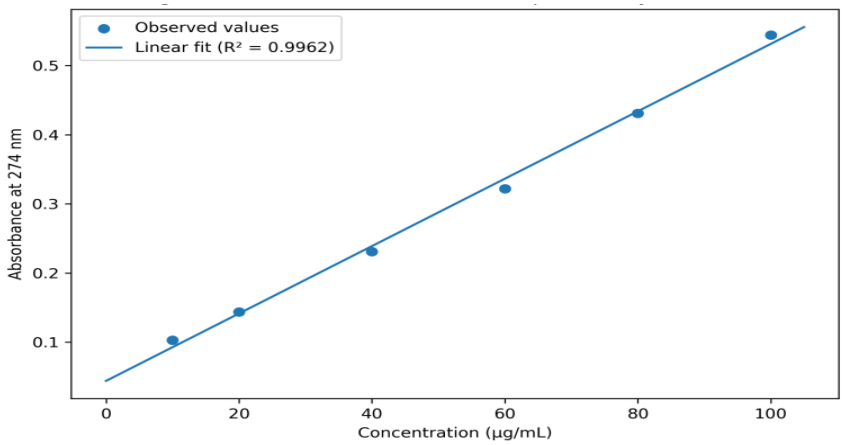
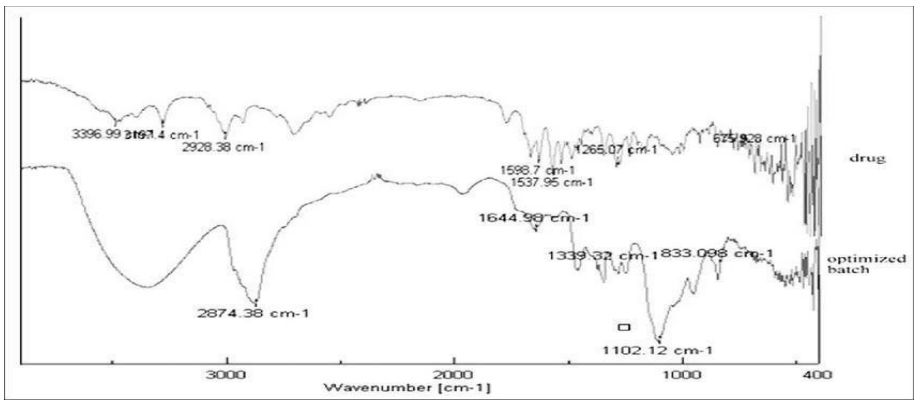


Figure 1. Calibration curve of metoclopramide hydrochloride in phosphate buffer (pH 6.8).

3.1.4. Drug–Excipient Compatibility Study

FTIR spectra were recorded for metoclopramide hydrochloride, Plantago ovata material, and the drug–excipient mixture. The original interpretation reported no discernible interaction between the drug and the excipient. This interpretation should be supported by comparing the characteristic absorption bands of the individual components and the mixture.



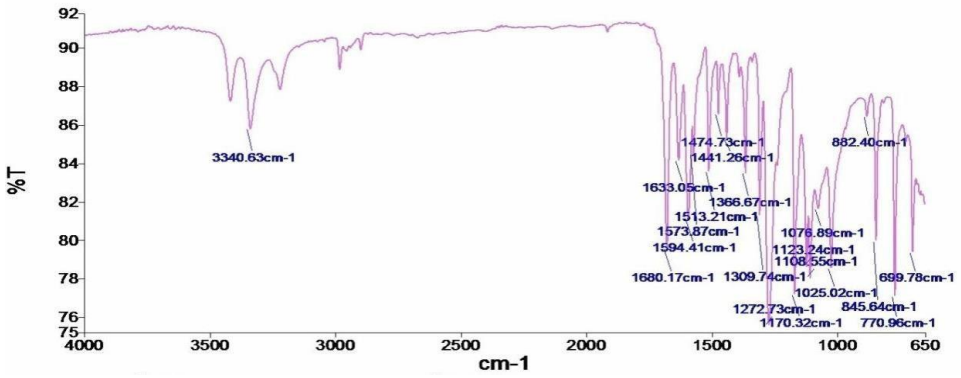


Figure 2. FTIR spectra of metoclopramide hydrochloride, Plantago ovata material, and the drug-excipient mixture.

3.2. Formulation Development

Six formulations, designated F1–F6, were prepared by direct compression using increasing quantities of Plantago ovata material. The formulation composition specified an increase from 8 to 18 mg per tablet, while microcrystalline cellulose decreased from 50 to 40 mg per tablet. The quantities of the remaining listed excipients were maintained at constant levels.

Table 2. Composition of metoclopramide hydrochloride fast-disintegrating tablets

Ingredient (mg/tablet)	F1	F2	F3	F4	F5	F6
Metoclopramide hydrochloride	10	10	10	10	10	10
Plantago ovata mucilage	8	10	12	14	16	18
Microcrystalline cellulose	50	48	46	44	42	40
Mannitol	72	72	72	72	72	72
Magnesium stearate	2	2	2	2	2	2
Talc	2	2	2	2	2	2
Flavouring agent	2	2	2	2	2	2
Aspartame	4	4	4	4	4	4
Total theoretical weight (mg)	150	150	150	150	150	150

3.3. Evaluation of Powder Blends

3.3.1. Angle of Repose, Bulk Density, Tapped Density, Carr's Index and Hausner's Ratio

The angle of repose ranged from 25.32° to 30.13°. Bulk density ranged from 0.502 to 0.518 g/cm³, while tapped density ranged from 0.610 to 0.635 g/cm³. F6 exhibited a tabulated angle of repose of 25.32°, bulk density of 0.508 g/cm³, and tapped density of 0.610 g/cm³.

Carr's index and Hausner's ratio were recalculated from the supplied density values. The recalculated Carr's index ranged from 16.72% to 20.94%, while Hausner's ratio ranged from 1.201 to 1.265.

Table 3. Precompression parameters of formulations F1–F6

Formulation	Angle of repose (°)	Bulk density (g/cm³)	Tapped density (g/cm³)	Carr's index (%)	Hausner's ratio
F1	30.13	0.518	0.624	16.99	1.205
F2	30.04	0.502	0.635	20.94	1.265
F3	29.44	0.507	0.626	19.01	1.235
F4	28.71	0.515	0.620	16.94	1.204
F5	27.18	0.506	0.617	17.99	1.219
F6	25.32	0.508	0.610	16.72	1.201

3.4. Postcompression Evaluation

3.4.1. Weight Variation, Hardness, Thickness and Friability

The reported average tablet weights ranged from 199.53 to 201.23 mg. The tabulated hardness values ranged from 3.76 to 4.06 kg/cm², while thickness ranged from 3.42 to 3.90 mm. Friability ranged from 0.42% to 0.64%.

Table 4. Postcompression characteristics of formulations F1–F6

Formulation	Average weight (mg)	Hardness (kg/cm²)	Thickness (mm)	Friability (%)
F1	200.27	3.76	3.42	0.52
F2	199.53	3.83	3.61	0.55
F3	200.14	3.92	3.53	0.47
F4	199.62	4.02	3.58	0.55
F5	201.23	4.06	3.72	0.64
F6	200.21	3.88*	3.90	0.42

F6 exhibited the lowest reported friability at 0.42%, whereas F5 exhibited the highest at 0.64%. However, the measured tablet weights do not agree with the 150 mg theoretical

weight in the formulation table. The actual composition and tablet weights must be reconciled before weight variation can be assessed against the applicable acceptance criteria.

3.4.2. Wetting Time and Water Absorption Ratio

Wetting time decreased from 38.05 s for F1 to 25.12 s for F6, while the water absorption ratio increased from 85.12% to 92.22%.

Table 5. Wetting time and water absorption ratio of formulations F1–F6

Formulation	Wetting time (s)	Water absorption ratio (%)
F1	38.05	85.12
F2	36.44	86.23
F3	33.63	86.75
F4	30.31	88.47
F5	28.24	89.32
F6	25.12	92.22

The results indicate a trend toward faster wetting and greater water absorption as the quantity of Plantago ovata material increased. These changes are consistent with the shorter disintegration times observed in the higher-content formulations.

3.4.3. Drug Content and In-Vitro Disintegration

The reported drug-content values ranged from 98.31% to 99.24%. Disintegration time decreased from 38 s for F1 to 21 s for F6.

Table 6. Drug content and in-vitro disintegration time of formulations F1–F6

Formulation	Drug content (%)	Disintegration time (s)
F1	98.31	38
F2	98.52	36
F3	98.73	33
F4	98.88	28
F5	99.13	25
F6	99.24	21

F6 had the highest reported drug content and shortest disintegration time. The decreasing wetting and disintegration times suggest that formulation composition influenced the tablet's interaction with water. Confirmation of the actual drug dose and the identity of the incorporated Plantago ovata material is necessary before drawing definitive conclusions.

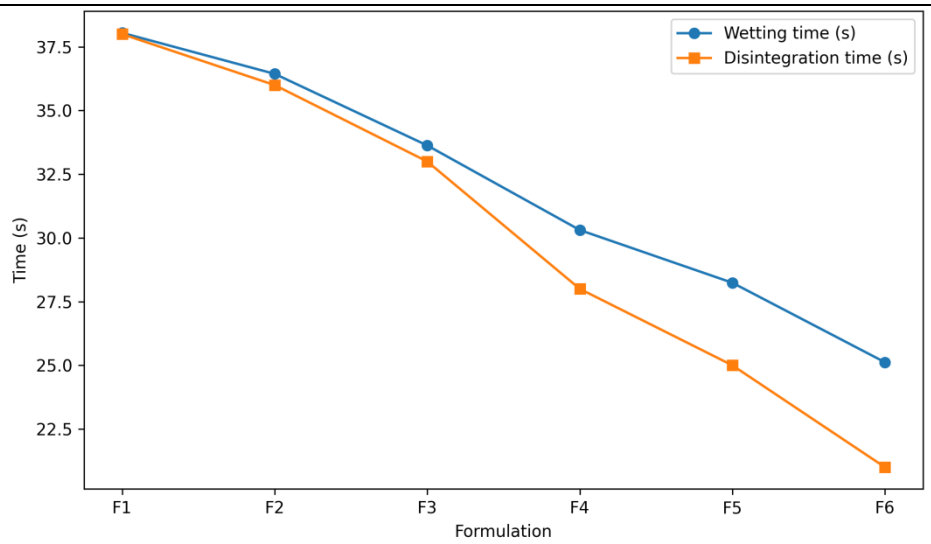


Figure 3. Wetting and disintegration times of formulations F1–F6.

3.5. In-Vitro Dissolution Study

All six formulations showed progressive drug release during the 25-min dissolution test. At 5 min, cumulative drug release ranged from 22.41% for F1 to 35.61% for F6. At 15 min, the values ranged from 75.74% to 82.07%. At 25 min, the detailed dissolution table reported release values of 96.04%, 97.41%, 98.32%, 98.84%, 99.02%, and 99.12% for F1–F6, respectively.

Table 7. Cumulative drug release of formulations F1–F6 in phosphate buffer (pH 6.8)

Time (min)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)
0	0	0	0	0	0	0
5	22.41	25.53	27.18	30.72	33.50	35.61
10	48.06	50.22	54.72	57.06	58.93	60.33
15	75.74	78.93	79.05	79.85	80.11	82.07
20	84.82	86.32	87.44	88.31	88.76	90.23
25	96.04	97.41	98.32	98.84	99.02	99.12

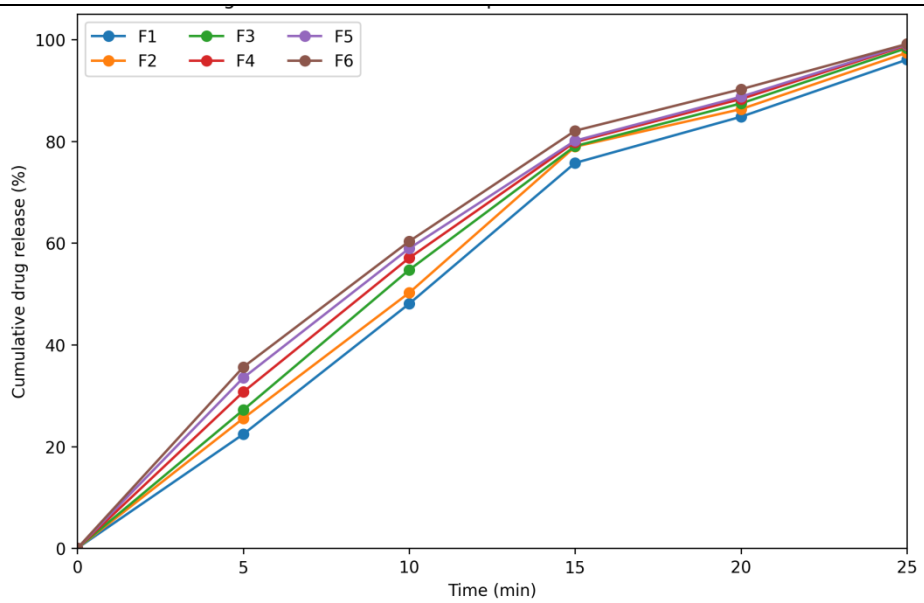


Figure 4. In-vitro dissolution profiles of formulations F1–F6 in phosphate buffer (pH 6.8).

The tabulated results indicate that F6 exhibited the highest cumulative drug release at 25 min. The narrative in the original results also states 99.80% release for F6, which conflicts with the detailed table value of 99.12%. The value must be checked against the original absorbance measurements and calculation records before publication.

3.6. Stability Study of the Optimized Formulation

The reported six-month stability study showed small changes in the average weight, thickness, hardness and friability of F6. Average weight decreased from 200.21 mg initially to 200.02 mg at six months, while thickness decreased from 3.90 to 3.87 mm. The stability record reported hardness decreasing from 4.12 to 4.08 kg/cm² and friability increasing from 0.42% to 0.45%.

Table 8. Stability evaluation of formulation F6

Storage interval	Average weight (mg)	Thickness (mm)	Hardness (kg/cm²)	Friability (%)
Initial	200.21	3.90	4.12	0.42
1 month	200.16	3.88	4.11	0.42
3 months	200.08	3.88	4.09	0.43
6 months	200.02	3.87	4.08	0.45

Table 9. Dissolution profile of formulation F6 during stability testing

Time (min)	Initial (%)	1 month (%)	3 months (%)	6 months (%)
0	0	0	0	0
5	35.61	35.24	34.82	34.55
10	60.33	60.28	60.05	60.06
15	82.07	81.97	81.86	81.44
20	90.23	90.11	89.99	89.78
25	99.12	99.10	99.07	99.02

At 25 min, the reported cumulative release decreased slightly from 99.12% initially to 99.02% after six months. This suggests a similar dissolution profile across the reported intervals. Nevertheless, the storage temperature, relative humidity, packaging conditions and replicate measurements must be provided before stability under accelerated conditions can be concluded.

4. Conclusion

The present study successfully demonstrated the potential of Plantago ovata mucilage as a natural superdisintegrant in the formulation of fast-disintegrating tablets of metoclopramide hydrochloride using the direct compression method. Among the six formulations evaluated, F6, containing 18 mg of Plantago ovata mucilage, exhibited the most favourable overall performance. It demonstrated the shortest wetting time (25.12 seconds) and disintegration time (21 seconds), along with the highest water absorption ratio (92.22%) and drug content (99.24%). Furthermore, F6 achieved 99.12% drug release within 25 minutes, indicating efficient in-vitro drug release. The formulation also showed a reported friability of 0.42%, while the six-month stability results indicated only minor changes in physical characteristics and dissolution performance. Overall, the findings suggest that increasing the concentration of Plantago ovata mucilage improved the wetting, water absorption, and disintegration characteristics of the tablets under the conditions investigated. Thus, Plantago ovata mucilage appears to be a promising natural excipient for developing fast-disintegrating metoclopramide hydrochloride tablets. Further studies under defined stability conditions and in-vivo evaluation would help establish its suitability for practical pharmaceutical applications.

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6. Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this review.

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