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Formulation and Characterization of Metoclopramide Oral Disintegrating Tablet using Natural Superdisintegrants

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ABSTRACT

Metoclopramide HCl, a potent dopamine receptor antagonist, is widely used for its antiemetic and prokinetic properties, particularly in the management of nausea, vomiting, and gastroparesis. In this study, a novel approach was employed to formulate orally disintegrating tablets (ODTs) of Metoclopramide HCl using natural superdisintegrants- Plantago ovata and Ocimum basilicum mucilages—aiming to improve patient compliance and enhance drug bioavailability through faster disintegration and dissolution. Tablets were prepared via direct compression method and optimized using a 3^2 full factorial design. A total of nine formulations were developed and evaluated for key physicochemical parameters including hardness, friability, weight variation, disintegration time, wetting time, water absorption ratio, drug content uniformity, and in vitro drug release. Among all, formulation F06 exhibited superior performance, with rapid dispersion (≈12 seconds), high water absorption (≈80%), and over 89% drug release within 12 minutes, outperforming conventional commercial tablets. IR spectroscopy confirmed the absence of drug-excipient interactions, while short term stability studies validated the formulation's integrity. The study highlights the potential of natural mucilages as effective, biocompatible alternatives to synthetic superdisintegrants in fast-dissolving dosage forms. These findings not only support the pharmaceutical utility of Plantago ovata and Ocimum basilicum mucilages but also pave the way for future research into scale-up, in vivo evaluations, and broader therapeutic applications of natural polymers in ODT technologies..

Keywords: *Orally Disintegrating Tablets, Metoclopramide HCl, Natural Superdisintegrants, Plantago ovata, Ocimum basilicum, ODTs*

1. INTRODUCTION

Oral drug delivery remains the most preferred route of administration due to its convenience, cost-effectiveness, and wide patient acceptability. However, the conventional oral solid dosage forms such as tablets and capsules are often associated with limitations in patient compliance, especially among pediatric, geriatric, and mentally challenged populations. These limitations have catalyzed the development of alternative formulations aimed at improving ease of administration, patient adherence, and therapeutic efficacy. Among these, Orally Disintegrating Tablets (ODTs) have gained significant traction due to their ability to disintegrate or dissolve rapidly in the oral cavity without the need for water. ODTs are especially advantageous for drugs that require quick onset of action or for conditions where swallowing is compromised. The technology behind ODTs leverages excipients that facilitate rapid disintegration, thereby ensuring quicker drug release and absorption. A critical component of ODT formulations is the use of superdisintegrants, which are agents that promote the breakup of tablets into smaller fragments in aqueous environments, enhancing dissolution and absorption.

Traditionally, synthetic superdisintegrants such as crospovidone, sodium starch glycolate, and croscarmellose sodium have been extensively used to achieve the desired disintegration profile in ODTs. These excipients offer reliable performance and are widely accepted in pharmaceutical applications. However, concerns regarding their cost, regulatory limitations, and potential for side effects have prompted a growing interest in natural alternatives. Natural polymers, particularly plant-. derived mucilages, have emerged as promising superdisintegrants owing to their biodegradability, biocompatibility, renewability, and cost- effectiveness Mucilages are polysaccharide complexes derived from various plant sources and have been traditionally used in the pharmaceutical and food industries as gelling, suspending, stabilizing, and thickening agents.

Their inherent swelling capacity and hydrophilicity make them ideal candidates for use as disintegrants in ODT formulations. In recent years, mucilages from *Plantago ovata* (commonly known as psyllium husk) and *Ocimum basilicum* (commonly known as sweet basil) have been investigated for their potential to replace synthetic disintegrants in fast-dissolving dosage forms. [2-3]

Metoclopramide HCl is a potent dopamine receptor antagonist used primarily for its antiemetic and gastroprokinetic effects. It possesses excellent water solubility and high oral bioavailability (>80%), making it a suitable candidate for ODT formulation. Traditional ODT formulations often rely on synthetic superdisintegrants like croscarmellose sodium and sodium starch glycolate. However, these may present limitations in terms of cost, sustainability, and regulatory acceptance.

Mechanism of Action for Tablet Disintegration

Tablet disintegration is primarilydriven by four keymechanisms:

Swelling

Disintegrants like starch absorb water and swell, creating internal pressure that breaks the tablet apart. Swelling is more effective in tablets with low porosity, where the force is sufficient to overcome interparticulate bonds. Excessive porosity or compactness, however, can hinder disintegration.

Porosity and Capillary Action (Wicking)

Non-swelling disintegrants promote disintegration byallowing water toenter thetablet through capillaryaction. The aqueous medium replaces air between particles, weakening bonds and breaking the tablet. Tablet porosity and hydrophilicity of excipients are crucial for this mechanism.

Particle Repulsion Forces

Even non-swelling disintegrants can cause disintegration through electrostatic repulsion between particles. This mechanism is secondary to wicking and also requires water to activate particle separation forces.

Deformation

During compression, certain disintegrant particles deform and store mechanical energy. Upon exposure to water, these particles attempt to return to their original shape, releasing energy and causing the tablet to break apart. This is especially relevant for elastic materials like starch. [4-5]

In this context, natural polymers such as *Plantago ovata* (psyllium husk) and *Ocimum basilicum* (sweet basil) mucilages have emerged as promising alternatives due to their biodegradability, biocompatibility, and functionality. The present research investigates the use of these natural superdisintegrants in the formulation of Metoclopramide HCl ODTs via direct compression, emphasizing rapid disintegration and enhanced bioavailability.

Drug and Polymer Profile

Metoclopramide HCl

Category: Antiemetic, Prokinetic agent

Mechanism of Action: Dopamine D2 receptor antagonist

Bioavailability: >80%

Solubility: Freelysoluble in water

Therapeutic Use: Management of nausea, vomiting, and gastroparesis

Dose in Formulation: Typically 10 mg per tablet

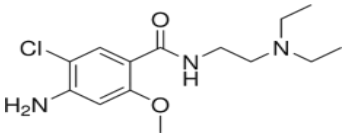

Fig. 1.1 Structural formula of Metoclopramide HCl

Metoclopramide HCl is rapidly absorbed from the gastrointestinal tract and undergoes hepatic metabolism. It is especially effective in conditions where rapid gastric emptying is required, making it an ideal drug candidate for ODT formulations. [6]

***Plantago ovata* (Psyllium Husk Mucilage)**

Source: Seeds of *Plantago ovata*

Constituents: Mucilage, arabinose, xylose

Pharmaceutical Use: Disintegrant, binder, thickener

Properties: High water absorption, swelling index, biocompatible

Fig. 1.2 Plantago Ovata Husk

Plantago ovata mucilage is widelyrecognized for its gelling and swelling properties, making it effective in facilitating tablet disintegration by increasing the porosity and promoting capillary action. [7]

Ocimum basilicum (Basil Mucilage)

Source: Seeds of *Ocimum basilicum*

Constituents: Mucilage polysaccharides, flavonoids

Pharmaceutical Use: Disintegrant, emulsifying agent

Properties: Rapid hydration, film- forming, stabilizing

Fig. 1.3 Ocimum basilicum Seeds

Ocimum basilicum seeds, are small, oval- shaped, and black. When hydrated, they develop a gelatinous, translucent coating. The mucilage from Ocimum basilicum seeds has been shown to rapidly absorb water and swell, providing efficient disintegration of solid dosage forms and improving dissolution characteristics. [8]

2. EXPERIMENTAL WORK

2.1 Preformulation Studies of Crude Drug

Preformulation Studies are crucial initial steps in drug development aimed at understanding the physical and chemical characteristics of the crude drug and its compatibility with excipients to guide formulation design [9-10].

Organoleptic Studies: These involve visual and sensory evaluation of the drug's physical characteristics such as color, odor, and appearance to ensure quality and consistency.

Solubility Studies: The drug's solubility is assessed by mixing it with various solvents and observing dissolution visually, which informs solvent selection for formulation.

Melting Point Determination: The melting point is measured using a capillary melting point apparatus by heating powdered drug in a sealed capillary tube and recording the temperature at which it melts. Triplicate measurements ensure accuracy.

Identification by UV Spectrophotometry: A standard calibration curve is generated by measuring absorbance of Metoclopramide solutions at 272.4 nm in pH 6.8 phosphate buffer, facilitating quantitative drug analysis.

Drug-Excipients Compatibility Studies: FT-IR spectroscopy is employed to detect potential interactions between drug and excipients by comparing spectra of pure drug and physical mixtures, ensuring formulation stability.

Pre-Compaction Evaluation of Granules

It assesses the flow and packing properties of drug powders critical for tablet manufacturing:

Angle of Repose: Measured by the funnel method, it indicates powder flowability; a lower angle suggests better flow.

Bulk Density: Calculated as the mass of powder divided by the untapped volume, reflecting initial packing.

Tapped Density: Determined by tapping the powder to minimize volume and calculating mass per final volume, indicating powder compressibility.

Compressibility Index (Carr's Index): Derived from bulk and tapped densities, it quantifies flow characteristics; lower values indicate better flow.

Hausner's Ratio: The ratio of tapped to bulk density, providing insight into powder flow and densification tendencies; values closer to 1 suggest good flow. [7-8]

Isolation and Evaluation of Plants Mucilage

Fig. 2.1 General extraction method of plant mucilage

Isolation of Plantago Ovata mucilage

For the isolation of mucilage, seeds of *Plantago ovata* were used. They were soaked in distilled water for 48 hours and then boiled for 1 h for complete release of mucilage into water. The material collected was squeezed through muslin cloth for filtering and separating out the marc. Then, an equal volume of acetone was added to the filtrate so as to precipitate the mucilage. The separated mucilage was dried (in oven at temperature less than 600), powdered, sieved (#60) and stored in a desicator until further use. [6]

Isolation of Ocimum Basilicum Mucilage

Basil seeds were rinsed with water to remove foreign particles. Seeds were soaked in water (Seed: Water = 1:10) for 20 minutes. The swollen seeds subjected to high agitation using homogenizer at 1500 rpm to separate gel layer from seeds. The separated gel layer was passed through muslin cloth to remove unwanted particles and then precipitated using acetone. The precipitate was washed with ethanol and dried in hot air oven at 400^0C. the dried mucilage was powdered and stored in airtight container. [6]

Physicochemical Evaluation of dried plants mucilage powder

The physicochemical evaluation of dried plant mucilage involved assessing its organoleptic properties, including appearance, color, odor, and taste. Solubility was tested by adding a small amount of mucilage to water, while total ash content was determined using a 1- gram sample. Loss on drying was measured by heating the mucilage at 105°C for five hours to calculate moisture content. Additionally, the swelling factor was evaluated by measuring the volume increase after soaking 1 gram of mucilage in water for 24 hours. Finally, flow properties such as angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio were also assessed to understand the powder's handling characteristics [9-10].

Formulation Development

The ODTs were formulated by direct compression method using Metoclopramide HCl as the active ingredient. Natural mucilages from Plantago ovata and Ocimum basilicum were extracted and used as superdisintegrants. All ingredients were individually passed through a #60 mesh sieve to ensure uniform particle size. Metoclopramide HCl and mannitol were initially blended by gradually combining small portions of each to achieve a homogenous mixture, which was then set aside [11]. Subsequently, the remaining excipients were incorporated using geometric dilution to ensure even distribution. The final blend was passed through a coarse #44 mesh sieve prior to compression. Tablets were then compressed using 6 mm flat-faced punches, targeting a uniform tablet weight of 100 mg [12]. The formulation table has been shown in Table 3.1.

Evaluation of Prepared Metoclopramide ODT Tablets

Tablet Shape: Examined visuallyusing a magnifying lens to ensure uniformity in shape.

Thickness: Measured using Vernier calipers; average calculated from three tablets.

Hardness: Assessed using a Monsantohardness tester to determinemechanical strength.

Friability: Evaluated with a Roche friabilator to check resistance to abrasion; expressed as percentage weight loss.

Weight Variation: Twentytablets were individually weighed to ensure weight uniformity within ±3% of the average weight.

Drug Content: Ten tablets were powdered; the amount of Metoclopramide HCl was determined spectrophotometrically at 272.6 nm.

Wetting Time & Water Absorption Ratio: A tablet was placed on wet tissue; time for complete wetting and weight before/after absorption were recorded to calculate water absorption.

***In-vitro* Disintegration Time**: Measured using a standard disintegration apparatus in phosphate buffer (pH6.8) at 37 ± 0.5°C.

***In-vitro* Dissolution Studies:** Conducted using USP Type-II dissolution apparatus in phosphate buffer (pH 6.8); absorbance measured at 272.4 nm to determine drug release profile. [9-10]

Stability Studies

The optimized formulation was stored at 40°C/75% RH for 90 days. Post-storage evaluation included drug content and in- vitro disintegration time to assess stability and shelf-life. [10]

3. RESULTS AND DISCUSSION

Results of Preformulation Studies

The organoleptic evaluation of Metoclopramide HCl confirmed compliance with the Indian Pharmacopoeia (IP), revealing it to be an almost white, odorless, crystalline substance. Solubility studies showed that the drug is freely soluble in solvents such as ethylene glycol, propylene glycol, ethanol, and transcutol, and very soluble in water. The observed melting point was 147°C, aligning well with the reference range of 146–151°C, confirming purity.

The identification of Metoclopramide HCl by UV spectrophotometry showed a strong linear relationship between concentration and absorbance in pH 6.8 phosphate buffer at 272.6 nm, with a correlation coefficient (R^2) of 0.9999, indicating high accuracy and precision. The calibration curve has been shown in fig. 4.1 and table in 4.1. FT- IR spectroscopy revealed no significant interactions between the drug and excipients, confirming compatibility. The spectra of the pure drug and optimized formulation (F06) showed the preservation of key functional groups. The graph has been shown in fig. 4.2 and 4.3.

Results of Pre- Compaction Evaluation of Granules

The pre-compaction flow properties of Metoclopramide HCl indicated suitability for direct compression. The angle of repose was found to be 28 ± 0.5°, suggesting fair flowability. The bulk densityand tapped densitywere 0.443 ±0.011 g/ml and 0.484 ± 0.013 g/ml, respectively. Based on these values, the compressibility index was calculated as 9.63 ± 1.277%, and the Hausner's ratio was 1.12 ± 0.005, both indicating good flow properties essential for uniform die filling and efficient tablet manufacturing.

Results of Physicochemical Evaluation of dried plants mucilage powder

Organoleptic properties of both *Plantago ovata* and *Ocimum basilicum* mucilages complied with IP standards. *Plantago ovata* appeared pinkish brown to gray with a mucilaginous taste, while *Ocimum basilicum* was light brown to white with a slightly odorous taste. Both were slightly soluble in water. The total ash values were within acceptable limits, recorded as 4% for *Plantago ovata* and 3.1% for *Ocimum basilicum*. Loss on drying was 10% and 4%, respectively. Swelling factors were found to be 9 and 8.2, indicating good hydration potential. Flow property evaluation showed acceptable compressibility and flowability, with both mucilages exhibiting low Hausner's ratios and Carr's indices, suitable for use as natural superdisintegrants in tablet formulations.

Results of Post Compaction Evaluation

Physical Evaluation

All tablet formulations (F01–F09) were circular in shape and had uniform appearance. Thickness ranged from 2.83 mm to mm, staying within acceptable limits. Hardness values varied between 4.04 to 4.5 kg/cm², indicating adequate mechanical strength. Friability was well below 1% for all batches, ensuring good durability. Weight variation was minimal across all formulations, confirming uniform dosage consistency. The results of physical evaluation have been documented in table 4.1.

Chemical Evaluation

Theresults of chemical evaluation have been documented in table 4.2.

Drug content was highly consistent across batches, ranging from 99.35% to 101.36%.

Wetting time was shortest in F09 (12.97 s), followed by F08 (25.41 s) and F06 (29.24 s).

Water absorption ratio was highest in F09 (84.19%), showing excellent liquid uptake.

***In-vitro* disintegration time** was lowest in F06 (24.53 s), F08 (24.69 s), and F09 (24.78 s), ideal for fast- dissolving tablets.

In-vitro Dissolution Studies

The results of in-vitro dissolution studies have been documented in table 4.3 & 4.4.

F06 formulation showed maximum drugrelease (89.5%) in 12 minutes, indicating superior performance.

Other formulations released between 83–86% in 12 minutes.

Comparison with Marketed Tablet (Reglan)

Commercial Reglan tablet showed only 72.4% drug release in 12 minutes.

F06 showed 89.5% drug release, making it significantlymore effective than the marketed product.

Graph (Fig. 4.5) illustrates the clear advantage of F06 over the commercial counterpart.

Results of Stability Studies

The stability studies for the optimized formulation F06 of Metoclopramide were conducted under accelerated conditions (40°C / 75% RH) for 90 days to evaluate its physical and chemical stability. Throughout the study period, there was no significant change observed in the physical appearance of the tablets. The drug content remained highly stable, with only a minimal decrease from 100.95% on day 0 to 100.76% on day 90. Similarly, the disintegration time showed negligible variation, increasing slightly from 24.53 to 25.03 seconds, indicating excellent integrity of the formulation. The in-vitro dissolution profile also demonstrated consistent drug release, with the cumulative release at 12 minutes decreasing only marginally from 89.5% to 88.9% over the study duration. These results confirm that the F06 formulation maintained its qualityand performance, proving its stabilityand suitabilityas an effective orallydisintegrating tablet. Theresults are shown in table 4.5 & 4.6.

4. SUMMARY & CONCLUSION

The present study successfully formulated and characterized Metoclopramide HCl ODTs using Plantago ovata and Ocimum basilicum mucilage as natural superdisintegrants. The direct compression method yielded tablets with satisfactory mechanical strength, rapid disintegration, and enhanced drug release. Among all formulations, F06 emerged as the optimized batch with desirable attributes including 12-second disintegration, high water absorption, and 89% drug release in 12 minutes.

These findings demonstrate the potential of natural polymers in pharmaceutical technology, offering safer, cost-effective, and patient-friendly alternatives to synthetic excipients. The study lays a foundation for further investigation into the scalability, long-term stability, and in vivo performance of such formulations.

The results confirmed that the optimal concentration of Plantago ovata (6 mg) and Ocimum basilicum mucilage (8 mg) led to the best-performing ODT in terms of disintegration and dissolution parameters.

Table No. 3.1 Formulation of Trial Batches from F01 to F09

Ingredient	F01	F02	F03	F04	F05	F06	F07	F08	F09
	Quantity (in mg/tab.)								
Metoclopramide HCl	10	10	10	10	10	10	10	10	10
***Plantago ovata* dried mucilage powder**	2	2	2	6	6	6	10	10	10
***Ocimum basilicum* dried mucilage powder**	4	6	8	4	6	8	4	6	8
Microcrystalline Cellulose	0	15	30	0	15	30	0	15	30
Aspartame	3	3	3	3	3	3	3	3	3
Sodium stearyl fumarate	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2
Banana Flavour	1	1	1	1	1	1	1	1	1
Mannitol SD-200	76	59	42	72	55	38	68	51	34
Total Weight	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**

Table 3.2: Calibration curve of Metoclopramide HCl

Concentration µg/ ml	Absorbance			
	I	II	III	Mean ± SD
0	0.000	0.000	0.000	0.000 ± 0.000
2	0.085	0.087	0.086	0.086 ± 0.001
4	0.174	0.161	0.164	0.166 ± 0.006
6	0.248	0.241	0.254	0.248 ± 0.006
8	0.334	0.328	0.330	0.330 ± 0.003
10	0.409	0.424	0.412	0.415 ± 0.007

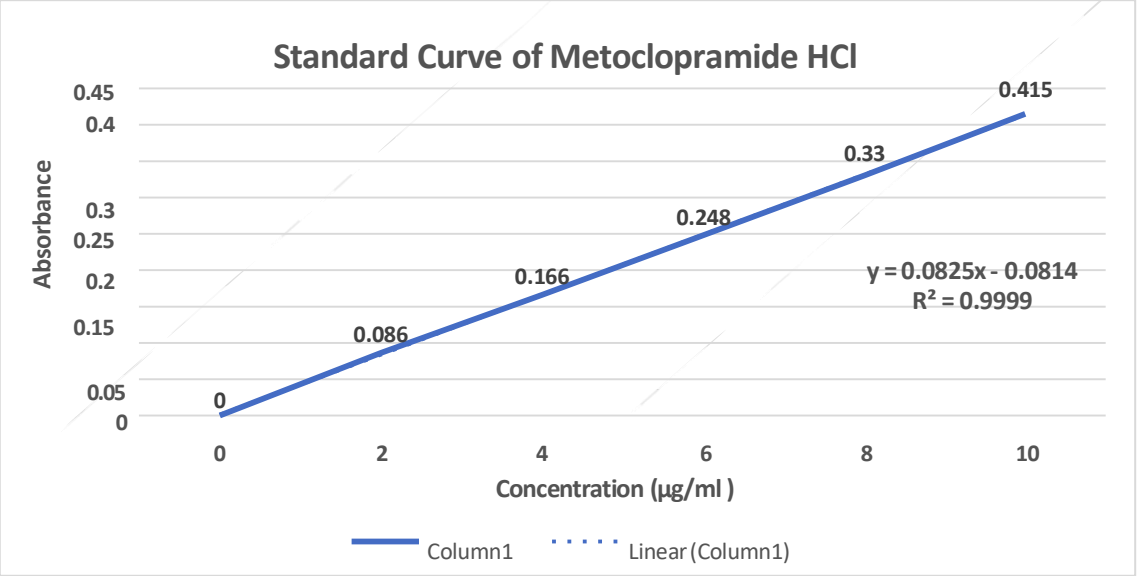

Fig. 4.1 Standard Curve of Metoclopramide HCl

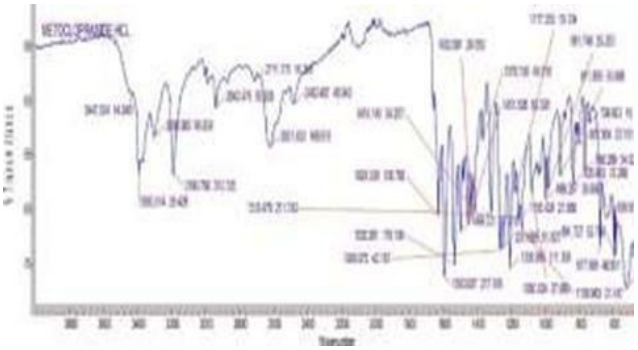

Fig. 4.2 IR Spectrum of Metoclopramide HCl

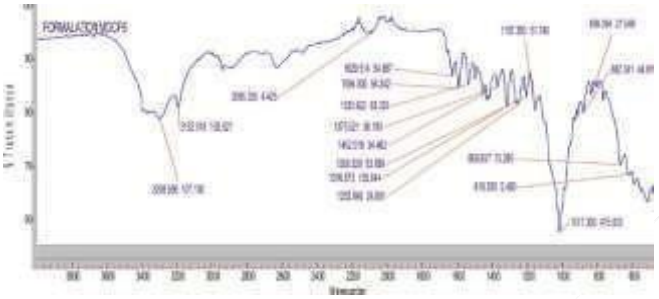

Fig. 4.3 IR Spectrum of Prepared Formulation F06

Table 4.1: Result of Physical Evaluation of different formulations

Formulation	Shape	Thickness (in mm)	Hardness (kg/ cm^2)	Friability (in %)	Weight Variation (in mg)
F01	Circular Disc	2.9 ± 0.1	4.05 ± 0.05	0.85 ± 0.025	97.63 ± 0.562
F02	Circular Disc	2.93 ± 0.05	4.12 ± 0.06	0.59 ± 0.024	98.12 ± 0.425
F03	Circular Disc	3 ± 0.5	4.2 ± 0.104	0.76 ± 0.014	99.25 ± 0.245
F04	Circular Disc	2.83 ± 0.125	4.4 ± 0.1	0.68 ± 0.065	99.31 ± 0.632
F05	Circular Disc	3.1 ± 0.105	4.25 ± 0.15	0.6 ± 0.087	98.66 ± 0.85
F06	Circular Disc	3.06 ± 0.057	4.34 ± 0.06	0.52 ± 0.152	99.28 ± 0.456
F07	Circular Disc	3.08 ± 0.16	4.5 ± 0.076	0.64 ± 0.14	98.99 ± 0.478
F08	Circular Disc	2.95 ± 0.2	4.43 ± 0.057	0.45 ± 0.8	99.85 ± 0.96
F09	Circular Disc	2.96 ± 0.152	4.04 ± 0.18	0.54 ± 0.13	98.65 ± 0.6

**The ± sign represents the acceptable standard deviation for each formulation.

Table 4.2: Result of Chemical Evaluation of different formulations

Formulation	Drug Content (%)	Wetting time (Seconds)	Water Absorption Ratio	In-vitro Disintegration time (Seconds)
F01	97.35 ± 0.476	76.14 ± 0.275	63.75 ± 0.57	80.11 ± 1.219
F02	98.85 ± 0.376	63.13 ± 0.446	57.96 ± 0.135	60.21 ± 0.784
F03	99.35 ± 0.433	37.25 ± 0.665	73.05 ± 0.16	36.52 ± 1.357
F04	99.18 ± 0.405	54.19 ± 0.444	69.47 ± 0.423	51.24 ± 1.242
F05	99.21 ± 0.25	39.34 ± 0.27	74.25 ± 0.206	38.15 ± 1.121
F06	99.70 ± 0.286	29.24 ± 0.43	77.1 ± 0.182	24.53 ± 0.305
F07	99.12 ± 0.543	52.89 ± 0.387	76.3 ± 0.235	50.36 ± 0.789
F08	98.85 ± 0.625	25.41 ± 0.205	80.14 ± 0.255	24.69 ± 1.148
F09	99.16 ± 0.319	12.97 ± 0.149	84.19 ± 0.09	24.78 ± 1.197

**The ± sign represents the acceptable standard deviation for each formulation.

Table 4.3: Drug Dissolution Rate of Prepared Formulation

Time (Minutes)	Sampled Volume (mL)	Absorbance	Concentration (µg/mL)	% Drug Released
0	10	0	0	0
2	10	0.363	36.3	36.3%
4	10	0.545	54.5	54.5%
6	10	0.673	67.3	67.3%
8	10	0.753	75.3	75.3%
10	10	0.826	82.6	82.6%
12	10	0.895	89.5	89.5%

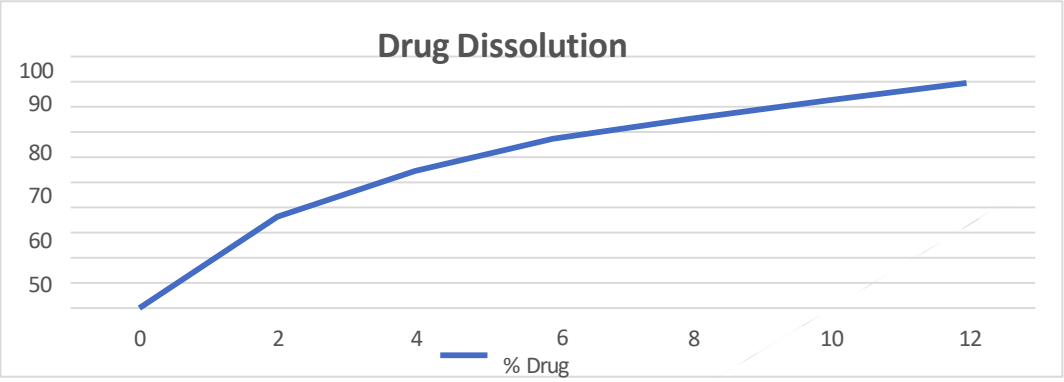

Fig. 4.4 Graphical representation of Drug Dissolution Rateof Prepared Formulation

Table 4.5: Cumulative % drug releaseof F06 and Commercially Used Tablet

Formulation	Cumulative % Drug Release (Time in Min.)						
	pH 6.8 Phosphate Buffer						
	0	2	4	6	8	10	12
F01	0	31.5	51.6	66.2	72.8	79.6	83.4
F02	0	30.8	52.1	65.3	73.1	78.9	84.5
F03	0	32.2	53.4	65.2	72.9	79.1	83.9
F04	0	34.1	55.6	66.8	73.8	80.1	85.6
F05	0	33.8	53.8	65.1	72.9	79.6	83.8
F06	0	36.3	54.5	67.3	75.3	82.6	89.5
F07	0	35.8	53.7	65.4	73.2	80.6	85.6
F08	0	32.8	56.7	67.2	70.1	81.8	87.2
F09	0	33.6	54.8	66.4	74.2	81.5	87.5

Formulation	Cumulative % Drug Release (Time in Min.)						
	pH 6.8 Phosphate Buffer						
	0	2	4	6	8	10	12
F06	0	36.3	54.5	67.3	75.3	82.6	89.5
Commercial Tablet	0	11.5	23.8	32.7	44.1	56.2	72.4

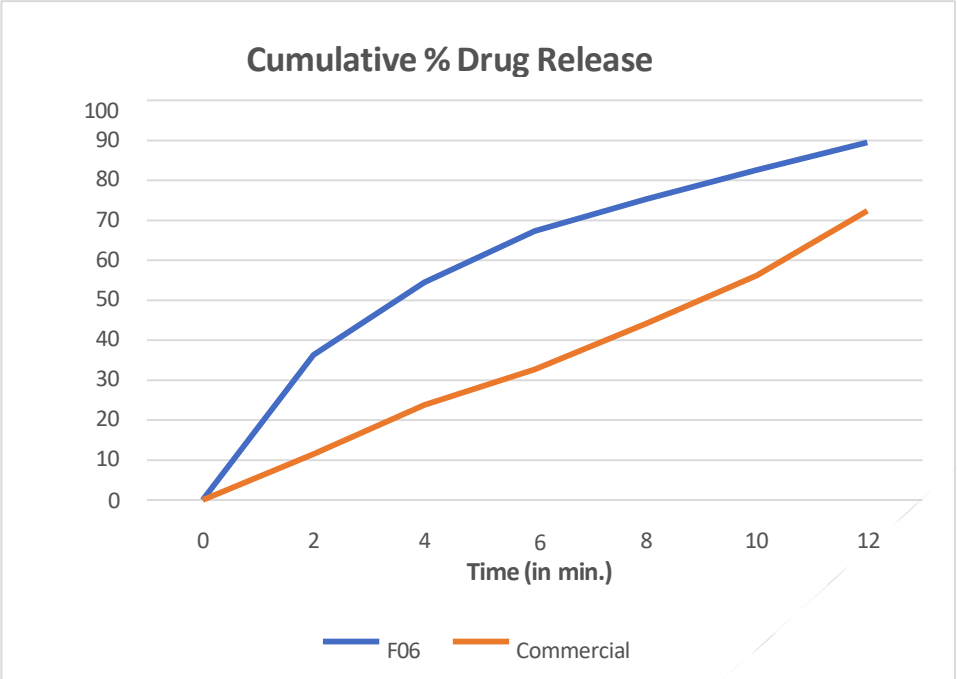

Fig. 4.5 Comparative Study of Cumulative % drug release of F06 and Commercially Used Tablet

Table 4.5: Drug content comparison of preserved formulation

Time	Drug Content (%)	Disintegration time (Seconds)
0 Day	100.95	24.53
30 Days	100.85	24.88
90 Days	100.76	25.03

Table 4.6: Cumulative % Drug Release of preserved formulation

Formulation	Cumulative % Drug Release (Time in Min.)						
	pH 6.8 Phosphate Buffer						
	0	2	4	6	8	10	12
0 Days	0	36.3	54.5	67.3	75.3	82.6	89.5
30 Days	0	36.1	53.8	67.1	74.9	81.6	89.2
90 Days	0	36.1	53.9	66.9	75.1	81.5	88.9

REFERENCES

[1] Kulkarni GT, Gowthamarajan K, Rao BG, Suresh B. Development of fast dissolving tablets of Metoclopramide HCl using natural superdisintegrants. Indian Drugs. 2004;41(10):554–556.

[2] Mohapatra S, Swain RP, Sahoo SK. Formulation development and optimization of fast dissolving tablets of an antiemetic drug. Int J PharmTech Res. 2011;3(2):938–945.

[3] The United States Pharmacopeia (USP 43–NF 38). Rockville, MD: United States Pharmacopeial Convention; 2020.

[4] Deshmukh KR, Mahale GH, Shinde GS. Natural polymers in fast dissolving tablets: A review. Int J Pharm Sci Rev Res. 2012;12(2):124–132.

[5] Indian Pharmacopoeia. Government of India, Ministry of Health and Family Welfare. 2020.

[6] Chandira M, Bhowmik D. Recent trends in ODT formulation and evaluation. J Chem Pharm Res. 2010;2(1):399–410.

[7] Gandhi AM, Patel RK. Natural disintegrants as an alternative to synthetic agents in FDT. Pharm Times. 2013;45(1):30–34.

[8] Avachat AM, Dash RR, Shrotriya SN. Recent investigations of plant- based mucilages as pharmaceutical excipients. Polym Med. 2011;41(3):37–42.

[9] Bhatt DA, Rane BR. Ocimum basilicum: A natural disintegrant in pharmaceutical formulations. Int J Pharm Pharm Sci. 2015;7(6):391– 394.

[10] Patel DM, Patel MM. Optimization of fast dissolving tablets using factorial design. AAPS PharmSciTech. 2008;9(3):998–1005.

[11] ICH Guidelines Q1A(R2) Stability Testing of New Drug Substances and Products. International Conference on Harmonisation; 2003.

[12] Sharma S, Jain CP. Formulation of fast disintegrating tablets using natural superdisintegrants. Pharmacogn Rev. 2014;8(16):202–208