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Design and Optimization of Fast Disintegrating Tablets for Anti Emetic Drugs Using Natural Super Disintegrants

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Abstract: *The present study aims to design and optimize fast disintegrating tablets (FDTs) of anti-emetic drugs—Domperidone, Metoclopramide HCl, and Ondansetron HCl—using natural superdisintegrants, Plantago ovata and Ocimum basilicum seed mucilages. Natural polymers were isolated, purified, and evaluated for key physicochemical properties, including solubility, swelling ratio, total ash, bulk/tapped density, angle of repose, Carr's index, and Hausner's ratio. These parameters confirmed their suitability as effective disintegrants with good flow properties and swelling capacity. Tablets were formulated via direct compression and wet granulation techniques using different excipients such as Mannitol, MCC, cross-povidone, and lactose. Evaluation of tablets included physical properties (hardness, friability, thickness, weight variation), drug content, in vitro dispersion time, wetting time, water absorption ratio, and dissolution studies. Plantago ovata mucilage exhibited higher swelling and compressibility, while Ocimum basilicum showed better flow and density properties. Among the formulations, tablets prepared using direct compression with natural superdisintegrants showed rapid dispersion (<30 seconds), shorter wetting time, and enhanced drug release profiles compared to wet granulated tablets and marketed formulations. Dissolution studies demonstrated that tablets with natural mucilage exhibited faster and complete drug release, confirming their utility in enhancing bioavailability and patient compliance. Overall, this study validates the potential of Plantago ovata and Ocimum basilicum mucilage as eco-friendly, cost-effective, and efficient natural superdisintegrants for developing FDTs of anti-emetic drugs.*

Keywords: *Fast disintegrating tablets, Domperidone, Metoclopramide HCl, Ondansetron HCl, Plantago ovata, Ocimum basilicum, natural superdisintegrants, wetting time, dispersion time, mucilage*

I. INTRODUCTION

Oral drug delivery remains the most preferred and widely accepted route of administration due to its convenience, patient compliance, cost-effectiveness, and non-invasive nature. However, conventional oral dosage forms such as tablets and capsules may pose difficulties in swallowing, especially for pediatric, geriatric, and dysphagic patients. To address these limitations, the pharmaceutical industry has advanced towards the development of fast disintegrating tablets (FDTs)—a novel drug delivery system designed to disintegrate or dissolve rapidly in the oral cavity without the need for water.[1,2]

FDTs offer multiple advantages including improved bioavailability, faster onset of action, and enhanced patient adherence, particularly for drugs that require immediate therapeutic effect. They are especially beneficial for managing conditions such as nausea and vomiting, where rapid onset is crucial. Anti-emetic drugs like Domperidone, Metoclopramide HCl, and Ondansetron HCl are commonly prescribed for acute and chronic emesis related to gastrointestinal disorders, chemotherapy, or postoperative care. These drugs, however, require prompt disintegration and absorption to be effective, making them ideal candidates for FDT formulation.[3,4]

One of the critical aspects of FDT development is the selection of an appropriate superdisintegrant, which governs the rate and extent of tablet disintegration. While synthetic superdisintegrants such as crospovidone and sodium starch glycolate are widely used, there is growing interest in natural polymers due to their biocompatibility, biodegradability,

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low toxicity, cost-effectiveness, and eco-friendliness. Among these, Plantago ovata (psyllium husk) and Ocimum basilicum (basil seeds) have gained attention owing to their high mucilage content, swelling capacity, and gelling properties, which can significantly enhance the disintegration and dissolution behavior of tablets.[5,6]

The present study aims to design and optimize FDTs of selected anti-emetic drugs using mucilage extracted from Plantago ovata and Ocimum basilicum as natural superdisintegrants. The mucilages were isolated and evaluated for their physicochemical properties, including flow behavior, swelling index, moisture content, and compressibility. Formulations were prepared using direct compression and wet granulation methods, followed by comprehensive evaluation of mechanical strength, disintegration parameters, drug content, and in vitro drug release.

This research not only explores the potential of natural mucilages as alternative disintegrants but also addresses the demand for greener pharmaceutical excipients. The successful development of these formulations could pave the way for eco-friendly, patient-centric, and industrially viable approaches in oral drug delivery systems.[7-12]

Materials and methods

The materials used in the experiments included Domperidone (Man Pharmaceuticals Pvt. Ltd., Mehsana), Metoclopramide HCl (Comed Chemicals Pvt. Ltd., Baroda), and Ondansetron HCl (Aurobindo Pharmaceuticals Pvt. Ltd., Hyderabad) as the active pharmaceutical ingredients. Excipients and other formulation aids comprised Mannitol SD-200, MCC PH 101 and 102 (Strides Arco Labs, Bangalore), Cros-povidone XL-10 (gift sample from Wockhardt Research), lactose, starch, magnesium stearate, and talc (all procured from SD Fine Chem Ltd., Mumbai), and sodium stearyl fumarate (Glenmark Ltd., Nashik). Natural binding and swelling agents included *Plantago ovata* and *Ocimum basilicum* seeds, sourced from the local market in Ongole. Aspartame was procured from Madrich, Bangalore, for use as a sweetening agent.

Preformulation Studies:

The melting points of Domperidone, Metoclopramide HCl, and Ondansetron HCl were determined using the capillary method, wherein finely powdered samples were sealed in capillary tubes and immersed in liquid paraffin within a melting point apparatus, and the temperature at which each drug melted was recorded, with triplicate readings averaged. Solubility studies for Metoclopramide HCl and Ondansetron HCl were conducted in buffer solutions of pH 1.2, 5.4, and 6.8 by shaking an excess amount of drug in each solvent for 24 hours, followed by filtration using Whatman filter paper No. 41; the filtrates were then analyzed spectrophotometrically, and average readings from three replicates were used. Drug-excipient compatibility was evaluated through Fourier-transform infrared (FT-IR) spectroscopy using KBr pellet method, analyzing both pure drugs and their physical mixtures with excipients. A standard calibration curve for Domperidone was prepared in 0.1 N HCl by initially dissolving 100 mg in 100 ml of the solvent to obtain a 1000 µg/ml stock solution, followed by serial dilutions to yield concentrations ranging from 5–30 µg/ml. The absorbance of these dilutions was measured at 283 nm, and a standard plot was constructed from the data.[13,14]

Isolation of Mucilage from Plantago ovata and Ocimum basilicum Seeds:

Mucilage from *Plantago ovata* seeds was isolated by soaking the seeds in distilled water for 48 hours followed by boiling for 1 hour to ensure complete mucilage release. The resultant mass was filtered through muslin cloth to remove the marc, and an equal volume of acetone was added to the filtrate to precipitate the mucilage. The precipitate was then dried in an oven at a temperature below 60°C, powdered, sieved through mesh #60, and stored in a desiccator for further use. For *Ocimum basilicum* seeds, initial rinsing with water was done to eliminate foreign matter, followed by soaking in water (seed-to-water ratio of 1:10) for 20 minutes. The swollen seeds were subjected to high-speed homogenization at 1500 rpm to separate the gel layer. The gel was filtered through muslin cloth, precipitated using acetone, washed with ethanol, and dried in a hot air oven at 40°C. The dried mucilage was powdered and stored in an airtight container for future application.[15]

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Evaluation of Tablets:

The prepared tablets were evaluated for various physicochemical parameters. Thickness was measured using a vernier caliper, while weight variation was assessed by weighing 20 individual tablets and comparing their weights to the average tablet weight. Hardness was determined using a Monsanto hardness tester, and friability was evaluated using a Roche friabilator. Drug content estimation was carried out individually for each drug. For Ondansetron HCl, tablets were crushed and extracted with dilute HCl and distilled water, followed by centrifugation and spectrophotometric analysis at 249 nm. For Domperidone, crushed tablets were dissolved in 0.1 N HCl, filtered, and analyzed at 283 nm. Metoclopramide HCl content was determined by extracting tablet powder in distilled water and measuring absorbance at 272.6 nm. Each drug content analysis was based on triplicate samples using respective standard calibration curves. Wetting time and water absorption ratio were determined using a folded tissue method placed in a petri dish containing 6 ml water; the time for complete wetting was recorded, and the absorption ratio was calculated using the difference in tablet weight before and after wetting. In vitro dispersion time was determined by placing the tablet in 10 ml of phosphate buffer (pH 6.8) maintained at 37±0.5°C, and the time for complete dispersion was recorded. In vitro dissolution studies were performed for Domperidone and Ondansetron HCl using USP type-II dissolution apparatus with 900 ml of 0.1 N HCl at 37±0.5°C and 50 rpm paddle speed, while for Metoclopramide HCl, phosphate buffer pH 6.8 was used as the dissolution medium. Samples were withdrawn at specific intervals, filtered, and analyzed at respective wavelengths (283 nm for Domperidone, 249 nm for Ondansetron HCl, and 272.6 nm for Metoclopramide HCl), and cumulative drug release was calculated. The dissolution profiles were also compared with those of marketed formulations.[16,17]

II. RESULTS AND DISCUSSION

The physicochemical characterization of *Plantago ovata* and *Ocimum basilicum* seed mucilages was conducted to evaluate their suitability as natural excipients, especially for their application in pharmaceutical formulations. Both mucilages were found to be slightly soluble in water, which is consistent with the behavior of hydrophilic polysaccharides. This property facilitates the formation of gels and enhances disintegration and swelling, making them suitable for tablet formulations. The loss on drying was significantly higher for *Plantago ovata* mucilage (10 ± 0.011%) compared to *Ocimum basilicum* mucilage (4 ± 0.05%). The higher moisture content in *Plantago ovata* could be due to its hygroscopic nature and the presence of more water-retaining polysaccharide components. A lower loss on drying, as seen in *Ocimum basilicum*, is favorable in terms of storage stability and microbial resistance.

Table 1: Physicochemical Tests for Mucilage

S. No.	Physicochemical Parameters	*Plantago ovata* Mucilage	*Ocimum basilicum* Seed Mucilage
1	Solubility	Slightly soluble in water	Slightly soluble in water
2	Loss on Drying (%)	10 ± 0.011	4 ± 0.05
3	Swelling Ratio	9 ± 0.145	8.2 ± 0.022
4	Total Ash (%)	4 ± 0.021	3.1 ± 0.062
5	Angle of Repose (°)	26.560 ± 0.251	20.440 ± 0.133
6	Bulk Density (g/cm³)	0.42 ± 0.055	0.73 ± 0.045
7	Tapped Density (g/cm³)	0.46 ± 0.085	0.84 ± 0.015
8	Carr's Index (%)	10.03 ± 0.012	12.6 ± 0.11
9	Hausner's Ratio	1.08 ± 0.056	1.14 ± 0.07

(All values are expressed as mean ± SD, n = 3)

The swelling ratio, a crucial parameter reflecting the hydration and gelling capability of mucilage, was observed to be higher for *Plantago ovata* (9 ± 0.145) than for *Ocimum basilicum* (8.2 ± 0.022). This suggests a superior swelling capacity for *Plantago ovata*, which is beneficial in fast-disintegrating formulations where rapid water uptake is desired. The total ash content, indicative of inorganic residue, was 4 ± 0.021% for *Plantago ovata* and 3.1 ± 0.062% for *Ocimum basilicum*, suggesting both mucilages are pharmaceutically acceptable as they fall within prescribed limits (<5%). A slightly lower ash content in *Ocimum basilicum* points toward higher organic purity.

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The angle of repose, an index of powder flowability, was found to be 26.560 ± 0.251° for *Plantago ovata* and 20.440 ± 0.133° for *Ocimum basilicum*, indicating that both mucilages exhibit excellent flow properties (angles <30°), with *Ocimum basilicum* exhibiting comparatively better flow behavior. The bulk density and tapped density were significantly higher for *Ocimum basilicum* (0.73 ± 0.045 and 0.84 ± 0.015 g/cm³, respectively) than for *Plantago ovata* (0.42 ± 0.055 and 0.46 ± 0.085 g/cm³, respectively). This difference reflects the more compactable nature of *Ocimum basilicum*, which might aid in direct compression processes.

The Carr's index, a measure of compressibility, was 10.03 ± 0.012% for *Plantago ovata* and 12.6 ± 0.11% for *Ocimum basilicum*, both values being within the acceptable range (<15%) for good flow and compressibility. However, *Plantago ovata* exhibited slightly superior compressibility, which may be attributed to its lighter, fibrous nature. Lastly, the Hausner's ratio, another index of flowability and densification, was found to be 1.08 ± 0.056 for *Plantago ovata* and 1.14 ± 0.07 for *Ocimum basilicum*, both falling within the range that indicates good flow (1.00–1.25). Again, *Plantago ovata* demonstrated slightly better flow characteristics based on this parameter.

In summary, both *Plantago ovata* and *Ocimum basilicum* seed mucilages exhibit favorable physicochemical properties, including good flowability, acceptable moisture content, and desirable swelling characteristics. While *Plantago ovata* mucilage shows a higher swelling ratio and slightly better compressibility, *Ocimum basilicum* mucilage excels in flow properties and bulk density, making both suitable candidates for use as natural disintegrants or binders in tablet formulations depending on the intended application.

Dispersion and Wetting time of Anti - Emetic drugs

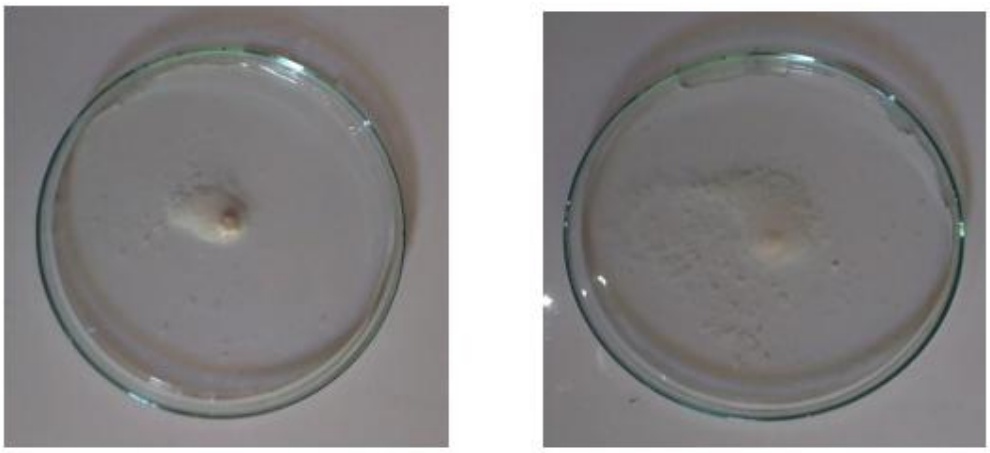

Fig 1: Dispersion time of Domperidone tablets prepared by Direct Compression method

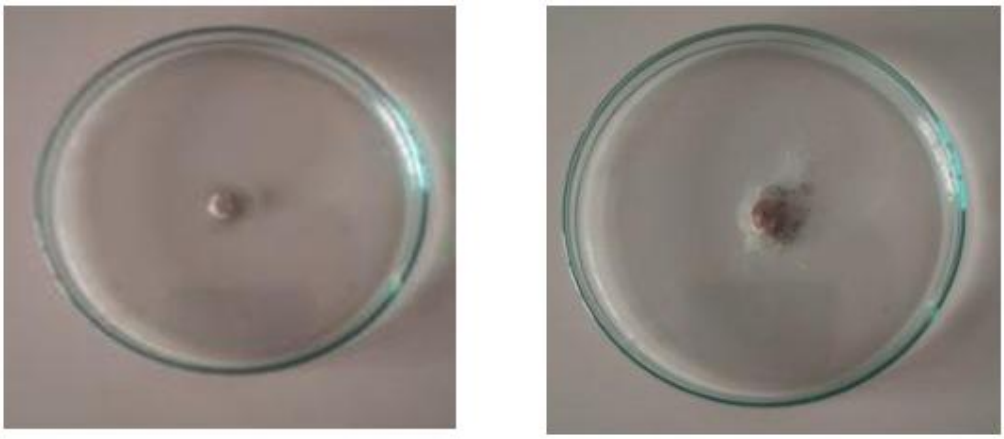

Fig 2: Dispersion time of Domperidone tablets prepared by Wet granulation

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Method

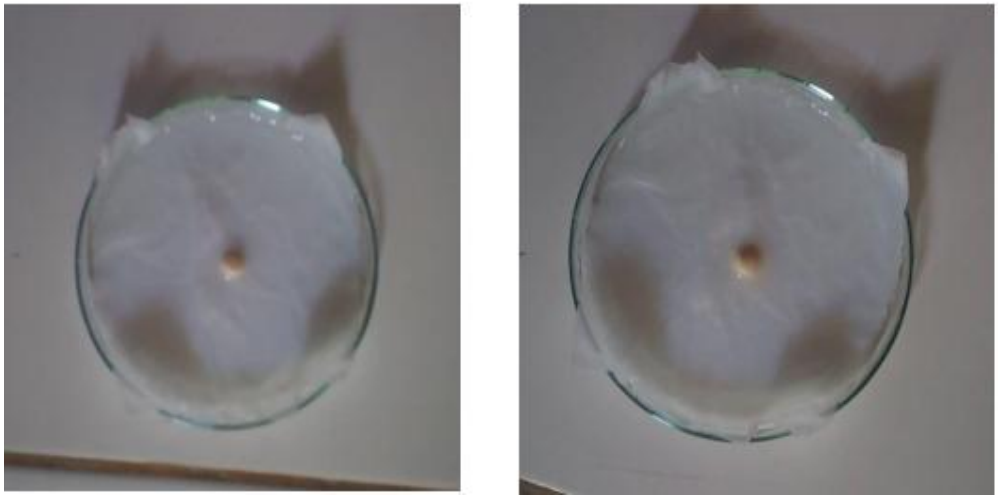

Fig 3: Wetting time of Domperidone tablets prepared by Direct Compression method

Fig 4: Dispersion time of Metoclopramide HCl tablets prepared by Direct Compression method

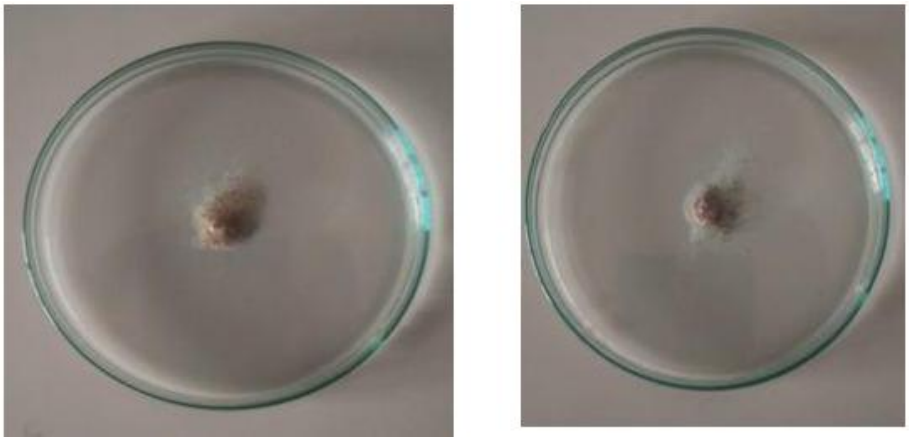

Fig 5: Dispersion time of Metoclopramide HCl tablets prepared by Wet granulation method

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Fig 6: Wetting time of Metoclopramide HCl tablets prepared by Direct compression method

III. CONCLUSION

The findings of this study demonstrate that mucilage from *Plantago ovata* and *Ocimum basilicum* seeds serve as effective natural superdisintegrants in the formulation of fast disintegrating tablets of anti-emetic drugs. Their superior swelling, flow, and compressibility properties significantly enhanced tablet performance in terms of dispersion and dissolution. Natural disintegrants offer a promising alternative to synthetic agents, aligning with the growing demand for safer and biocompatible pharmaceutical excipients.

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