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Research Paper

Engineering Rapidly Disintegrating Oral Dosage Forms of Metoclopramide via Tridax procumbens–Mediated Natural Superdisintegration

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ABSTRACT

The present study aimed to formulate and evaluate fast disintegrating tablets (FDTs) of Metoclopramide HCl using a natural polymer, Tridax procumbens mucilage, alone and in combination with synthetic super disintegrants to achieve rapid drug release and improved patient compliance. A total of twelve formulations (F1–F12) were prepared by direct compression technique, incorporating varying concentrations of Tridax mucilage (4–16 mg) either alone or in combination with croscarmellose sodium (CCS), sodium starch glycolate (SSG), and Crospovidone. Precompression parameters such as angle of repose, Carr's index, and Hausner's ratio indicated good flow properties of all blends. Post compression evaluation confirmed that all tablets complied with pharmacopeial limits for weight variation, hardness, friability, and drug content uniformity. In-vitro dissolution studies revealed that formulations containing only Tridax mucilage exhibited comparatively slower drug release due to viscous gel formation at higher concentrations. In contrast, combination formulations demonstrated enhanced dissolution, with Crospovidone-based formulations showing the fastest release. Among all, formulation F12 (Tridax mucilage 12 mg and Crospovidone 4 mg) was identified as the optimized formulation, exhibiting approximately 70% drug release within 5 minutes, 92% within 10 minutes, and nearly complete release (100%) within 20 to 25 minutes. The improved performance was attributed to the synergistic effect of swelling and rapid wicking action without gel barrier formation. Stability studies of F12 confirmed no significant changes in physicochemical properties and drug release profile under accelerated conditions. The study concludes that the combination of natural and synthetic super disintegrants is an effective approach for developing stable and efficient FDTs of Metoclopramide HCl

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INTRODUCTION

The oral route of drug administration continues to be the most widely accepted owing to its numerous advantages, such as ease of intake, avoidance of pain, convenience, versatility, and most importantly, strong patient compliance. Among the various oral dosage forms, tablets remain the most common. Despite their widespread use, conventional tablets pose a significant challenge for certain patient groups particularly the elderly and children because they often experience difficulty in swallowing. Dysphagia affects more than 35% of the general population, with the highest prevalence in young and elderly individuals, resulting in poor compliance and ineffective therapy. In children, this difficulty is frequently linked to immature neuromuscular coordination. Other groups who may struggle with swallowing solid dosage forms include patients with tremors, mental or developmental disorders, noncooperative individuals, patients with limited fluid intake, and those suffering from nausea.

Swallowing difficulties are also common in conditions such as motion sickness, allergic reactions, persistent coughing, or dehydration. To overcome these limitations, formulation scientists have developed innovative oral dosage systems that rapidly dissolve in saliva without requiring water. These dosage forms, once placed in the mouth, break down or disperse within the saliva typically within 15 seconds to 2 minutes. A faster disintegration process promotes quicker dissolution, absorption, and an earlier onset of therapeutic effect.¹

Over the past years, significant efforts have been directed toward the development of rapidly dissolving tablet technology. These tablets are specifically engineered to disintegrate in the oral cavity without the need for additional water. Various terms have been used to describe them, including orally disintegrating tablets (ODTs), fast

dissolving tablets, rapid-melt tablets, fast dispersing tablets, and quick-dissolve tablets.²

Fast Dissolving Tablets (FDTs)

Fast dissolving tablets are solid oral dosage forms designed to disintegrate quickly in the mouth—generally within 60 seconds—without the need for water. The FDA's Center for Drug Evaluation and Research (CDER) defines them as “solid dosage forms containing medicinal substances that disintegrate rapidly, usually within seconds, when placed on the tongue” (FDA Guidance for Industry, 2007). Both academic researchers and pharmaceutical industries recognize their growing relevance. By 2004 and 2006, the estimated global sales of fast dissolving tablets reached USD 2.4 billion and USD 3 billion, respectively.³

More than 50 marketed products are currently available using different technologies. Common examples include piroxicam (NSAID), risperidone (antipsychotic), rizatriptan (antimigraine), famotidine (antiulcer), ondansetron (antiemetic), selegiline (anti-Parkinson), roxithromycin (antibacterial), and desloratadine (antihistamine). The European Pharmacopoeia defines an orodispersible tablet as a tablet that disperses and disintegrates in the mouth within three minutes before swallowing. In updated FDA draft guidance, orally disintegrating tablets are recommended to be classified as solid oral preparations that dissolve rapidly in the oral cavity, with an in vitro disintegration time of approximately 30 seconds or less, when tested according to USP or alternative validated methods. Once administered, FDTs release the drug in the oral cavity, enabling absorption across the oromucosal tissues, as well as through the pregastric regions (mouth, pharynx, esophagus), and subsequently the gastric and intestinal segments of the gastrointestinal tract.⁴



Advantages of Fast Dissolving Tablets (FDTs)⁵⁻⁶

Fast dissolving tablets offer several notable advantages: Ease of administration FDTs are ideal for pediatric, geriatric, and psychiatric patients, as well as for individuals who cannot swallow conventional tablets, such as those with neurological impairments, disabilities, lack of cooperation, stroke history, or those who are bedridden or institutionalized. Convenient discontinuation of therapy Since these tablets dissolve rapidly in the mouth, treatment can be easily stopped whenever necessary. Rapid dissolution and faster onset of action Quick disintegration increase immediate drug dissolution and absorption. Some drugs may be absorbed in the mouth, pharynx, or esophagus as the dissolved drug travels with saliva, facilitating pregastric absorption. This may enhance bioavailability and reduce the required dose, especially for drugs undergoing extensive first-pass hepatic metabolism, leading to better clinical outcomes and fewer side effects.

Advantages of solid dosage forms FDTs offer the benefits of conventional tablets such as good stability, accurate dosing, ease of manufacturing, smaller packaging, and convenient handling while eliminating swallowing difficulties. Useful for patients without access to water These tablets are especially beneficial for travelers, busy individuals, or anyone who may not have immediate access to water. Combines benefits of liquid and solid dosage forms FDTs provide the ease of administration found in liquid formulations without the risk of choking or obstruction associated with traditional solid forms. Commercial benefits FDTs represent a novel dosage system, offering opportunities for product line extension, lifecycle management, patent protection, product differentiation, and enhanced marketability for pharmaceutical companies.

The effectiveness of FDTs is primarily attributed to their rapid water uptake and fast particle disintegration, resulting in quick drug dissolution. Because absorption can occur through the oral mucosa, these formulations may bypass first-pass metabolism and improve systemic availability. This property, however, depends largely on the physicochemical characteristics of the drug molecule. Market research suggests that over 50% of patients prefer FDTs, and more than 70% would request or purchase them due to their ease of administration, pleasant taste, and availability in multiple flavors.

Methods for Manufacturing Fast Dissolving Tablets⁷⁻¹¹:

Fast dissolving tablets can be produced using several formulation approaches, among which freeze drying, molding, and compression are the most widely adopted techniques

○ Freeze Drying (Lyophilization)

Freeze drying involves removing water from a formulation by sublimation, following the freezing of the product. This technique can be adapted in various ways but always aims to produce a highly porous structure that enables rapid tablet disintegration. One of the major advantages of freeze drying is that it can be conducted at low temperatures, minimizing heat related degradation of thermolabile drugs. Additionally, lyophilized products generally exhibit favorable stability profiles during storage because they remain in a dehydrated state. However, the freeze-drying process is cost-intensive, time-consuming, and requires specialized equipment. Tablets produced using this technique tend to be fragile, making them difficult to package using standard equipment. They may also show reduced stability under extreme conditions such as high humidity or elevated temperatures.

○ Molding



Molded tablets are typically formulated with water-soluble ingredients. During preparation, the powder blend is moistened using a suitable solvent—usually water or ethanol—and then shaped into tablets under lower compression pressures compared to conventional tableting (a process often referred to as compression molding). After shaping, the solvent is removed through air drying. Because molded tablets undergo minimal compression, they possess a highly porous structure that promotes rapid disintegration. Their high sugar content also enhances palatability and provides a pleasant mouthfeel. Despite these advantages, molded tablets generally exhibit poor mechanical strength, making them prone to erosion, chipping, or breaking during handling and packaging. Adding hardness-enhancing agents may improve strength but often slows the disintegration process.

○ **Compression Method**

Compression is the most commonly used method for manufacturing fast dissolving tablets. Researchers have employed various compression-related granulation techniques—including wet granulation, dry granulation, melt granulation, and spray drying—to optimize tablet characteristics. Among these, direct compression stands out as the most efficient, economical, and widely accepted approach. Direct compression is favored because it utilizes standard tableting equipment and readily available excipients, making it highly suitable for large-scale production. By selecting appropriate combinations of superdisintegrants, fillers, and other functional excipients, formulators can achieve FDTs that exhibit rapid disintegration while maintaining adequate mechanical strength.

Patented Technologies for Fast Dissolving Tablets (FDTs) ¹²⁻¹⁵ :

Several patented technologies have been developed for the manufacture of Fast Dissolving

Tablets. These technologies are generally categorized based on the method used freeze drying, molding, or compression—with compression being the most widely employed technique.

ORASOLV and DURASOLV Technologies

Both systems utilize polyols as fillers, disintegrants (often including an effervescent couple), flavoring agents, sweeteners, and lubricants. Drug taste-masking may be achieved through fluid bed coating. Tablets are manufactured by direct compression and can accommodate a wide dosage range from 1mg up to 500 mg.

LYOC Technology

This technology involves preparing a liquid solution or suspension containing the drug, fillers, thickening agents, surfactants, non-volatile flavoring agents, and sweeteners. The homogeneous liquid is deposited into blister cavities and subjected to freeze drying.

ZYDIS Technology

ZYDIS tablets are produced by lyophilizing a drug solution or suspension containing polymers, polysaccharides, preservatives, pH modifiers, flavors, sweeteners, and colorants directly inside blisters. Advantages: extremely rapid disintegration in the Limitations: low throughput, high manufacturing cost, and limited taste-masking capability.

FLASHDOSE Technology

This method uses materials rich in fibrous polysaccharides, which undergo simultaneous flash-melting and centrifugal processing to produce fine sugar fibers. Tablets formed from these fibers are highly porous, hydrophilic, and disintegrate within seconds. They are soft, friable and sensitive to moisture.



WOWTAB Technology

WOWTAB combines low-moldable sugars (e.g., mannitol, lactose, glucose) for rapid dissolution and high-moldable sugars (e.g., maltose, sorbitol, maltitol) to ensure sufficient hardness upon compaction. FLASHTAB Technology Tablets in this system contain a matrix of swellable agents

(e.g., modified starch, microcrystalline cellulose) and superdisintegrants such as croscopovidone or croscarmellose. The active ingredient is taste masked by direct coating. Tablets produced using this technology show good mechanical strength and durability.

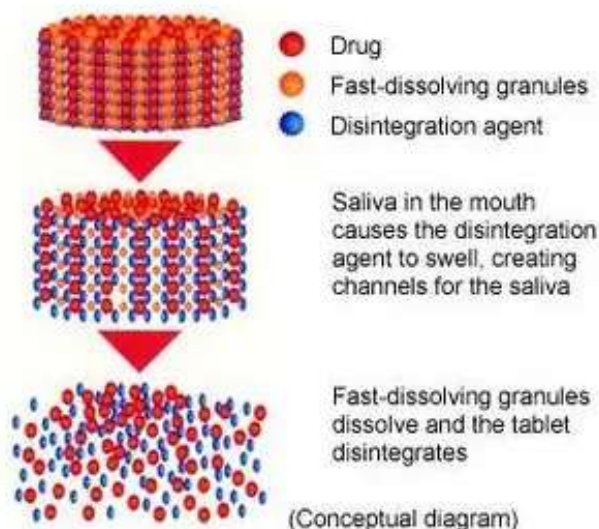


Figure 1: Fast dissolving tablet action to release drug¹⁶

Table 1 : Marketed fast-dissolving/orodispersible tablet (FDT/ODT) products¹⁶⁻¹⁷

Brand (Formulation)	Active ingredient (typical strength)	Technology / Manufacturer (notes)
Zofran ODT	Ondansetron 4–8 mg	Freeze-dried ODT — GlaxoSmithKline / Novartis (Zydis-type lyophilized ODT). (FDA Access Data)
RISPERDAL® M-TAB	Risperidone 0.5, 1, 2 mg	Orally disintegrating tablet — Janssen (direct/compression ODT). (DailyMed)
CLARITIN® RediTabs	Loratadine 5–10 mg	Rapidly disintegrating/orodispersible — Bayer. (FDA Access Data)
Zyprexa Zydis	Olanzapine 5–10 mg	Zydis (lyophilized ODT) — Eli Lilly (very fast mouth disintegration). (Wikipedia)
Abilify Discmelt	Aripiprazole (various strengths)	Discmelt ODT — Otsuka/Bristol-Myers Squibb (orodispersible formulation). (Wikipedia)
Benadryl FastMelt	Diphenhydramine (age-dependent strengths)	Fast-melting ODT — Pfizer (consumer ODT antihistamine). (Wikipedia)
Allegra ODT	Fexofenadine (age-dependent strengths)	Orally disintegrating tablet — Sanofi/Aventis (ODT antihistamine). (Wikipedia)
Zomig-ZMT	Zolmitriptan (migraine)	ZMT orally disintegrating tablet — AstraZeneca (ODT/trade formulation). (Wikipedia)

RATIONALE OF THE STUDY :

Metoclopramide hydrochloride is an antiemetic and prokinetic agent commonly prescribed for

nausea, vomiting, gastroesophageal reflux, and migraine-related gastric stasis. However, traditional tablets may be difficult to swallow for pediatric, geriatric, bedridden, and dysphagic



patients leading to poor compliance and therapeutic failure.

Fast dissolving tablets overcome this limitation by disintegrating quickly in the oral cavity without water, ensuring rapid onset of action and improved patient convenience. Natural polymers and mucilages are gaining attention as safe, biodegradable, economical, and biocompatible alternatives to synthetic excipients.

Tridax procumbens, a widely available medicinal plant, contains mucilage with promising swelling and disintegration properties, yet its application in fast dissolving tablet formulations remains underexplored.

Using Tridax procumbens mucilage as a natural superdisintegrant may:

- Enhance tablet disintegration and dissolution
- Reduce dependency on costly synthetic excipients

- Offer eco-friendly and biocompatible formulation options
- Exploit local, easily available plant resources
- Improve mouthfeel and patient acceptability
- Support development of novel natural excipient based FDTs

Therefore, incorporating Tridax procumbens mucilage into Metoclopramide FDTs presents an innovative and sustainable approach to improving drug delivery, ensuring rapid therapeutic response, and enhancing patient compliance.

EXPERIMENTAL WORK:

MATERIALS:

The following materials collected for the experimental work done.

Table 2 : List of materials

SR.NO.	DRUG/EXCIPIENTS	GRADE	GIFTED/MFG.BY
1	Metoclopramide hydrochloride	AR	Angle Bio Pharma
2	Croscarmellose Sodium	AR	Merck, India
3	Sodium Starch Glycolate	AR	S.D. Fine Chemicals Ltd
4	HPMC	AR	Merck, India
5	Magnesium stearate	AR	S.D. Fine Chemicals Ltd
6	Microcrystalline cellulose	AR	S.D. Fine Chemicals Ltd
7	Lactose	AR	S.D. Fine Chemicals Ltd
8	Aspartame	AR	S.D. Fine Chemicals Ltd

Table 3: Natural Polymer List

Polymer	Isolated From	Botanical Name
Tridax procumbens mucilage	Leaves (mainly fresh leaves)	Tridax procumbens L.

Mucilage Overview

Mucilage from Tridax procumbens is a natural, hydrophilic polysaccharide that exhibits gel-forming properties in water. It is biodegradable, non-toxic, and biocompatible, which makes it an attractive natural excipient for pharmaceutical applications.

Plant Part Used : leaves or aerial parts are commonly used to extract mucilage.

Physical Nature: Typically appears as a pale, off-white to yellowish powder after extraction and drying.

Solubility: Hydrophilic; forms viscous gel upon contact with water.

Extraction Procedure

The mucilage can be extracted through the following steps:



1. Collection and Cleaning: Fresh aerial parts or leaves are collected, washed thoroughly to remove dirt and impurities.
2. Powdering: Dried plant material is powdered.
3. Aqueous Extraction: Powder is soaked in distilled water for several hours to allow mucilage to dissolve.
4. Filtration: The solution is filtered to remove insoluble plant residues.
5. Precipitation: Alcohol (ethanol or isopropanol) is added to the filtrate to precipitate the mucilage.
6. Drying: The precipitate is dried in a hot air oven or lyophilized to obtain a fine powdered mucilage. This method yields pure, concentrated mucilage suitable for pharmaceutical formulation

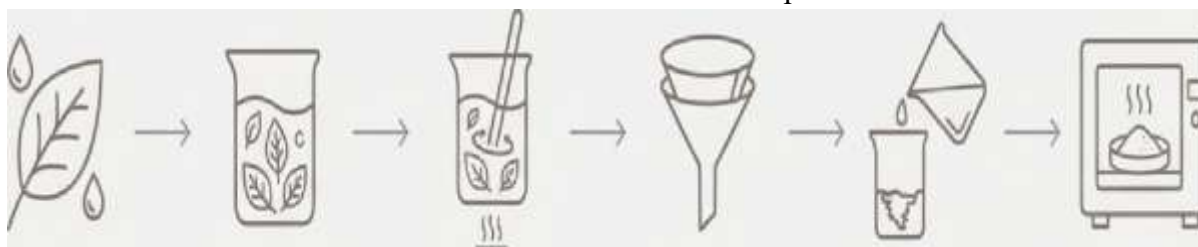


Figure 2 : Extraction Procedure of mucilage

Preparation Tablet :

A. Fast disintegrating tablets of Metoclopramide hydrochloride using Tridax procumbens mucilage(F1 to F3)

Formulations F1–F4 were developed to evaluate the suitability of Tridax procumbens mucilage as a sole natural superdisintegrant in fast dissolving tablets. The concentration of mucilage was systematically increased from 4 mg to 16 mg to

determine its optimum level for achieving acceptable tablet performance. The purpose of this design was to establish a baseline formulation and to assess whether the natural polymer alone can provide sufficient disintegration efficiency while maintaining tablet integrity. These batches also used in identifying the ideal concentration range of Tridax mucilage for further combination studies.¹⁸⁻¹⁹

Table 4 : Composition of Tridax procumbens mucilage based fast disintegrating tablets of Metoclopramide hydrochloride

Ingredients	F1	F2	F3	F4
Metoclopramide HCl	10	10	10	10
Tridax mucilage	4	8	12	16
CCS	—	—	—	—
SSG	—	—	—	—
Crospovidone	—	—	—	—
MCC	40	40	40	40
Aspartame	7	7	7	7
Talc	4	4	4	4
Magnesium stearate	3	3	3	3
Mannitol (q.s. to 200 mg)	132	128	124	120
Total weight (mg)	200	200	200	200

*All the quantities are in mg

B. Fast disintegrating tablets of procumbens & Croscarmellose sodium (F5 to F8) using Tridax Metoclopramide hydrochloride

Formulations F5–F8 were designed to study the combined effect of Tridax mucilage with Croscarmellose Sodium (CCS). A fixed quantity of CCS (4 mg) was incorporated along with increasing concentrations of Tridax mucilage (4–16 mg) to evaluate the potential improvement in tablet performance compared to natural polymer

alone. The purpose of this combination was to determine whether the addition of a synthetic superdisintegrant can enhance the efficiency of the natural polymer and provide a more optimized formulation. These batches also help in comparing the performance of hybrid systems with individual components.¹⁸

Table 5 : Composition of Croscarmellose sodium based fast disintegrating tablets of Metoclopramide hydrochloride

Ingredients	F5	F6	F7	F8
Metoclopramide HCl	10	10	10	10
Tridax mucilage	4	8	12	16
CCS	4	4	4	4
SSG	–	–	–	–
Crospovidone	–	–	–	–
MCC	40	40	40	40
Aspartame	7	7	7	7
Talc	4	4	4	4
Magnesium stearate	3	3	3	3
Mannitol (q.s. to 200 mg)	128	124	120	116
Total weight (mg)	200	200	200	200

*All the quantities are in mg

C. Fast disintegrating tablets of Metoclopramide hydrochloride using Tridax procumbens & Sodium Starch Glycolate (F9 & F10)

Formulations F9 and F10 were prepared using Sodium Starch Glycolate (SSG) in combination with Tridax mucilage to examine another synthetic-natural combination. The concentration

of Tridax mucilage was varied (8 mg and 12 mg) while keeping SSG constant at 4 mg. The objective of these formulations was to evaluate the effectiveness of SSG as a complementary superdisintegrant with the natural polymer and to compare its performance with CCS-based formulations.¹⁸⁻¹⁹

Table 6 : Composition of Tridax procumbens & Sodium Starch Glycolate based fast disintegrating tablets of Metoclopramide hydrochloride

Ingredients	F9	F10
Metoclopramide HCl	10	10
Tridax mucilage	8	12
CCS	–	–
SSG	4	4
Crospovidone	–	–
MCC	40	40
Aspartame	7	7
Talc	4	4
Magnesium stearate	3	3
Mannitol (q.s. to 200 mg)	124	120
Total weight (mg)	200	200

*All the quantities are in mg



D Fast disintegrating tablets of Metoclopramide hydrochloride using Tridax procumbens & Crospovidone (F11 to F12)

Formulations F11 and F12 were designed using Crospovidone in combination with Tridax mucilage to assess the performance of another widely used synthetic superdisintegrant. Crospovidone was incorporated at a fixed level (4 mg), while Tridax mucilage was used at 8 mg and

12 mg. The rationale of these formulations was to explore whether this combination can produce superior tablet characteristics compared to other batches and to identify the most effective formulation approach. These batches also serve to compare the efficiency of different synthetic superdisintegrants when combined with the same natural polymer.

Table 7: Composition of Tridax procumbens & Crospovidone based fast disintegrating tablets of Metoclopramide hydrochloride

Ingredients	F11	F12
Metoclopramide HCl	10	10
Tridax mucilage	8	12
CCS	—	—
SSG	—	—
Crospovidone	4	4
MCC	40	40
Aspartame	7	7
Talc	4	4
Magnesium stearate	3	3
Mannitol (q.s. to 200 mg)	124	120
Total weight (mg)	200	200

*All the quantities are in mg

RESULT

Evaluation of fast disintegrating tablets Evaluation of matrix tablet²⁰⁻²⁴

Physical characterization of tablet

Hardness

The susceptibility of tablets to transportation or breakage during circumstances of storage, journey and handling before consuming relies on their hardness. The hardness of tablet for each formulation has been measured using Monsanto hardness tester. The hardness was measured in units of kg/cm².

Thickness

Thickness and diameter of tablets were essential for constancy of tablet size. Thickness and diameter have been determined using Vernier Calipers.

Friability

Friability is an indicator of tablet strength. Roche friabilator was implemented for measuring the friability using the following approach. Ten tablets have been weighed appropriately and inserted in the tumbling contraption which revolves at 25 rpm dropping the tablets throughout a distance of six inches during each rotation. Following 4 min., the



tablets were weighed as well as the % reduction in tablet weight was taken into account.

(% loss)

$$= \frac{\text{Initial weight of tablet} - \text{Final weight of Tablets}}{\text{Initial weight of tablet}}$$

Uniformity of Weight

Weigh 10 tablets taken at random and compute the average weight. Not more than two of the individual weights vary from the average weight by more than the percentage stated in Table 5.14.

Table 8 : IP Standards of Uniformity of weight

Sr. No.	Avg. wt. of tablet	% of deviation
1	80 mg or <80	10
2	>80 to <250mg	7.5
3	➤ 250 or more	5

As the total tablet weight was 200 mg, according to IP 1996, out of twenty tablets $\pm 7.5\%$ variation can be allowed for not more than two tablets.

According to USP 2004, $\pm 10\%$ weight variation can be allowed for not more than two tablets out of twenty tablets.

Determination of drug content

Five tablets were weighed individually, then put in a mortar and ground using a pestle. A quantity comparable to 50 mg drugs was extracted in phosphate buffer pH 6.8 and shaken for 15 minutes. The 2ml of this solution had been again diluted to 10ml with phosphate buffer pH 6.8. This solution was then examined spectrophotometrically at 272nm.²⁵

Water Absorption Ratio (R) Test

It is an essential evaluation parameter for Loratadine Fast Dissolving Tablets (FDTs) to assess their ability to absorb moisture and facilitate rapid disintegration. This test helps determine the hydrophilicity and porosity of the tablet formulation, which directly influences the wetting time and disintegration efficiency. The procedure begins by placing a circular tissue paper (10 cm diameter) inside a Petri dish and saturating it with 5 mL of distilled water. A pre-weighed tablet (W_1) is carefully placed on the wet tissue paper, ensuring uniform contact with moisture. As the tablet absorbs water, it begins to swell, and after 30 seconds, the tablet is carefully removed using

forceps and immediately weighed again (W_2). The Water Absorption Ratio (R) is then calculated using the formula:

$$R = \frac{W_2 - W_1 \times 100}{W_1}$$

where W_1 is the initial tablet weight, and W_2 is the weight after water absorption. A higher water absorption ratio indicates better hydrophilicity and improved wettability, which are crucial for FDT formulations to disintegrate quickly in the oral cavity.

This test is particularly important for evaluating the effectiveness of superdisintegrants and ensuring that the tablet dissolves efficiently with minimal saliva, providing a fast onset of action and enhanced patient compliance, especially for individuals with swallowing difficulties.

Invitro studies

The USP type II dissolution apparatus has been used to carry out an in vitro drug release experiment utilizing dissolving System Lab india Analytical Instruments Pvt Ltd. Mumbai with an unchanged temperature water bath at $37^\circ\text{C} \pm 1^\circ\text{C}$. Drug release was assessed by dissolution test under the following conditions: $n = 3$, USP type II dissolution apparatus (paddle method) at 50 rpm in 900 mL of pH6.8 Phosphate buffer for one hours maintained at $37^\circ\text{C} \pm 0.5^\circ\text{C}$. An aliquot (5mL) was withdrawn at specific time intervals and replaced with the same volume of preheated ($37^\circ\text{C} \pm 0.5^\circ\text{C}$)



fresh dissolution medium. The samples withdrawn were filtered through Whatman filter paper (No.1) and drug content in each sample was analyzed by UV-visible spectrophotometer at 272 nm.

Details of dissolution test:

Dissolution test apparatus : USP II
 Speed : 50 ± 0.1 rpm
 Stirrer : Paddle type
 Volume of medium : 900 ml
 Time interval : 5, 10, 15, 20, 25, 30, 45, 60 min
 Medium used : pH 6.8 Phosphate buffer
 Temperature : 37 ± 0.5 °C

Stability studies of the optimized formulation:²⁶⁻³²

Stability of a pharmaceutical preparation can be defined as “the capability of a particular formulation in a specific container/closure system to remain within its physical, chemical, microbiological, therapeutic and toxicological specifications throughout its shelf life.”

The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under influence of a

variety of environmental factors such as temperature, humidity and light, and enables recommended storage conditions, re-test periods and shelf-lives to be established.

ICH specifications for stability study:

Long term testing: $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $60\% \text{ RH} \pm 5\% \text{ RH}$ for 12 months. Accelerated testing: $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75\% \text{ RH} \pm 5\% \text{ RH}$ for 6 months. Procedure:

In the present study, stability studies were carried out at 40°C and 75% RH for a specific time period up to 60 days for optimized formulations.

For stability study, the tablets were sealed in aluminum packaging coated inside with polyethylene. These sample containers were placed in desiccator's maintained at 75% RH.

U.V scanning of Metoclopramide Hcl :

Measurement of Absorbance

- **UV Spectrophotometer Setup:** Wavelength range for UV-Vis spectrophotometry (typically 200-400 nm) is set and select the wavelength at which Metoclopramide Hcl shows maximum absorbance (λ_{max} 272 nm).
- **Scanning:** Scan the prepared standard solutions in the UV-Vis spectrophotometer.³³⁻³⁴

Table 9: Calibration curve Metoclopramide Hcl in pH 6.8 phosphate buffer

Concentration (mcg/ml)	Absorbance (272nm)
0	0
4	0.09
8	0.184
12	0.266
16	0.359
20	0.463
24	0.555



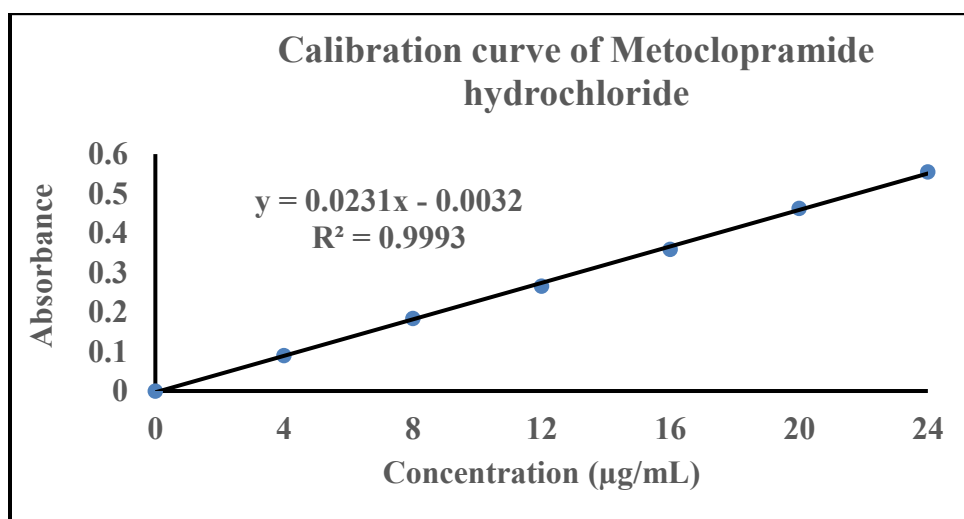


Figure 3 : Calibration curve Metoclopramide Hcl in pH 6.8 phosphate buffer

The absorbance maximum (λ max) of Metoclopramide Hcl was found to be 272 nm. The standard calibration curve of Metoclopramide Hcl is shown in Figure 6.1. The standard calibration curve was shown good linearity with the r^2 value 0.9993.

FTIR studies

In the current investigation, Fourier transforms infrared spectroscopy (FTIR) data of the most effective formulation has been correlated with the reference spectrum of pure drugs Metoclopramide Hcl over the range 400-4000 cm^{-1} examined.

The spectrum shows characteristic absorption peaks corresponding to its chemical structure. A prominent peak at around 3191 cm^{-1} indicates N–H stretching of secondary amine groups, while the peak at 2930 cm^{-1} corresponds to aliphatic C–H stretching. The strong band observed near 1629 cm^{-1} is attributed to C=O stretching (amide group), which is a key functional group in the drug molecule. Peaks at 1534–1590 cm^{-1} represent aromatic C=C stretching and N–H bending, confirming the presence of an aromatic ring system. The band around 1454 cm^{-1} is due to C–H bending, while peaks at 1255 cm^{-1} and 1007 cm^{-1} indicate C–N and C–O stretching vibrations.

Additionally, peaks in the region of 933 cm^{-1} and 763 cm^{-1} correspond to aromatic substitution patterns (out-of-plane bending). These peaks collectively confirm the identity and structural integrity of the drug.

FTIR of Metoclopramide hydrochloride with mixture (drug + excipients):

In the mixture spectrum, all the characteristic peaks of Metoclopramide hydrochloride are retained with only minor shifts. The N–H stretching peak appears at 3189 cm^{-1} , and C–H stretching remains around 2929 cm^{-1} , indicating no significant alteration. The amide C=O peak (1628 cm^{-1}) and aromatic peaks (1591–1537 cm^{-1}) are still present, confirming preservation of the drug's core structure. Additional peaks such as 1149 cm^{-1} and 1335 cm^{-1} may arise from excipients (e.g., polysaccharides or mucilage), indicating their presence in the formulation. Importantly, there is no disappearance of major peaks, no formation of new peaks, and only slight shifts in peak positions, which suggests absence of chemical interaction between the drug and excipients. These minor shifts can be attributed to physical interactions such as hydrogen bonding or molecular dispersion rather than incompatibility.

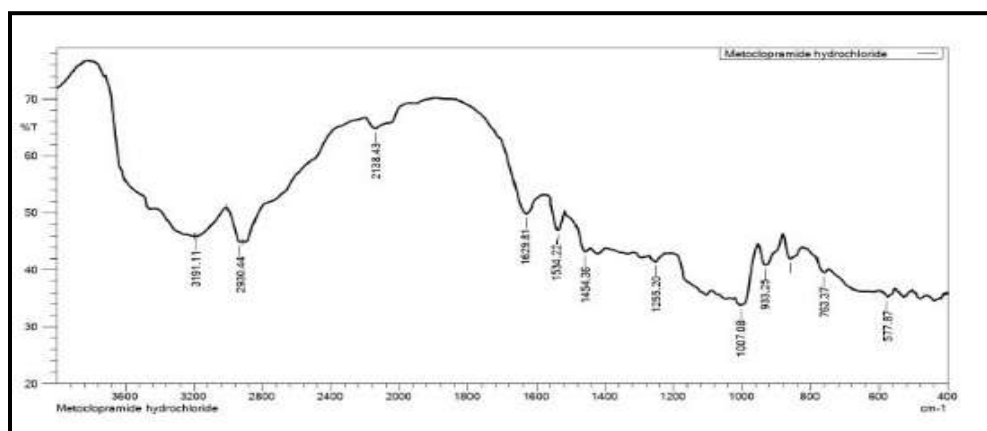


Figure 4 : FTIR spectrum of Metoclopramide Hcl

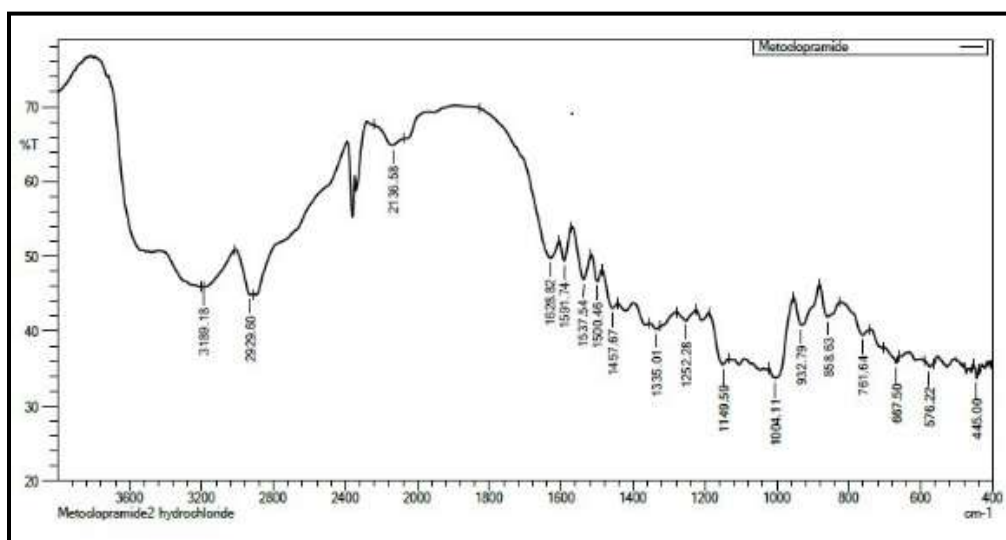


Figure 5 : FTIR spectrum of Metoclopramide Hcl with Excipients

SUMMARY AND CONCLUSION

The present study successfully developed fast disintegrating tablets (FDTs) of Metoclopramide HCl using *Tridax procumbens* mucilage as a natural superdisintegrant, both alone and in combination with synthetic superdisintegrants.

The rationale for selecting Metoclopramide HCl was based on its need for rapid onset of action in the management of nausea and vomiting, where FDTs provide improved patient compliance and faster therapeutic effect.

The study aimed to formulate and optimize FDTs by evaluating the performance of natural polymer alone and in combination with croscarmellose sodium (CCS), sodium starch glycolate (SSG), and

Crospovidone. A total of twelve formulations (F1–F12) were prepared using direct compression, with varying concentrations of *Tridax mucilage* and different synthetic superdisintegrants.

Precompression studies confirmed that all powder blends exhibited good flow properties, with acceptable angle of repose, Carr's index, and Hausner's ratio, ensuring uniform die filling and suitability for tablet compression.

Postcompression evaluation showed that all formulations complied with pharmacopeial limits for weight variation, hardness, friability, and drug content, indicating good mechanical integrity and uniformity. Disintegration time and wetting time were significantly influenced by the type and concentration of polymer used, with combination

formulations showing faster disintegration compared to those containing only mucilage.

In-vitro dissolution studies revealed that formulations containing only Tridax mucilage (F1–F4) showed slower drug release due to formation of a viscous gel barrier at higher concentrations, despite improved swelling.

Formulations with CCS (F5–F8) demonstrated enhanced drug release due to combined swelling and wicking mechanisms, while SSG-containing formulations (F9–F10) showed moderate release owing to gel formation tendencies.

The most rapid drug release was observed in Crospovidone-based formulations (F11–F12), attributed to its strong capillary action and non-gelling behavior, which facilitated quick disintegration and immediate drug release.

Among all formulations, F12 was identified as the optimized formulation, containing 12 mg of Tridax mucilage and 4 mg of Crospovidone. This formulation exhibited superior performance with approximately 70% drug release within 5 minutes, about 92% release within 10 minutes, nearly 99% release at 15 minutes, and complete drug release (100%) within 20–25 minutes.

Additionally, F12 showed rapid disintegration, minimal wetting time, excellent drug content uniformity, and satisfactory mechanical strength. The enhanced performance of F12 can be attributed to the synergistic effect of Tridax mucilage providing adequate swelling and Crospovidone promoting rapid wicking without forming a viscous barrier, resulting in efficient tablet disintegration and drug dissolution.

Furthermore, stability studies of the optimized formulation F12 indicated no significant changes in physical characteristics, drug content, disintegration time, or dissolution profile under accelerated conditions, confirming its stability and reliability. In conclusion, the study demonstrates that the combination of natural and synthetic superdisintegrants is an effective strategy for

developing high-performance FDTs. The optimized formulation F12 offers rapid drug release, improved patient compliance, and stable performance, making it a promising candidate for the effective delivery of Metoclopramide HCl.

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