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Research Article

Review on use of Natural Disintegrants for formulation of Metoclopramide Oral Disintegrating Tablet

Priyanshi Mehta^{1*}, Dr. Akanksha Jagwani², Mr. Narendra Gehalot³, Dr. Vikas Jain⁴

^{1*}(Student) Mahakal Institute of Pharmaceutical Studies, Ujjain, MP, India

²Associate Professor Mahakal Institute of Pharmaceutical Studies, Ujjain, MP, India

³Associate Professor, Mahakal Institute of Pharmaceutical Studies, Ujjain, MP, India

⁴Principal Mahakal Institute of Pharmaceutical Studies, Ujjain, MP, India

Abstract

The development of orally disintegrating tablets (ODTs) has revolutionized drug delivery, particularly for populations with swallowing difficulties such as pediatric, geriatric, and psychiatric patients. Traditional synthetic superdisintegrants have long played a pivotal role in ODT formulation, but growing interest in natural, sustainable, and biocompatible alternatives has prompted extensive research into plant-derived excipients. This review focuses on the evolving landscape of natural superdisintegrants, with particular emphasis on *Plantago ovata* (psyllium husk) and *Ocimum basilicum* (sweet basil) mucilages, which have demonstrated significant potential in enhancing the disintegration and dissolution profiles of ODTs. Natural mucilages offer several advantages, including biodegradability, non-toxicity, economic viability, and multifunctionality as disintegrants, binders, and release modifiers. Their physicochemical properties, mechanisms of action, extraction techniques, and comparative performance with synthetic disintegrants are critically evaluated. Recent advancements in the formulation of Metoclopramide HCl ODTs using these natural polymers are discussed as a case example, highlighting improved dispersion time, enhanced water absorption, and rapid drug release. The review also explores formulation challenges, regulatory considerations, and future prospects including industrial scalability, in vivo performance evaluation, and broader applicability to other therapeutic classes. By synthesizing current literature and research findings, this article underscores the growing promise of natural superdisintegrants in ODT technology and advocates for their wider adoption as part of a patient-centric, eco-friendly approach to oral drug delivery.

Keywords: Orally disintegrating tablets, ODTs, Metoclopramide, Superdisintegrants, *Plantago ovata*, *Ocimum basilicum*

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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.[1-3] 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. [4] 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 croscopovidone, sodium starch glycolate, and croscarmellose sodium have been extensively used to achieve the desired disintegration profile in ODTs. [5]

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. [6-8] Metoclopramide HCl, a dopamine D₂ receptor antagonist, is a well-established antiemetic and gastroprokinetic agent used in the management of nausea, vomiting, and delayed gastric emptying associated with gastroparesis. [9] The drug exhibits high aqueous solubility and oral bioavailability (>80%), making it an ideal candidate for incorporation into ODT formulations. The conventional tablet form of Metoclopramide is often associated with delayed onset of action and difficulty in swallowing, particularly in patients experiencing nausea or gastrointestinal discomfort. Therefore, developing an ODT formulation of Metoclopramide offers significant clinical and therapeutic benefits. [10-11]

In light of these considerations, the present review explores the formulation and optimization of Metoclopramide HCl ODTs using natural superdisintegrants, with a focus on *Plantago ovata* and *Ocimum basilicum* mucilages. [12]

The selection of these mucilages was based on their well-documented swelling behavior, ease of extraction, and proven pharmaceutical applicability. This review integrates findings from recent studies, including our own research, where a systematic approach involving factorial design and direct compression technique was employed to develop and evaluate a series of Metoclopramide ODT formulations.

The tablets were assessed for various pre-compression and post-compression parameters such as hardness, friability, weight variation, disintegration time, wetting

time, water absorption ratio, and in vitro drug release. Notably, the formulation designated as F06, containing 6 mg of *Plantago ovata* mucilage and 8 mg of *Ocimum basilicum* mucilage, demonstrated excellent performance with rapid dispersion (~12 seconds), high water absorption (~80%), and drug release exceeding 89% within 12 minutes. These outcomes highlight the functional efficacy of these natural disintegrants in enhancing the disintegration profile of ODTs and ensuring rapid therapeutic onset.

This review article aims to present a holistic overview of the role of natural superdisintegrants in ODT technology, with specific reference to *Plantago ovata* and *Ocimum basilicum* mucilages. [13] The review discusses the origin, extraction, and physicochemical properties of these mucilages; their mechanisms of action as superdisintegrants; comparative performance with synthetic counterparts; formulation challenges; and future research prospects. Moreover, the findings from our experimental study on Metoclopramide ODTs are integrated to provide practical insights into formulation strategies and optimization techniques using natural polymers.

In addition to addressing the technical aspects, this review also delves into the broader implications of adopting natural excipients in pharmaceutical formulations. With increasing emphasis on green chemistry, sustainability, and patient-centric drug design, natural disintegrants offer a compelling alternative that aligns with modern pharmaceutical goals. Their use not only enhances product safety and acceptability but also supports eco-friendly manufacturing practices, thereby contributing to environmental stewardship.

Furthermore, this article underscores the potential for scaling up such natural polymer-based formulations for industrial production, provided that challenges related to standardization, microbial load, and batch-to-batch variability are effectively addressed. Regulatory aspects, safety evaluations, and pharmacokinetic profiling also warrant further exploration to enable widespread adoption of these excipients in commercial pharmaceutical products.

This review consolidates the current knowledge on natural superdisintegrants in ODTs, presents empirical data from experimental studies, and identifies critical avenues for future research aimed at optimizing natural polymer-based oral drug delivery systems.

Metoclopramide HCl

Metoclopramide HCl is a well-established dopamine D₂ receptor antagonist with pronounced antiemetic and gastroprokinetic properties. It is commonly prescribed for the management of nausea and vomiting, especially associated with chemotherapy, postoperative recovery, and gastrointestinal disorders such as gastroparesis. The drug exerts its therapeutic action by enhancing the response of the upper gastrointestinal tract to acetylcholine, thereby increasing gastric emptying without stimulating gastric, biliary, or pancreatic secretions. [14-18]

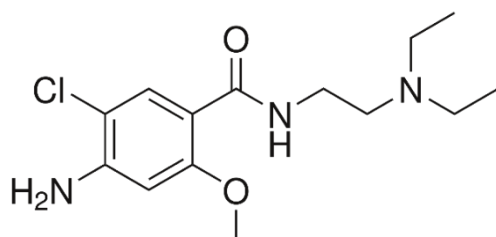


Fig. 1. Structural formula of Metoclopramide

Metoclopramide is classified as a Biopharmaceutical Classification System (BCS) Class I drug, indicating high solubility and high permeability. Its aqueous solubility ensures rapid dissolution in the gastrointestinal tract, while its oral bioavailability exceeds 80%, which makes it an ideal candidate for immediate-release formulations like ODTs. [19-21]

Despite these advantages, conventional tablet forms of Metoclopramide can be suboptimal for certain patient populations. In individuals experiencing nausea, the swallowing of tablets can be difficult or unpleasant, potentially leading to reduced adherence and delayed therapeutic effect. Furthermore, conventional oral tablets may not provide the rapid onset of action required for acute emetic episodes. These limitations create a compelling case for the development of an ODT formulation of Metoclopramide that can rapidly disintegrate and release the drug in the oral cavity, bypassing the need for water and ensuring faster onset of therapeutic action.

Advantages of Orally Disintegrating Tablets (ODTs)

ODTs are solid dosage forms that disintegrate rapidly in the mouth, typically within 60 seconds, without the need for water. The advantages of ODTs extend across several therapeutic and patient-centric dimensions:

- Improved patient compliance, especially among pediatric and geriatric populations, and patients with dysphagia.
- Rapid onset of action, due to faster disintegration and absorption, sometimes directly through the oral mucosa.
- Convenient administration for travelers, during motion sickness, or when access to water is limited.
- Reduced risk of choking, making them safer for elderly and pediatric patients.
- Enhanced bioavailability in certain cases, by bypassing hepatic first-pass metabolism via buccal absorption. [22- 26]

The formulation of effective ODTs hinges on multiple formulation parameters, chief among them being the selection of superdisintegrants. These agents are crucial for ensuring the tablet breaks apart quickly upon contact with saliva.

Mechanisms of Superdisintegrants

Superdisintegrants are excipients specifically added to oral solid dosage forms to promote rapid breakup of the tablet into smaller fragments, thereby enhancing

dissolution.[27-30] The primary mechanisms by which superdisintegrants act include:

- **Swelling:** Absorption of water leads to expansion and rupture of the tablet matrix. [31]
- **Wicking (capillary action):** Water is drawn into the tablet through pores, breaking the interparticle bonds. [32]
- **Deformation recovery:** Particles compressed during tableting expand upon hydration, aiding disintegration. [33]
- **Heat of wetting and repulsion:** Less common mechanisms but contribute in specific formulations. [34]

The efficacy of a superdisintegrant depends on its particle size, hydrophilicity, gel-forming ability, and interaction with other excipients. Synthetic superdisintegrants like croscopovidone and croscarmellose sodium have dominated the pharmaceutical industry due to their reproducible performance. [35-38] However, they are not without limitations, such as cost, synthetic origin, regulatory scrutiny, and occasional mucosal irritation, prompting the exploration of natural alternatives.

Natural Superdisintegrants: Rising Alternatives

In recent years, the pharmaceutical industry has witnessed a growing trend toward the use of natural polymers due to their wide availability, cost-effectiveness, biocompatibility, and sustainability. Natural disintegrants often display multi- functionality—acting not only as isintegrants but also as binders, stabilizers, and viscosity modifiers. [39-40]

Some commonly explored natural superdisintegrants include:

- *Plantago ovata* (psyllium husk)
- *Ocimum basilicum* (sweet basil seeds)
- *Lepidium sativum* (garden cress)
- *Hibiscus rosa-sinensis*
- *Fenugreek* (*Trigonella foenum- graecum*)
- *Guar gum* and *Locust bean gum*

These materials primarily act through swelling and gel formation, facilitating rapid water uptake and disintegration of the tablet matrix.[41-42] Among them, *Plantago ovata* and *Ocimum basilicum* mucilages have received increasing attention due to their robust swelling capacity and ease of extraction.

Plantago ovata and *Ocimum basilicum* Mucilages in ODTs

Plantago ovata, commonly known as psyllium, is a plant native to India and other parts of Asia. The seed husk contains a high proportion of hydrophilic mucilage, which can swell up to ten times its original volume in aqueous environments. This property makes psyllium an excellent disintegrant, binder, and controlled-release agent in pharmaceutical formulations.[43-44]

Key properties:

- High swelling index
- Excellent water absorption ratio
- Non-toxic and biocompatible
- Readily available and cost-effective

Psyllium husk has been used in ODTs as a disintegrant due to its ability to rapidly swell and disrupt the tablet matrix, promoting faster drug release.

Ocimum basilicum, commonly known as sweet basil, contains mucilaginous substances predominantly made up of complex polysaccharides like glucomannans and xyloglucans. When hydrated, basil seed mucilage forms a gel-like layer that enables rapid swelling and disintegration. [45-46]

Key advantages:

- High hydration capacity
- Smooth gel formation that contributes to mouthfeel
- Stabilizing and thickening properties
- Natural origin with low toxicity

Basil seed mucilage also demonstrates potential for taste-masking and improved mouthfeel, making it particularly suitable for ODT formulations targeting sensitive populations. [47-48]

The synergistic use of *Plantago ovata* and *Ocimum basilicum* mucilages can result in optimized disintegration performance by leveraging the swelling capacity of psyllium and the hydrating gel-forming ability of basil seeds. This combination, as demonstrated in your research with formulation F06, significantly improves dispersion time and drug release, validating their potential in replacing synthetic disintegrants.

Comparative Evaluation of Natural and Synthetic Superdisintegrants

To assess the performance of superdisintegrants in orally disintegrating tablet (ODT) formulations, a range of physicochemical and pharmacotechnical parameters are evaluated.[49-50] These include:

- Disintegration time

- Wetting time
- Water absorption ratio
- In vitro drug release profile
- Mechanical strength (hardness and friability)
- Uniformity of content
- Stability (short-term and long-term)
- Organoleptic properties (e.g., mouthfeel, taste masking)

An ideal superdisintegrant should offer rapid disintegration, high water uptake, minimal impact on tablet hardness, and no adverse interaction with the drug or other excipients. [51-53]

Numerous comparative studies have shown that natural superdisintegrants perform competitively with or even better than their synthetic counterparts in specific contexts. For example:

- *Plantago ovata* mucilage has been found to disintegrate faster than sodium starch glycolate at similar concentrations due to its superior swelling capacity.
- *Ocimum basilicum* mucilage exhibits a smooth gel formation upon hydration, which contributes to uniform wetting and rapid dispersion of ODTs.
- A combination of natural mucilages often results in synergistic effects, producing faster disintegration times and enhanced drug release profiles.

In this study, formulation F06, prepared with 6 mg of *Plantago ovata* and 8 mg of *Ocimum basilicum* mucilages, showed:

- Disintegration time: ~12 seconds
- Wetting time: 12–13 seconds
- Water absorption ratio: ~80%
- In vitro drug release: >89% within 12 minutes
- No drug-excipient interaction (confirmed via IR spectroscopy)
- Stable under short-term storage conditions

These results not only matched but outperformed conventional Metoclopramide tablets in terms of disintegration and drug release.

Advantages of Natural Disintegrants Over Synthetic Ones

Feature	Natural Superdisintegrants	Synthetic Superdisintegrants
Source	Biodegradable, plant-based	Chemically synthesized
Cost	Generally lower	Moderate to high
Toxicity	Non-toxic, biocompatible	May cause irritation in rare cases
Regulatory Approval	Subject to validation	Widely accepted

Feature	Natural Superdisintegrants	Synthetic Superdisintegrants
Functionality	Multifunctional (binder, stabilizer, etc.)	Primarily disintegrant
Environmental Impact	Sustainable	Less eco- friendly

Natural mucilages offer not only functional performance but also alignment with clean-label trends and eco-friendly pharmaceutical practices. [55-58]

Challenges in the Use of Natural Superdisintegrants

Despite their promising attributes, natural superdisintegrants present certain challenges that must be acknowledged and addressed for their successful integration into commercial pharmaceutical formulations. [59-60]

1. Variability and Standardization

- Botanical variability due to differences in soil, climate, and harvest conditions can lead to batch-to-batch inconsistency.
- Lack of standardized monographs or pharmacopeial guidelines for many plant-based excipients complicates quality assurance. [61-62]

2. Microbial Load and Contamination

- Natural materials are susceptible to microbial contamination, particularly if not properly stored or processed.
- This necessitates sterilization or preservation techniques such as heat treatment or gamma irradiation, which may affect functional properties. [63-64]

3. Extraction and Processing Complexities

- Extraction of mucilages can be labor-intensive and requires optimization to retain activity.
- Drying and purification processes need to be standardized to prevent degradation. [65-66]

4. Regulatory and Safety Considerations

- Unlike synthetic disintegrants, many natural polymers lack comprehensive toxicological data and regulatory approval.
- Full GRAS (Generally Recognized as Safe) status and ICH-compliant stability testing are necessary before clinical and commercial use. [67-68]

5. Formulation Interactions

- Natural mucilages may interact with certain drugs or excipients, affecting release kinetics or stability.
- Detailed preformulation studies are essential to identify and mitigate such interactions. [69-70]

Future Research Directions

The use of *Plantago ovata* and *Ocimum basilicum* mucilages in Metoclopramide ODTs marks a successful step toward the integration of natural polymers in pharmaceutical delivery systems. [71-73] However, further research is essential to explore the full potential of natural superdisintegrants:

1. Industrial Scale-Up and Cost Analysis: Transitioning from lab-scale to commercial production requires studies on scalability, process

reproducibility, and cost-benefit analysis.

2. Long-Term Stability Studies: Extended stability testing under ICH guidelines should be performed to determine shelf-life and product robustness.
3. In Vivo Pharmacokinetic Studies: Clinical and preclinical studies are required to evaluate in vivo disintegration, absorption rates, and bioavailability relative to standard tablets.
4. Advanced Characterization Techniques: Use of techniques like DSC, FTIR, SEM, and XRD can help elucidate the mechanisms of interaction between mucilages and drugs.
5. Broader Therapeutic Applications: The same natural polymers could be applied to other BCS Class I and III drugs, especially those needing rapid onset of action.
6. Patient-Centric Design: Taste-masking, mouthfeel, and organoleptic properties should be studied through sensory evaluations, especially for pediatric and geriatric users.
7. Regulatory Profiling and Safety Testing: Conduct toxicity assessments, allergenicity testing, and compile regulatory documentation to meet global standards (FDA, EMA, etc.). [74-80]

Conclusion

The formulation and characterization of Metoclopramide orally disintegrating tablets (ODTs) using natural superdisintegrants such as *Plantago ovata* and *Ocimum basilicum* mucilages represent a promising advancement in the field of pharmaceutical dosage forms. These natural polymers offer a sustainable, biocompatible, and effective alternative to synthetic superdisintegrants, exhibiting rapid disintegration, enhanced water absorption, and superior drug release profiles.

The optimized formulation (F06) demonstrated remarkable performance in key parameters such as disintegration time (~12 seconds), wetting time, and in vitro drug release (>89% in 12 minutes), surpassing conventional Metoclopramide tablets. Moreover, the absence of drug-excipient interactions and stability under short-term storage conditions further endorse the suitability of these mucilages in ODT formulations.

While challenges such as variability in natural polymer sources, microbial contamination risk, and regulatory hurdles exist, they are not insurmountable with appropriate standardization, quality control, and regulatory strategies.

Future research focusing on industrial scalability, long-term stability, in vivo bioavailability, and patient acceptability will be critical to transitioning these formulations from the laboratory to clinical and commercial use. The broader applicability of these natural superdisintegrants to other therapeutic agents also offers fertile ground for innovation.

In conclusion, the integration of natural mucilages in ODT technology aligns with contemporary demands for greener, safer, and more patient-friendly pharmaceutical products, heralding a new era in oral drug delivery.

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