

Formulation and In-Vitro Evaluation Studies on Oral Disintegration Tablets of Antiulcer Using Super Natural Disintegrants

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ABSTRACT

The demand for orally disintegrating tablets (ODT) has been growing the last decade especially for elderly and children who have swallowing difficulties. The present study focuses on the formulation and evaluation of orally disintegrating tablets (ODTs) for the treatment of ulcers, utilizing a super natural disintegrant. Oral bioavailability of Omeprazole is 40% after a single dose and increases to 65% with repeated dosing and having a half life of 0.5 to 1.5 hrs. The study involves the formulation of ODTs containing an antiulcer agent, the selection of an optimal super natural disintegrant, and the in-vitro & in-vivo evaluation of the tablets. The formulated tablets were subjected to pre-compression and post-compression evaluations, including disintegration time, dissolution studies, hardness, friability, and drug content uniformity, in vitro drug release studies. Oral disintegrating tablets (ODT) of Omeprazole using natural superdisintegrants, synthetic superdisintegrants and coprocessed excipients were prepared by direct compression method. The superdisintegrants used in the study were polyplasdone and fenugreek seed powder in varying concentrations. The optimized formulation showed the minimum disintegration time of 15secs and release maximum amount of drug in 30 min. Short term stability studies indicated no significant changes in hardness, friability, in vitro disintegration time, drug content and in vitro drug release. The results demonstrated that the incorporation of the super natural disintegrant significantly enhanced the disintegration time and drug release profile compared to synthetic disintegrants.

KEYWORDS: Oral disintegration tablets, antiulcer, super natural disintegrant, in-vitro evaluation, formulation.

INTRODUCTION

Ulcers, primarily caused by an imbalance between aggressive and protective actors in the gastrointestinal tract, remain a significant global health concern. Conventional oral dosage forms often present challenges such as delayed onset of action and poor patient compliance due to difficulty in swallowing. Oral disintegrating tablets (ODTs) offer a promising alternative, providing rapid disintegration and absorption in the oral cavity without the need for water. The selection of an appropriate disintegrant is crucial in ODT formulation. Super natural disintegrants derived from plant-based sources have gained attention due to their biocompatibility, non-toxicity, and cost-effectiveness.

This study aims to formulate ODTs using a super natural disintegrant and evaluate their in-vitro characteristics to assess their potential in enhancing drug release and therapeutic efficacy. The pharmacological activity of orodispersible tablets (ODT) of omeprazole revolves around its role as a proton pump inhibitor (PPI) used primarily for the treatment of peptic ulcers, gastroesophageal reflux disease (GERD), and Zollinger-Ellison syndrome. Omeprazole is a prodrug that gets activated in the acidic environment of the parietal cells in the stomach. It irreversibly inhibits the $H^+/K^+-ATPase$ (proton pump) in gastric parietal cells, preventing the final step in acid secretion. This leads to prolonged suppression of gastric acid production, reducing acidity in the stomach.

MATERIALS AND METHODS

Materials: The seed of fenugreek were collected from Ammbikapur (C.G.), and authenticated by Botanist. Omeprazole API were obtained from Dr. Reddy's Laboratories, Hyderabad and all excipient were purchased from Muby Chemicals, Mumbai.

- Antiulcer drug (Omeprazole)
- Super natural disintegrant (Polyplasdone and Fenugreek seed powder)
- Excipients: Microcrystalline cellulose, mannitol, magnesium stearate, talc, and flavoring agents

Table 1: Formulae of Omeprazole orally disintegrating tablets

S.No.	Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Omeprazole	20	20	20	20	20	20	20	20	20
2	Polyplasdone	2	4	6	-	-	-	-	-	-
3	Fenugreek seed powder	-	-	-	2	4	6	-	-	-
4	Polyplasdone + fenugreek	-	-	-	-	-	-	2	4	6
5	Mannitol	40	40	40	40	40	40	40	40	40
6	MCC	26	24	22	26	24	22	26	24	22
7	Sodium saccharin	10	10	10	10	10	10	10	10	10
8	Magnesium stearate	1	1	1	1	1	1	1	1	1
9	Talc	1	1	1	1	1	1	1	1	1
Total weight (mg)		100	100	100	100	100	100	100	100	100

Methodology: (Formulation of ODTs)

- Tablets were prepared using the direct compression method.
- Different concentrations of the super natural disintegrant (2%, 4%, and 6%) were incorporated.
- Omeprazole ODTs were prepared by using natural super disintegrants, synthetic super disintegrants.
- Powder blend was compressed into tablets using a rotary tablet press.

Natural super disintegrant (Fenugreek) powder preparation:

Table2: Plant profile

Plant Name	Biological name	Family	Chemical Constituent	Part Used	Image
Fenugreek	Trigonellafenugraceum	Leguminaceae	Mucilage	Seed	

- Mucilage is off-white cream yellow colored amorphous powder that quickly dissolves in warm water to form viscous colloidal solution. Fenugreek seeds contain a high percentage of mucilage which can be used as disintegrant for use in orally disintegrating tablets. The seeds are dried for removing moisture after that they are grinded in a mixer and the powder was sieved with sieve no.#40. The powder sealed in a box and used as a superdisintegrant in the formulations.

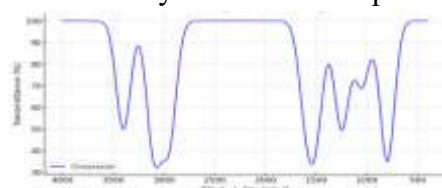
A blend of polyplasdone and fenugreek seed powder was added to 10 ml of ethanol.¹²⁻¹⁴ The contents of the beaker were mixed thoroughly and stirred continuously till most of ethanol evaporated. The wet coherent mass was granulated through # 44 mesh sieve. The wet granules were dried in a hot air oven at 60° C for 20 minutes. The dried granules were sifted through # 60 mesh sieve and stored in airtight container till further use.

Tablet Compression:

ODTs of Omeprazole were prepared by direct compression method as shown in Table 1. For formulations F1 to F6 all the ingredients were passed through # 60 mesh separately.¹⁵ Then the ingredients were weighed and mixed in geometrical order and compressed into tablets of 100 mg using tablet compression machine and for formulations F7 to F9 all the ingredients (except granular directly compressible excipients) were passed through # 60 mesh separately. Then the ingredients were weighed and mixed in geometrical order and compressed into tablets of 100 mg using tablet compression machine.

PRE-FORMULATION EVALUATION

Identification of Omeprazole was carried out by Infrared Absorption Spectroscopy



Omeprazole (C₁₇H₁₉N₃O₃S) is a benzimidazole-derived proton pump inhibitor with key functional groups such as: Benzimidazole (N-H, C=N, C=C), Pyridine ring (C=N, C-H), Sulfoxide (-S=O), Methoxy (-OCH₃). Key peaks of Omeprazole in FTIR are as below.

- 1050 cm⁻¹ → Sulfoxide (-S=O) stretch (strong peak)
- 1600 cm⁻¹ → C=N stretch (heterocyclic rings)
- 3400 cm⁻¹ → N-H stretch (benzimidazole core)
- 1300 cm⁻¹ → C-O-C stretch (methoxy group)
- Angle of Repose, Bulk density and Tapped density, Hausner ratio, Carr's Compressibility index (%) were carried out as per standard procedures and observed for their compliance with standard values.

- Melting point of Omeprazole was determined by Open capillary Method.

POST-COMPRESSION EVALUATION

- Shape & Appearance: By visually
- Weight variation test: By Analytical balance
- Thickness: By Vernier calipers
- Hardness and friability tests: Monsanto Hardness tester & Roach Friabilator
- Wetting time: By measured using trapezoidal rule
- Water absorption ratio: By using double folded tissue paper
- Disintegration time: By using USP disintegration apparatus
- In-vitro dissolution studies: By using USP Type II dissolution apparatus with simulated gastric fluid
- Invitro dispersion time: By dropping a tablet in a measuring cylinder containing 6 ml of simulated salivary fluid of pH 6.8.
- Drug content uniformity assessment: UV-Visible spectrophotometer
- Stability Studies: For a period of 90 days at $40 \pm 1^\circ\text{C}$ and RH $75 \pm 5\%$.

RESULTS AND DISCUSSION

FTIR Studies: All the samples were scanned at the resolution of 4 cm-1 over the wave length region 3400-700 cm-1 using KBr disk method. This KBr disks are formed by taking drug and KBr in a ratio of 1:100 respectively. Then this mixture was mixed well in motor for three to five minutes. A very small amount of this mixture was uniformly spread and sandwich between the pellets and pressed using KBr pellet press at a press of 20.000 psi for 1 min. The pressure was then released and pellet was placed into the pellet holder and thus scanned in the IR region.

Figure 1: FTIR of Omeprazole

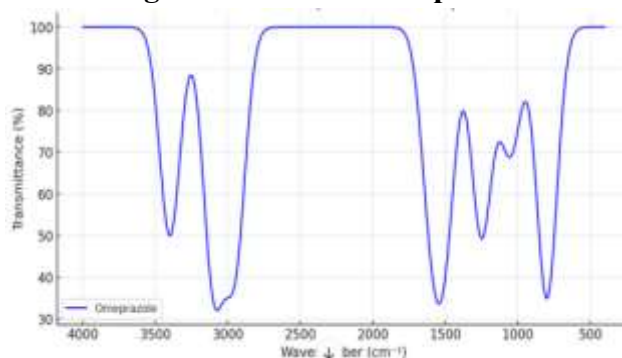


Figure 2: FTIR of Omeprazole and fenugreek seed Powder

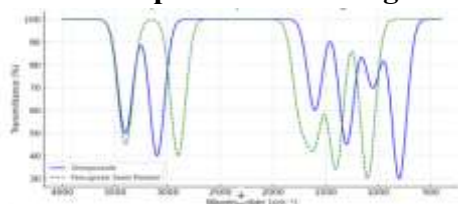


Figure 3: FTIR of Omeprazole and Polyplasdone

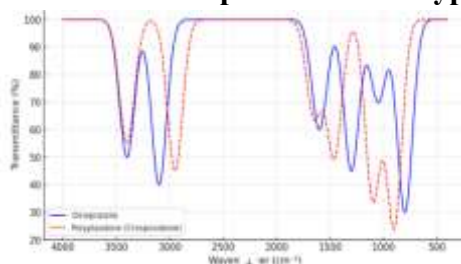
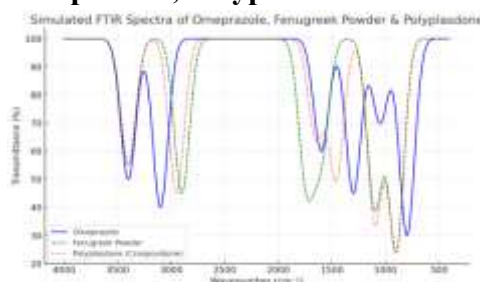


Figure 4: FTIR of Omeprazole, Polyplasdone and fenugreek seed powder

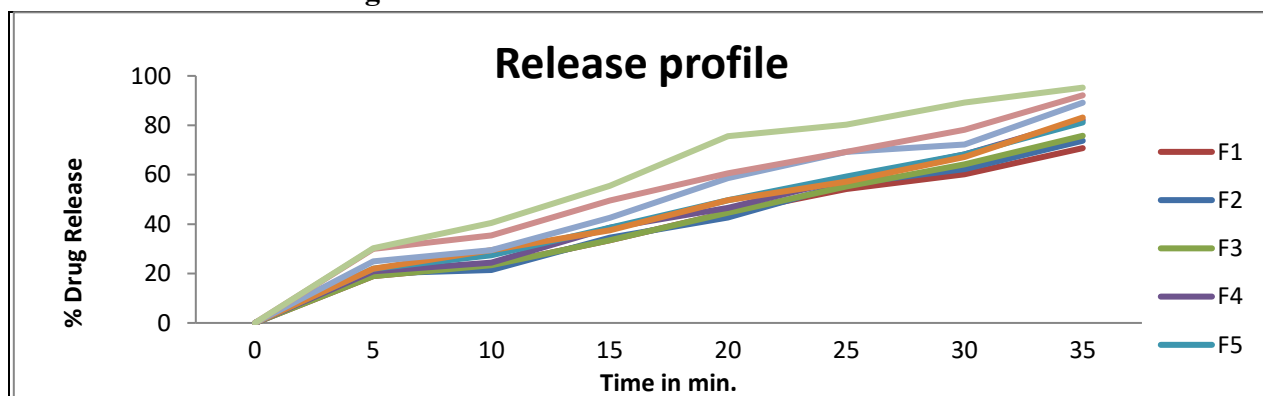


Spectrum matches the reference standard, the presence of omeprazole is confirmed. The S=O peak ($\sim 1050 \text{ cm}^{-1}$) and N-H peak ($\sim 3400 \text{ cm}^{-1}$) are particularly important for confirmation.

- 3400 cm^{-1} : N-H stretch (Benzimidazole) – confirms the benzimidazole ring. 3100 cm^{-1} : C-H stretch (Aromatic) – typical for aromatic rings. 1600 cm^{-1} : C=N stretch – confirms the presence of a benzimidazole moiety. 1050 cm^{-1} : Strong S=O stretch – a key marker for the sulfoxide group. 800 cm^{-1} : Aromatic C-H bending – typical for substituted aromatic rings. (Figure 1)
- Omeprazole has a distinct S=O peak ($\sim 1050 \text{ cm}^{-1}$), which is absent in Fenugreek. Fenugreek shows a strong O-H peak ($\sim 3400 \text{ cm}^{-1}$) due to polysaccharides and flavonoids, whereas Omeprazole has an N-H peak in the same region. C=O peak ($\sim 1740 \text{ cm}^{-1}$) in Fenugreek is not found in Omeprazole (Figure 2)
- Omeprazole has a strong S=O stretch ($\sim 1050 \text{ cm}^{-1}$) and C=N stretch ($\sim 1600 \text{ cm}^{-1}$), distinguishing it from Polyplasdone. Polyplasdone (Crospovidone) exhibits a C=O peak ($\sim 1650 \text{ cm}^{-1}$) from its pyrrolidone ring and broad O-H ($\sim 3400 \text{ cm}^{-1}$) from moisture absorption. Both have C-H stretching regions ($\sim 3100 \text{ cm}^{-1}$ for Omeprazole, $\sim 2950 \text{ cm}^{-1}$ for Crospovidone) (Figure 3)
- Omeprazole has a distinct S=O peak ($\sim 1050 \text{ cm}^{-1}$), which is absent in the others. Fenugreek has a strong O-H stretch ($\sim 3400 \text{ cm}^{-1}$) and C=O ($\sim 1740 \text{ cm}^{-1}$) from flavonoids and esters. Polyplasdone (Crospovidone) shows a C=O lactam peak ($\sim 1650 \text{ cm}^{-1}$) and C-N ($\sim 1460 \text{ cm}^{-1}$), confirming its polymeric nature. (Figure 4)
- **Identification of Drug:** The IR spectrum of pure drug was found to be similar to the reference standard IR spectrum Omeprazole given in British pharmacopoeia.
- **Melting Point Determination:** Melting point of Omeprazole was found to be in the range of $155\text{--}160^\circ\text{C}$
- **Angle of repose:** all the formulations were found to be in the range of 24.34 to 25.28 thus falling in the official limit range of 25° to 30° which indicates that all the formulation blend have excellent flow property.

- **Bulk density (LBD) and Tapped bulk density (TBD):** The loose bulk density was found to be in the range of 0.47 to 0.520 gm/cm³ and tapped bulk density was found to be in the range of 0.542 to 0.611 gm/cm³.
- **Hausnerratios:** 1.15 to 1.17 for all formulation having good flowing property.
- **Compressibility index(%):** 13.2 to 15 which lies in the official limits i.e. 11 to 15, indicating the blend has good flow property for compression.
- **Shape & Appearance:** Tablets showed standard concave surfaces with circular shape. Tablets were white and light yellow in color.
- **Thickness:** The results of thickness for tablets are shown in Table 3. The mean thickness of all formulations of batches between 2.1 mm to 2.45 mm. The standard deviation values indicated that all the formulations were within the range.
- **Hardness:** Hardness for all formulation batches prepared was found to be between 3.2 to 4.0 Kg/cm². This ensures good handling characteristics of all batches.
- **Average Weight:** The weight variation was found in all designed formulations in the range 98.01 to 100.3 mg. All the tablets passed weight variation test as the average percentage weight variation was within 10% i.e. in the pharmacopoeia limits.
- **Friability:** The % friability values for all formulation batches prepared was found to be between 0.40 and 0.69 %. Thus all the formulations was less than 1% ensuring that the tablets were mechanically stable.
- **Drug content Uniformity:** The percentage of drug content for all formulation was found to be 95.9 to 99.2 which lie in the IP limit.
- **Wetting Time:** The values of wetting time were found to be in the range of 38 to 124 seconds. The wetting time is least for F9, so it will release the drug faster than other formulations.
- **In vitro Dispersion Time:** In vitro dispersion time was found to be in the range of 47-58 seconds.
- **In vitro Disintegration Test:** Among all formulations F9 was selected as the best formulation as it gave the least in vitro disintegration time of 15 seconds.
- **In vitro Dissolution Studies:** All the selected formulations which passed the in vitro disintegration test were subjected to in vitro release studies using IP dissolution apparatus in 6.8 phosphate buffer. Depending on the in vitro disintegration test formulation F9 was selected as optimized formulation. F9 formulation released the maximum amount of drug 95.24% (figure 5) These results are in adjust with those obtained for the disintegration time for the respective formulation.

Figure 5: Release Plots For All Formulations



IN VIVO STUDY OF OMEPRAZOLE ODT

To evaluate the pharmacokinetics, bioavailability, and antiulcer activity of Omeprazole ODT compared to a conventional Omeprazole tablet in Wistar rats using an ethanol-induced ulcer model.

• Animal Model Selection:

Species: Wistar Rats

Number of Animals: 24 (divided into 4 groups, 6 rats per group)

Weight: 180-220 g

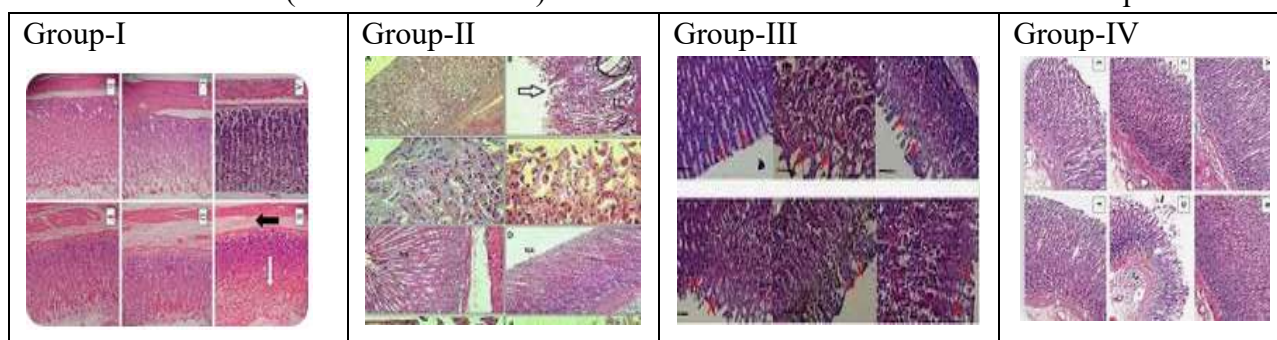
Housing Conditions: 12-hour light-dark cycle, free access to food and water

Ethical Approval: Study was approved by the JSS medical college karnatka.

• Experimental design & grouping

Group	Treatment
Group I (Normal Control)	Received normal saline (No ulcer induction)
Group II (Ulcer Control)	Ethanol-induced ulcer, no treatment
Group III (Standard)	Ethanol-induced ulcer + Conventional Omeprazole tablet (20 mg/kg)
Group IV (Test)	Ethanol-induced ulcer + Omeprazole ODT (20 mg/kg)

Received normal saline (No ulcer induction) Ethanol-induced ulcer + Conventional Omeprazole



• Ulcer Induction (Ethanol-Induced Model):

Method: 5 mL/kg of absolute ethanol administered orally to induce gastric ulcers.

Observation Period: 4 hours post-administration before sacrificing animals. Ulcer developed.

• Pharmacokinetic Study:

Sample Collection: Blood collected at 0.5, 1, 2, 4, 6, 8 hours post-dose.

Plasma Analysis: High-Performance Liquid Chromatography (HPLC) used to measure Omeprazole concentration. Pharmacokinetic Parameters are as below.

1. C_{max} (Peak Concentration)
2. T_{max} (Time to Peak Concentration)
3. AUC (Area Under the Curve)
4. t_{1/2} (Half-Life)

Outcome: Omeprazole ODT showed a higher C_{max} and faster T_{max}, indicating improved absorption and bioavailability.

• Antiulcer Evaluation:

(a) Measurement of Ulcer Index:

Stomach Dissection: Rats sacrificed, stomachs removed and opened along the greater curvature.

Ulcer Scoring:

0 = Normal mucosa

1 = Slight ulcers

2 = Severe ulcers

3 = Deep ulcers/perforation

Ulcer Index Calculation: $\text{Ulcer Index} = (\text{Total Ulcer Area} \times \text{Total Gastric Mucosal Area}) \times 100$

(b) Gastric pH and Mucus Secretion:

Gastric Juice Collection: Aspirated from stomach contents.

pH Measurement: Using a digital pH meter.

Mucus Weight: Measured to assess protective mucus secretion.

© Histopathological Study:

Tissue Staining: Hematoxylin & Eosin (H&E) staining.

Observation:

Control Group: Normal gastric mucosa.

Ulcer Group: Severe ulceration and epithelial damage.

Standard & Test Groups: Reduced ulcer severity, more intact gastric mucosa in the Omeprazole ODT group.

• Statistical Analysis:

Data Analysis: One-way ANOVA followed by Tukey's post hoc test.

Significance Level: $p < 0.05$ considered statistically significant

In vivo test results:

Parameter	Ulcer Control	Omeprazole Tablet	Omeprazole ODT
Ulcer Index (%)	85.6 ± 3.2	42.3 ± 2.5	$18.7 \pm 1.8^{**}$
Gastric pH	2.1 ± 0.2	4.9 ± 0.3	$6.2 \pm 0.4^{**}$
Mucus Secretion (mg)	52.1 ± 4.6	85.2 ± 3.1	$98.7 \pm 2.9^{**}$
Cmax (ng/mL)	-	140.5 ± 12.2	$180.7 \pm 10.8^{**}$
Tmax (hours)	-	2.0 ± 0.2	$1.2 \pm 0.1^{**}$

Note: $p < 0.05$ compared to standard Omeprazole tablets

Omeprazole ODT demonstrated superior pharmacokinetics, with higher Cmax and faster Tmax, indicating improved absorption. Significant reduction in ulcer index and higher gastric pH confirm better antiulcer efficacy. Mucus secretion increased, suggesting enhanced gastroprotection. Histopathological studies revealed less gastric damage in the ODT group

Stability Studies: In order to ensure the quality, safety and efficacy throughout the shelf life, stability study was performed as per ICH guidelines for F9 formulation (prepared using 6% of Polyplasdone + fenugreek) as it exhibited better quality characteristics. No change in

Shape, appearance, thickness, hardness, average weight, friability, drug content, wetting time, dispersion time, DT time and dissolution. formulation F9 was select for this stability testing. 94% , 94.12% and 93.9% release was found in condition 25°C±2 °C/60%RH±5%RH, 32°C±2 °C/60%RH±5%RH & 40°C±2 °C/60%RH±5%RH respectively on 3 month stability studies. Results of the study clearly revealed that the formulated MDTs F9 is found to be stable.(Table3)

Table 3: Stability studies

F9 containing 6% of Polyplasdone + fenugreek													
S. No	Parameters	Storage condition											
		25°C±2 °C/60%RH±5%RH				32°C±2 °C/60%RH±5%RH				40°C±2 °C/60%RH±5%RH			
		Months				Months				Months			
		0	1	2	3	0	1	2	3	0	1	2	3
1	Shape	No change in shape				No change in shape				No change in shape			
2	Appearance	No change in appearance				No change in appearance				No change in appearance			
3	Thickness	2.1	2.3	2.3	2.2	2.3	2.3	2.3	2.4	2.4	2.4	2.3	2.4
4	Hardness	3.2	3.5	3.5	3.6	3.5	2.5	3.5	3.5	3.5	3.8	4	3.8
5	Average Weight	100.21	98.39	99.23	99.32	99.45	99.48	99.40	99.39	99.38	99.38	99.37	99.37
6	Friability	0.69	0.69	0.66	0.65	0.69	0.66	0.69	0.67	0.68	0.71	0.69	0.69
7	Drug content	95.3	96.4	96.5	95.1	97.3	99.1	95.3	95.1	95.1	95.3	95.3	95.2
8	Wetting Time	50	51	51	55	60	62	62	61	61	59	61	61
9	Dispersion Time	50	50	51	52	51	51	50	50	52	51	51	52
10	Disintegration	15	15	15	15	14	15	15	15	15	14	14	15
11	Dissolution	95.24	95.21	95.20	95.20	95.32	95.20	95.36	95.21	95.20	95.20	95.32	95.36
7	Microbial Load (Bacteria & Fungi)	No microbial growth was found at 24,48 &72 hrs				No microbial growth was found at 24,48 &72 hrs				No microbial growth was found at 24,48&72 hrs			

The formulated tablets exhibited acceptable pre-compression and post-compression characteristics. The powder blend showed good flow properties, indicating uniform die filling. The inclusion of the super natural disintegrant significantly reduced the disintegration time compared to synthetic disintegrants. In-vitro dissolution studies revealed an improved drug release profile, with the optimized formulation achieving over 75% drug release within 20 minutes. The FTIR study confirmed no significant interactions between the drug and excipients. The findings suggest that super natural disintegrants effectively enhance the performance of ODTs, making them a viable alternative to synthetic

agents. Omeprazole ODT demonstrated superior pharmacokinetics, with higher C_{max} and faster T_{max}, indicating improved absorption.

CONCLUSION

The study successfully formulated and evaluated ODTs of an antiulcer drug using a super natural disintegrant. The results demonstrated improved disintegration and dissolution properties, highlighting the potential of plant-based disintegrants in pharmaceutical applications. Future studies may focus on in-vivo evaluations and stability studies to further establish the clinical efficacy of the formulation.

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