Formulation And Characterization of Oral Dispersible Tablet of Ondansetron Using Different Natural Super Disintegrants

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***Abstract*—Oro dispersible tablets (ODTs) are designed to disintegrate rapidly in the oral cavity without the need for water, making them particularly suitable for paediatric, geriatric, dysphagic, and bedridden patients. The present study aimed to formulate and evaluate Ondansetron HCl ODTs using natural super disintegrants to improve tablet disintegration and drug release while enhancing patient compliance.**

Methods: Oro dispersible tablets of Ondansetron HCl (5 mg) were prepared by the direct compression method using fenugreek seed mucilage and banana powder as natural super disintegrants at different concentrations. The prepared formulations (F1–F7) were evaluated for pre-compression parameters, drug-excipient compatibility by FTIR, and post-compression characteristics including weight variation, hardness, thickness, friability, wetting time, disintegration time, drug content, and in vitro dissolution using USP type II paddle apparatus in 0.1 N HCl (pH 1.2).

Results: FTIR studies confirmed the absence of drug-excipient interactions. All powder blends exhibited good flow properties suitable for direct compression. The prepared tablets complied with pharmacopeial specifications for weight variation, hardness (3.10–3.47 kg/cm²), thickness (2.35–2.45 mm), and friability (<1%). Wetting time ranged from 42.23 to 91.36 seconds, while disintegration time ranged from 22.03 to 70.29 seconds. Drug content ranged from 81% to 94%. Among all formulations, F7 containing 8 mg banana powder demonstrated the best performance, showing the shortest disintegration time (22.03 s) and the highest cumulative drug release (95.09% at 10 min). Increasing the concentration of natural super disintegrants significantly enhanced tablet disintegration and dissolution.

Conclusion: Ondansetron HCl Oro dispersible tablets prepared using natural super disintegrants were successfully developed by the direct compression method. Among the tested formulations, F7 containing 8 mg banana powder exhibited superior physicochemical properties, rapid disintegration, and enhanced drug release, indicating that banana powder is an effective natural super disintegrant for the development of patient-friendly Ondansetron HCl ODTs.

***Index Terms*—Ondansetron HCl, Oro dispersible tablets, Direct compression, Natural super disintegrants, Banana powder, Fenugreek seed mucilage, Drug release.**

I. INTRODUCTION

Tablets intended for oral administration are formulated to disintegrate and dissolve rapidly, ensuring quick release of the active pharmaceutical ingredient. These are commonly referred to as "conventional tablets." Disintegrating tablets typically include agents that promote faster breakdown compared to traditional forms, resulting in quicker dissolution. This issue is estimated to impact nearly half the population, contributing to poor patient compliance and reduced therapeutic effectiveness. Consequently, there has been growing interest in tablets that disintegrate or dissolve directly in the mouth.

Oral drug delivery remains the most widely used route due to its ease of use, non-invasive nature, suitability for self-administration, cost-effectiveness, accurate dosing, and versatility factors that collectively enhance patient adherence. However, individuals who suffer from dysphagia, as well as elderly patients, young children, and those frequently on the move, often struggle with swallowing conventional tablets. [1]

Oro dispersible tablets (ODTs) are solid oral dosage forms that rapidly disintegrate or dissolve in the oral cavity, usually within 30 seconds, without the need for water. ODTs offer significant advantages over conventional tablets, including ease of administration, rapid onset of action, improved patient compliance, and enhanced convenience, particularly for paediatric, geriatric, dysphagic, and bedridden patients. Due to these benefits, ODTs have gained considerable attention in the pharmaceutical industry for improving therapeutic outcomes and patient acceptability.[2,3,4]

Ondansetron HCl is a highly effective antiemetic agent, commonly prescribed for managing nausea and vomiting associated with chemotherapy, radiotherapy, and early stages of alcoholism. In such situations, taking medication with water can be challenging, making Oro dispersible tablets (ODTs) a suitable alternative. However, Ondansetron HCl has a very bitter taste, which necessitates effective taste-masking strategies. Therefore, certain polymers were incorporated into the formulation for this purpose. The aim was to create a patient-friendly dosage form by masking the drug's unpleasant taste and using natural super disintegrants to ensure the tablet disintegrates quickly in the mouth without the need for water.[5]

Super-disintegrants are agents that promote the rapid breakup of tablets or capsules into smaller fragments, enhancing the dissolution of the active drug compared to traditional disintegrants. These agents are typically included in solid dosage forms in small amounts, usually ranging from 1% to 10% of the total formulation weight. In recent times, many plant-derived excipients have been identified and studied for their potential use as natural super-disintegrants. These naturally sourced agents offer several advantages over synthetic ones, including cost-effectiveness, wide availability, and a favorable safety profile as they are generally non-toxic, non-irritant, and eco-friendly. [6]

Hence the goal of this study to develop and evaluate Oro dispersible tablets (ODTs) of Ondansetron by incorporating natural super disintegrants in order to enhance disintegration time, patient compliance.

II. MATERIALS AND METHODS

Materials

Ondansetron HCl purchased from Dham Tech Pharma, fenugreek seed mucilage, banana powder bought from the market; xanthan gum, and mannitol obtained from shreeji Chemicals, Mumbai. Microcrystalline cellulose, sodium saccharine, and magnesium stearate were obtained from SD Fine Chemical Ltd., Mumbai. Talc obtained from Lesar Chemicals, Ahmedabad.

Method

Preparation of banana powder

The unripe banana fruit of the market was taken. Then the banana fruit was cleaned, and the peel was removed. Then the pulp was dried and powdered using a mixer. Powdered substance was collected and stored in a well-closed container for further use.

Fenugreek seed mucilage

The seeds of fenugreek were powdered using a mortar and pestle, and 50g of the powder was soaked in distilled water for 48 hours and then boiled for few minutes to release the mucilage into the water. Then the fenugreek mucilage present in the water was filtered through muslin cloth to separate the marc, and subsequently equal volume of acetone was added to the marc to precipitate the mucilage. The obtained mucilage was dried and stored in desiccator for the further use.

Pre formulation studies

The drug was characterized for melting point (capillary method), λmax in phosphate 0.1 N HCl pH 1.2 (UV scan 200–400 nm), and calibration curve (5–25 µg/ml at 248 nm). Drug excipient compatibility was assessed using FTIR spectra (4000–500 cm^{-1}) of pure drug and physical mixtures with polymers.

Table 1: Formulation code of Oro-dispersible tablets

Sl. No	INGREDIENTS	F1 mg	F2 mg	F3 mg	F4 mg	F5 mg	F6 mg	F7 mg
1	Ondansetron HCl	5	5	5	5	5	5	5
2	Fenugreek seed mucilage	0	2	4	8	-	-	-
3	Banana powder	0	-	-	-	2	4	8
5	Mannitol	108.5	106.5	104.5	100.5	106.5	104.5	100.5

6	Microcrystalline cellulose	30	30	30	30	30	30	30
7	Magnesium Stearate	4	4	4	4	4	4	4
8	Talc	2	2	2	2	2	2	2
9	Sodium saccharine	0.5	0.5	0.5	0.5	0.5	0.5	0.5

Preparation of oral dispersible tablets by the direct compression method:

All ingredients were collected as per the formulation requirements. The drug and other excipients (except directly compressible granular excipients) were passed separately through a #60 mesh sieve to remove lumps and ensure uniform particle size. All the sieved ingredients were accurately weighed according to the formulation table. Then mixed in geometrical order and compressed into tablets by using a rotary tablet-compression machine.

Evaluation of Pre-compression Parameters [7, 8]

Evaluated different flow properties of powder like bulk and tapped density, angle of repose, Hausner's ratio, and Carr's index.

Evaluation of tablet

Determined Weight Variation, Hardness, Thickness, Friability, Wetting Time, Disintegration Time.

Determination of Drug Content Uniformity

The tablets were tested for their drug content uniformity. At random 20 tablets were weighed and powdered. The powder equivalent to 150 mg was weighed accurately and dissolved in 100 ml of 0.1 N HCl, pH 1.2. Then 1 ml of this solution was transferred to the 10 ml volumetric flask, and the final volume was made by the same solutions. Finally, absorbance of the prepared solution was measured at 248 nm using a UV-visible spectrophotometer. The percentage drug content was calculated.

In-vitro dissolution studies

In vitro release studies of Ondansetron HCl from all formulations were performed according to USP type II, the paddle method. Paddle speed was maintained at 50 rpm, and 500 ml of 0.1 N HCl, pH 1.2, was used as the dissolution medium. Samples were collected at predetermined time intervals and replaced with an equal volume of fresh medium, filtered through a Whatman filter paper, and analyzed with a UV-visible spectrophotometer at λmax 248 nm. Drug concentration was calculated from a standard calibration plot and expressed as cumulative % drug dissolved.

II. RESULT AND DISCUSSION

The melting point of the drug sample was found to be 178°C by Thiel's tube method, which complied with IP standards, thus indicating the purity of the drug.

The solubility analysis of Ondansetron HCl was determined by the UV method. Solubility is shown in Table 5.2. The solubility of Ondansetron HCl in water was found to be freely soluble; pH 6.8 phosphate buffer was found to be very slightly soluble, methanol was found to be slightly soluble, 0.1 N HCl was found to be completely soluble.

Drug-excipient compatibility studies were carried out using FT-IR. FTIR spectra of pure ondansetron HCl, pure drug, and polymer mixtures showed sharp characteristic peaks for functional groups. The results revealed that there was no deviation in the wave number of the peaks nor in the intensity of the peaks of the pure drug/polymer mixture, confirming that there was no interaction between the drug and polymers.

The precompression parameters of powder blends, including bulk and tapped density, angle of repose, Carr's index, and Hausner's ratio, were within pharmacopeial limits, demonstrating good flow and compressibility. This ensured smooth granulation and compression processes. Post-compression evaluation confirmed that all tablet formulations met standard requirements for The hardness of all formulations ranged from 3.10–3.47 kg/cm², indicating adequate mechanical strength for handling and packaging. F7 showed the highest hardness (3.47 kg/cm²), while F2 exhibited the lowest (3.10 kg/cm²).

The tablet thickness ranged from 2.35–2.45 mm, demonstrating good uniformity among all formulations. The minimal variation indicates consistent die filling and compression during tablet manufacturing.

All formulations exhibited friability below 1% (0.44–0.72%), indicating acceptable mechanical strength and resistance to abrasion. The wetting time ranged from 42.23 to 91.36 s, with F7 showing the fastest wetting due to enhanced water uptake.

The disintegration time ranged from 22.03 to 70.29 s, with F7 exhibiting the fastest disintegration, indicating superior oral dispersibility.

Weight variation was between 147 to 150.1%. All formulations complied with USP/IP requirements (±7.5% depending on tablet weight). The low variation confirms uniform die filling and blend flow during compression. Drug content uniformity (81–94%) indicated homogeneous distribution of the drug across all batches.

The in vitro release study of the Ondansetron HCl Oro dispersible tablets formulation F1 to F7 was within 11 minutes, using a USP type II dissolution test apparatus and using 0.1 N HCl pH 1.2. The amount of drug release from formulation Among all formulations, F7 exhibited the highest drug release (95.09%) at 10 minutes, indicating superior dissolution performance. F1 showed the lowest drug release (71.11%), suggesting comparatively slower dissolution. Overall, the results suggest that increasing the concentration of natural super disintegrants enhanced tablet disintegration and dissolution, leading to improved drug release from Ondansetron HCl Oro dispersible tablets.

Overall Ondansetron HCl Oro dispersible tablets prepared by the direct compression method F1 served as the control formulation without any super disintegrant and showed the slowest disintegration and dissolution.

Increasing the concentration of fenugreek seed mucilage (F2→F4) progressively improved tablet disintegration and drug release.

Similarly, increasing the concentration of banana powder (F5→F7) enhanced tablet performance.

F4 (8 mg fenugreek seed mucilage) and F7 (8 mg banana powder) demonstrated the best overall performance among their respective groups due to the highest super disintegrant concentration.

Table 1: Melting point drug: Ondansetron HCl

Trials	Melting point	Average
1	177°C	178°C
2	179°C	
3	178°C	

Table 2: Solubility analysis of Ondansetron HCl

Solvents	Solubility criteria
Water	Freely soluble
Buffer pH 6.8	Very slightly soluble
Methanol	slightly soluble
0.1 N HCl	Completely soluble

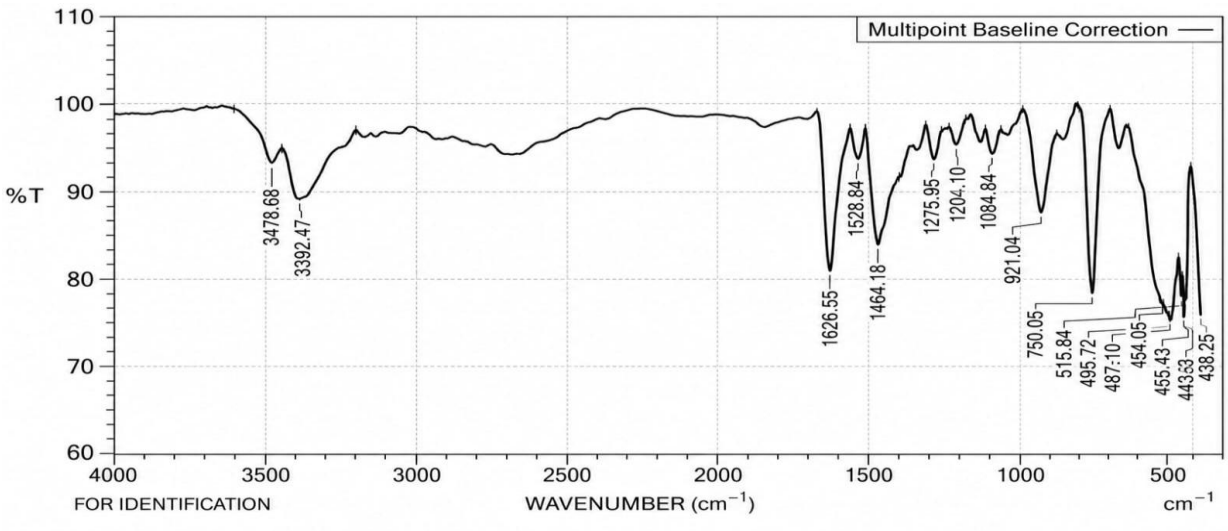

Fig. 1: FTIR spectra of pure drug

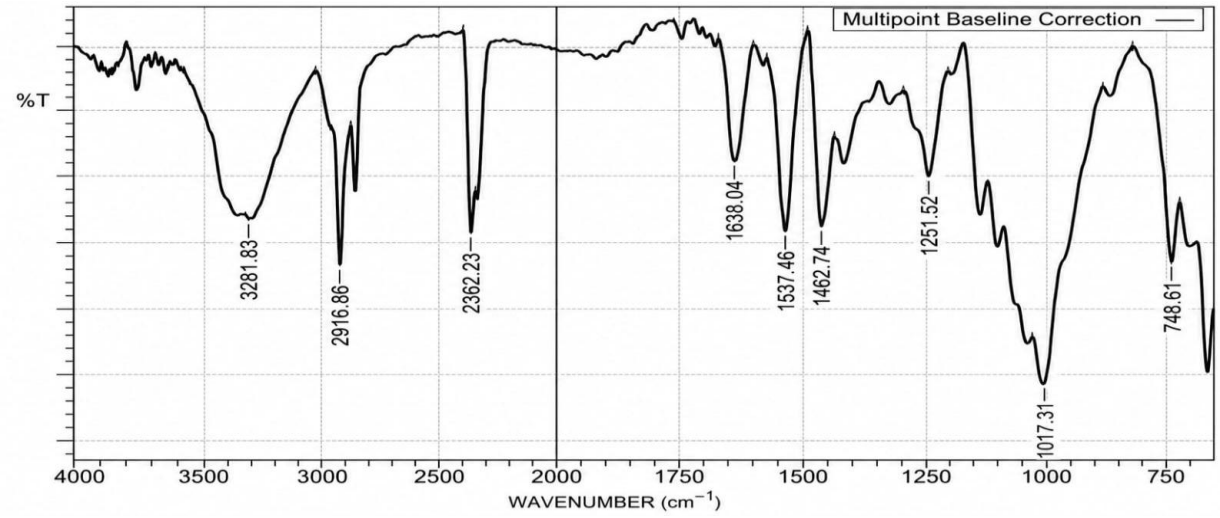

Fig. 2: FTIR spectra of physical mixtures.

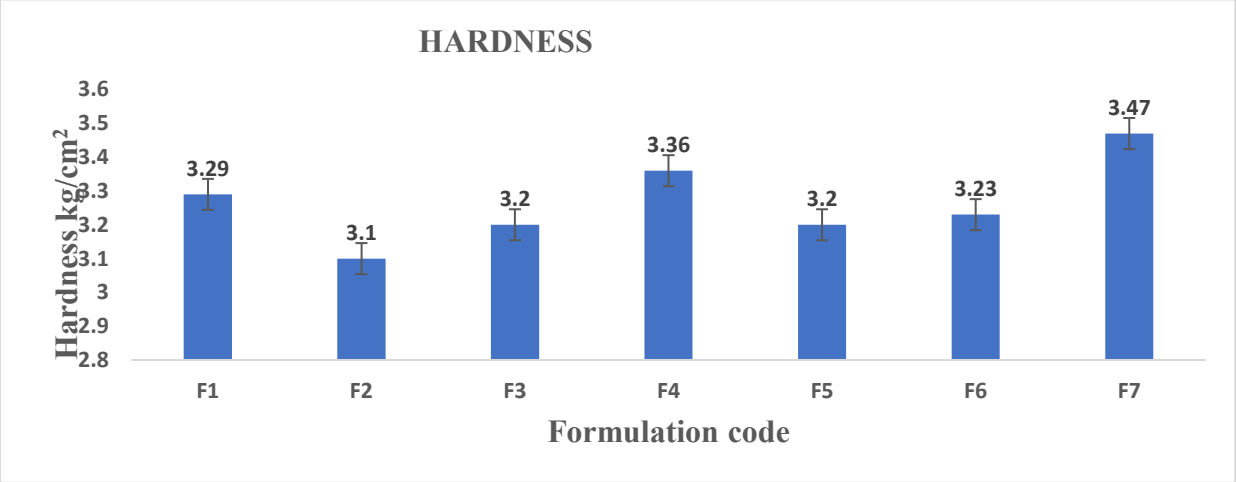

Fig. 3: Hardness of Oral dispersible tablet

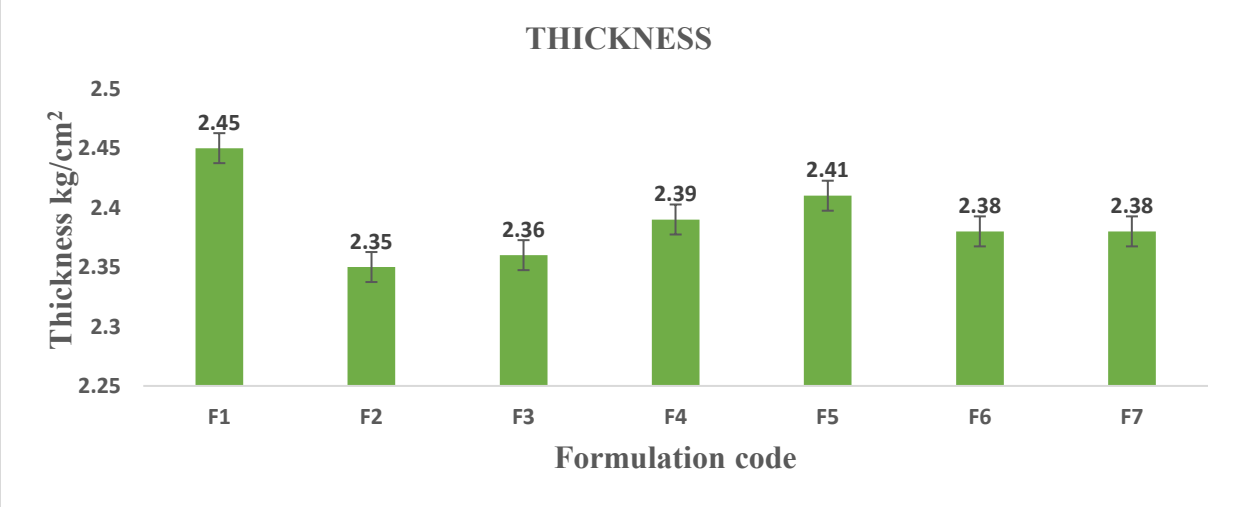

Fig. 4: Thickness of Oral dispersible tablet

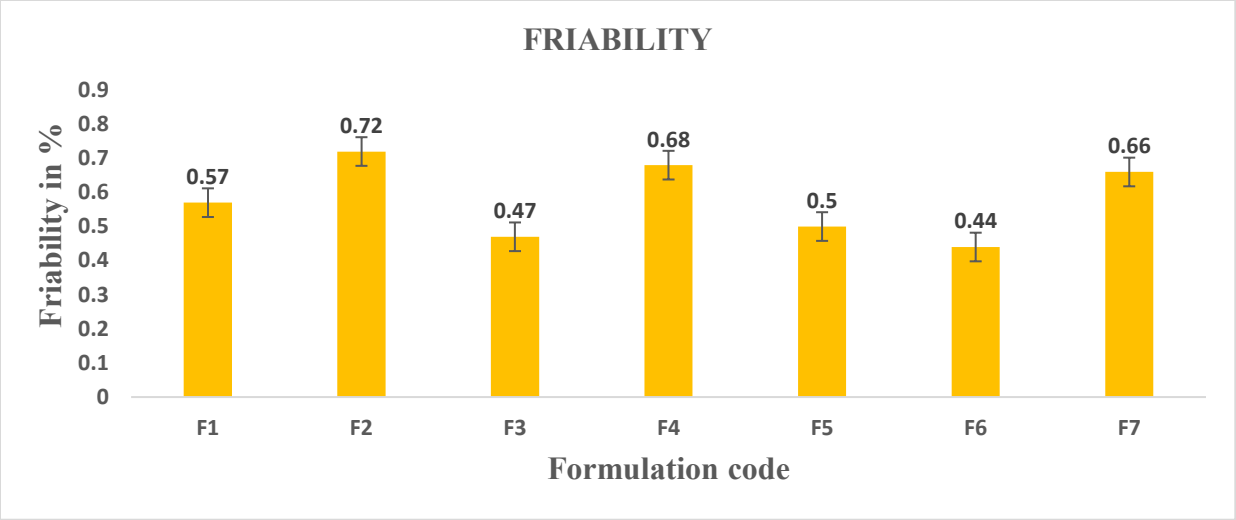

Fig. 5: Friability of Oral Dispersible Tablet

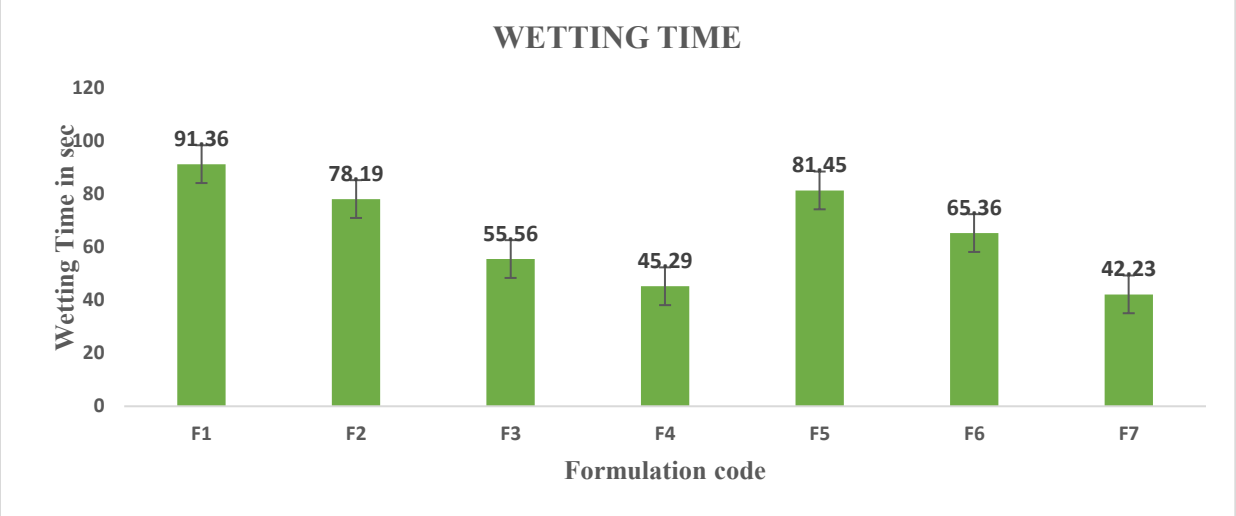

Fig. 6: wetting time of Oral dispersible tablet

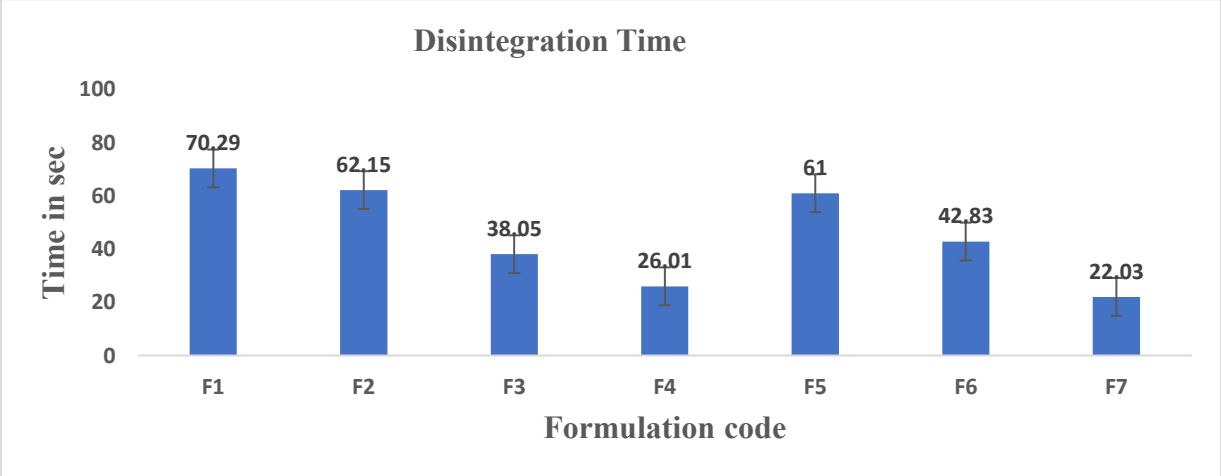

Fig. 7: Disintegration time of oral dispersible tablet

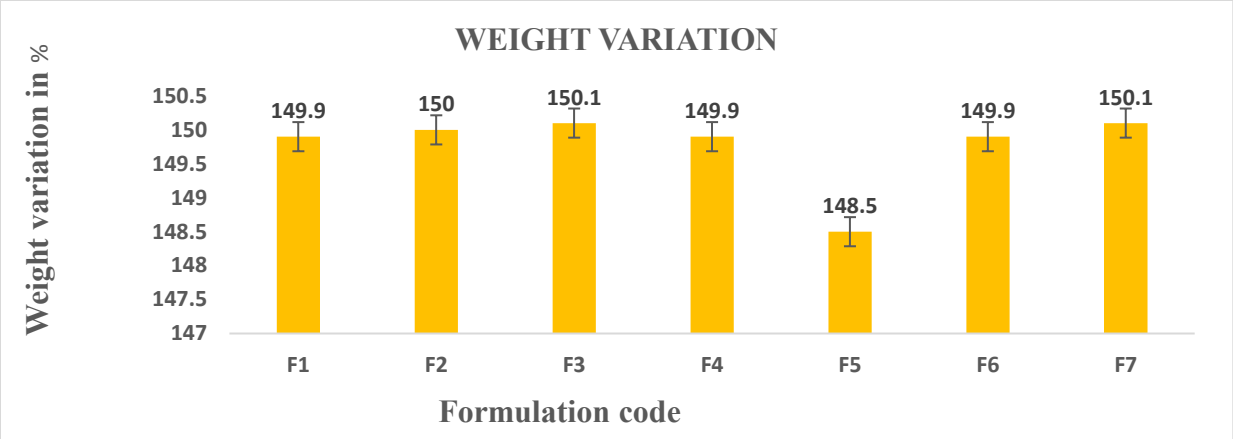

Fig. 8: Weight variation of oral dispersible tablet

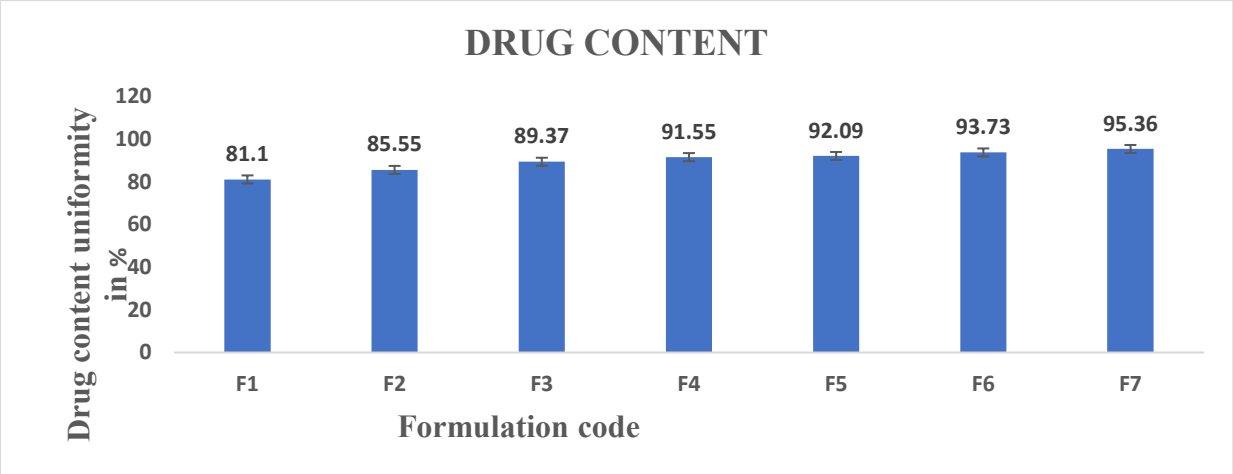

Fig. 9: Drug content of Oral dispersible tablet

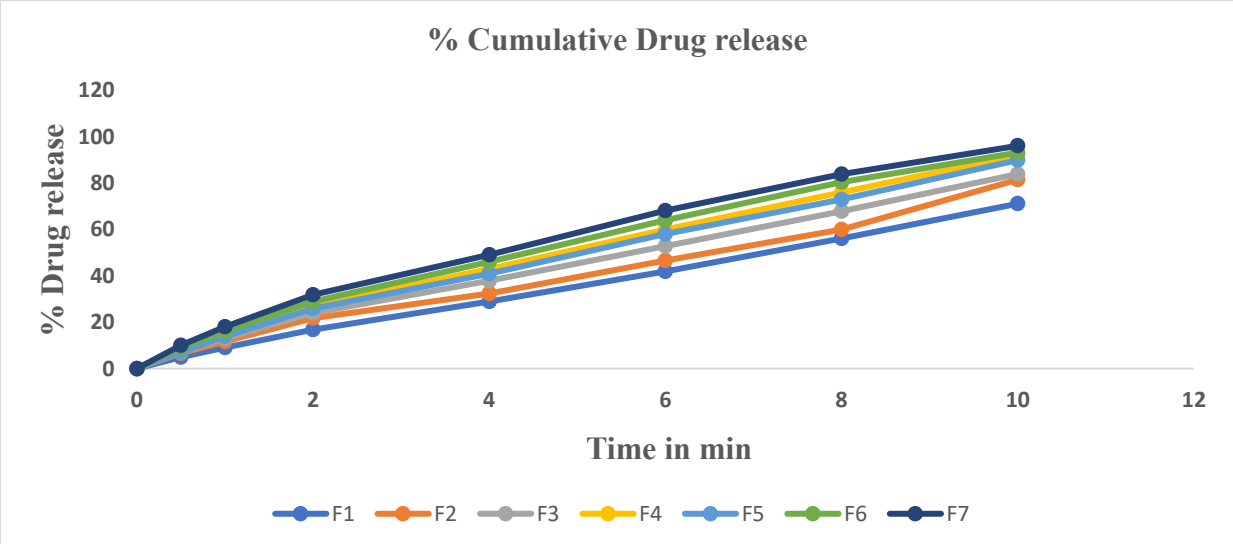

Fig. 10: *In vitro* drug release profile of F1-F7 formulation

III. CONCLUSION

The present study successfully developed Oro dispersible Tablets of Ondansetron HCl using natural super disintegrants by the direct compression method. All formulations showed acceptable pre-compression and post-compression characteristics and complied with pharmacopeial standards. Among all formulations, F7 containing 8 mg banana powder exhibited the shortest disintegration time and the highest drug release (95.09%). The results indicate that banana powder is an effective natural super disintegrant for improving the performance of Ondansetron HCl Oro dispersible Tablets and enhancing patient compliance.

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