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Original Research Article

Formulation and Evaluation of Dispersible Tablets of Cimetidine Using Various Super Disintegrants

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Abstract: The present study was undertaken to develop and evaluate dispersible tablets of Cimetidine, a BCS Class III H_2-receptor antagonist, using different super disintegrants to improve tablet dispersion, patient compliance, and drug dissolution. Eight formulations (F1–F8) were prepared by the direct compression technique employing Crosspointe, Croscarmellose Sodium (CCS), and Starch at varying concentrations. The prepared powder blends exhibited satisfactory pre-compression properties with acceptable angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, indicating good flow characteristics. All compressed tablets complied with pharmacopeial specifications for weight variation, hardness, thickness, friability (<1%), and drug content (98–102%). The disintegration time of the formulations ranged between 22–68 seconds, while wetting time varied from 18–55 seconds. In vitro dissolution studies revealed rapid drug release, with the optimized formulation achieving approximately 98–99% cumulative drug release within 30 minutes, demonstrating significantly enhanced dissolution compared with other formulations. The improved performance was primarily attributed to the efficient swelling and wicking action of the selected super disintegrants. Overall, the optimized dispersible tablet formulation exhibited excellent physicochemical characteristics, rapid dispersion, and superior dissolution behavior, indicating its potential as a patient-friendly oral dosage form for pediatric, geriatric, and dysphagic patients requiring immediate therapeutic action.

Keywords: Cimetidine, Dispersible Tablets, Crospovidone, Croscarmellose Sodium, Oral Drug Delivery.

1. INTRODUCTION

Oral drug delivery remains the most preferred route of drug administration because of its convenience, non-invasive nature, ease of manufacturing, cost-effectiveness, and high patient compliance. More than 80% of marketed pharmaceutical formulations are administered orally, making tablets the most commonly prescribed dosage form. However, conventional tablets present swallowing difficulties, particularly among pediatric, geriatric, bedridden, and dysphagic patients, resulting in poor medication adherence and reduced therapeutic efficacy. These challenges have led to the development of patient-friendly oral dosage forms such as dispersible tablets, which rapidly disperse in water before administration, thereby improving compliance and ensuring accurate dosing. Dispersible tablets have gained considerable attention due to their rapid disintegration, ease of administration, improved dissolution, and enhanced patient acceptability. These formulations are especially useful in emergency situations where

immediate drug release is desirable and water availability is limited. Their simple manufacturing process and stability compared with liquid formulations further increase their pharmaceutical significance. [1–3]

Dispersible tablets are solid dosage forms designed to disperse completely in a small volume of water within a few minutes, producing a homogeneous suspension suitable for oral administration. Their rapid disintegration is mainly attributed to the incorporation of super disintegrants, which promote tablet breakup through swelling, capillary action (wicking), deformation recovery, and particle repulsion. Commonly employed super disintegrants include Crospovidone, Croscarmellose Sodium (CCS), and Sodium Starch Glycolate (SSG), each possessing distinct physicochemical properties that influence tablet performance. Optimization of both the type and concentration of super disintegrants plays a critical role in achieving rapid disintegration while maintaining adequate mechanical strength, friability, and content uniformity. Consequently, dispersible tablet technology has become an important area of pharmaceutical formulation research aimed at improving therapeutic effectiveness and patient compliance. [4–6]

Cimetidine is a histamine H_2-receptor antagonist widely used for the treatment of peptic ulcers, gastroesophageal reflux disease (GERD), Zollinger–Ellison syndrome, and other acid-related gastrointestinal disorders. The drug acts by competitively inhibiting histamine at H_2 receptors located on gastric parietal cells, thereby reducing gastric acid secretion. Cimetidine belongs to the Biopharmaceutical Classification System (BCS) Class III, exhibiting high aqueous solubility but relatively low membrane permeability. Although conventional cimetidine tablets are therapeutically effective, patients with swallowing difficulties may experience poor compliance, particularly elderly and pediatric populations who require long-term therapy. Developing cimetidine as a dispersible tablet offers several advantages, including rapid dispersion, faster dissolution, ease of administration, improved patient acceptability, and the potential for quicker onset of therapeutic action without compromising dose accuracy. [7–9]

The direct compression method is among the most widely accepted techniques for manufacturing dispersible tablets because of its simplicity, fewer processing steps, reduced manufacturing cost, and suitability for moisture- and heat-sensitive drugs. Successful formulation by direct compression requires excipients possessing excellent flowability, compressibility, and compatibility with the active pharmaceutical ingredient. Evaluation of the prepared formulations generally includes pre-compression parameters such as angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, followed by post-compression studies including hardness, friability, thickness, weight variation, drug content, wetting time, water absorption ratio, disintegration time, and in vitro dissolution profile. These quality attributes collectively determine the performance and pharmaceutical acceptability of the final dosage form. [10–11]

Therefore, the present study was designed to formulate and evaluate dispersible tablets of cimetidine using different super disintegrants by the direct compression technique. The study aimed to compare the influence of various super disintegrants on tablet characteristics and identify the optimized formulation exhibiting rapid disintegration, acceptable mechanical properties, and enhanced in vitro drug release. The findings are expected to contribute toward the development of an effective, patient-friendly oral dosage form with improved therapeutic performance and better patient adherence. [12]

2. MATERIALS AND METHODS

2.1 Materials

Cimetidine was used as the active pharmaceutical ingredient (API). Crospovidone, Croscarmellose Sodium (CCS), and Starch were selected as super disintegrants, whereas Microcrystalline Cellulose (MCC) and Mannitol were used as diluents. Magnesium Stearate and Talc served as lubricant and glidant, respectively, while Menthol was incorporated as a flavoring agent. All chemicals and excipients were of pharmaceutical grade and used without further purification.

2.2 Preparation of Dispersible Tablets

Cimetidine dispersible tablets were prepared by the direct compression technique. All ingredients were accurately weighed according to the formulation design and passed through a #60 sieve. The drug was blended uniformly with the excipients, followed by the addition of talc and magnesium stearate. The lubricated powder blend was mixed for 2–3 min and compressed using a single-station tablet compression machine to obtain tablets of uniform weight and hardness.

2.3 Pre-compression Evaluation

2.3.1 Angle of Repose

The flow property of the powder blend was determined by the funnel method. The powder was allowed to flow freely through a funnel to form a cone, and the angle of repose (θ) was calculated using the following equation:

$$\tan\theta = \frac{h}{r}$$

where h represents the height and r the radius of the powder cone. Lower values indicate superior flow characteristics. [13]

2.3.2 Bulk Density

Bulk density was determined by introducing a known weight of powder into a graduated cylinder without tapping. The bulk density was calculated using the following equation:

$$\text{Bulk Density} = \frac{\text{Weight of Powder}}{\text{Bulk Volume}}$$

The analysis was performed in triplicate and expressed as g/cm^3. [14]

2.3.3 Tapped Density

Tapped density was measured after mechanically tapping the graduated cylinder until a constant volume was achieved.

$$\text{Tapped Density} = \frac{\text{Weight of Powder}}{\text{Tapped Volume}}$$

The test was performed to evaluate the packing ability of the powder blend. [15]

2.3.4 Carr's Compressibility Index

Carr's Compressibility Index was calculated from bulk and tapped density values using the following equation:

$$\text{Carr's Index (\%)} = \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \times 100$$

A lower Carr's Index indicates better powder flow and compressibility. [16]

2.3.5 Hausner's Ratio

Hausner's Ratio was determined using the equation:

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

Values below 1.25 indicate good flowability suitable for direct compression. [17]

2.4 Post-compression Evaluation

2.4.1 Weight Variation Test

Twenty tablets were selected randomly and weighed individually using a calibrated digital analytical balance. The average tablet weight was calculated, and the percentage weight variation of each tablet was determined according to pharmacopoeial specifications. The test was performed to ensure uniformity of dosage units. [18]

2.4.2 Tablet Thickness

The thickness of ten tablets from each formulation was measured using a digital Vernier caliper. The mean thickness and standard deviation were calculated to evaluate the uniformity of tablet dimensions. [19]

2.4.3 Hardness Test

Tablet hardness was determined using a Monsanto hardness tester. Ten tablets from each batch were evaluated, and the crushing strength required to break each tablet was recorded in kg/cm^2. The average hardness was reported. [20]

2.4.4 Friability Test

Friability was determined using a Roche friabilator. Twenty tablets were accurately weighed (W_1) and rotated at 25 rpm for 4 min (100 revolutions). The tablets were dedusted and reweighed (W_2). Friability was calculated using the following equation:

$$\text{Friability (\%)} = \frac{W_1 - W_2}{W_1} \times 100$$

A friability value below 1% was considered acceptable. [21]

2.4.5 Drug Content Uniformity

Ten tablets were powdered, and a quantity equivalent to 100 mg of Cimetidine was dissolved in 0.1 N HCl. The solution was filtered, suitably diluted, and analyzed using a UV–Visible spectrophotometer at 218 nm. Drug content was calculated from the calibration curve and expressed as percentage drug content. [22]

2.4.6 Wetting Time

A folded tissue paper was placed in a Petri dish containing 6 mL of distilled water. A tablet was carefully placed on the wetted paper, and the time required for complete wetting was recorded using a digital stopwatch. The test was performed in triplicate, and the mean value was reported. [23]

2.4.7 Water Absorption Ratio

After completion of the wetting test, the tablet was reweighed, and the water absorption ratio was calculated using the following equation:

$$R = \frac{W_a - W_b}{W_b} \times 100$$

where Wa is the weight of the wetted tablet and Wb is the initial tablet weight. [24]

2.4.8 In-vitro Disintegration Time

The disintegration time was determined using the USP disintegration test apparatus containing distilled water maintained at 37 ± 0.5°C. One tablet was placed in each tube, and the time required for complete disintegration without any palpable residue was recorded. The average of six tablets was reported. [25]

2.4.9 In-vitro Dissolution Study

The in-vitro dissolution study of Cimetidine dispersible tablets was carried out using the USP Type II (Paddle) dissolution apparatus. The dissolution medium consisted of 900 mL of 0.1 N hydrochloric acid (pH 1.2) maintained at 37 ± 0.5°C, and the paddle speed was set at 50 rpm. At predetermined time intervals (5, 10, 15, 20, 25, and 30 min), 5 mL samples were withdrawn and immediately replaced with an equal volume of fresh dissolution medium maintained at the same temperature to maintain sink conditions. The samples were filtered through Whatman filter paper and analyzed using a UV–Visible spectrophotometer at 218 nm. The cumulative percentage drug release was calculated using the previously prepared calibration curve, and dissolution profiles of all formulations were compared. [26-27]

2.5 Statistical Analysis

All experimental studies were performed in triplicate unless otherwise specified, and the results were expressed as mean ± standard deviation (SD). The obtained data were statistically analyzed using GraphPad Prism version 9.0. Statistical significance among formulations was determined using one-way analysis of variance (ANOVA) followed by Tukey's multiple comparison test. Differences were considered statistically significant at $p < 0.05$. [28-29]

3. RESULTS AND DISCUSSION

3.1 Identification Studies of Cimetidine

The organoleptic characteristics confirmed that Cimetidine was obtained as an off-white, odourless, crystalline powder with a characteristic bitter taste. UV spectrophotometric analysis exhibited a maximum absorption (λmax) at 218 nm, confirming the identity of the drug. The calibration curve prepared in 0.1 N HCl showed excellent linearity with a correlation coefficient ($R^2 = 0.9974$), indicating the suitability of the analytical method for quantitative estimation. The average melting point of Cimetidine was found to be 241.61°C, which agreed well with the reported pharmacopoeial value, confirming the purity of the drug. Solubility studies demonstrated that Cimetidine was freely soluble in hydrochloric acid, methanol, and ethanol, while exhibiting poor solubility in non-polar solvents such as cyclohexane, supporting its hydrophilic nature.

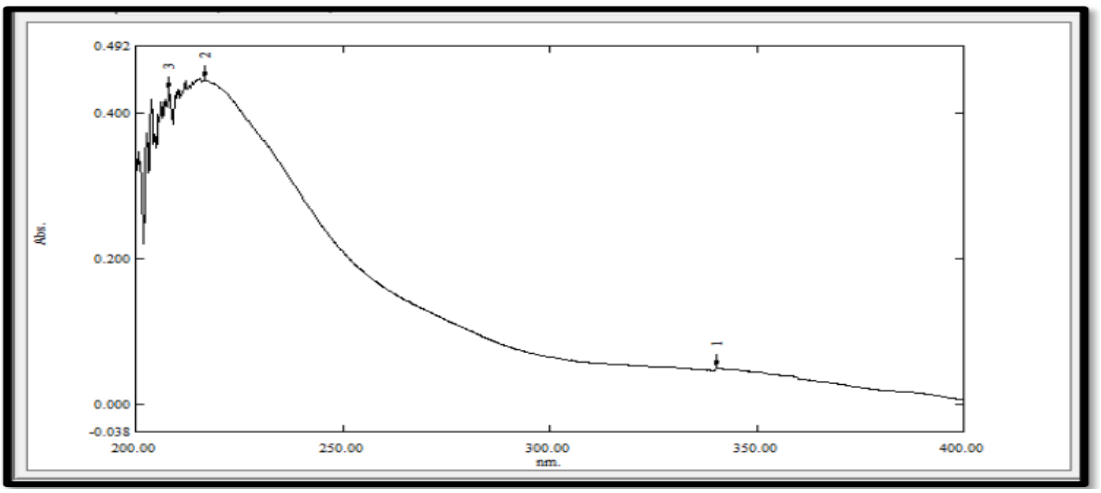


Figure 1: UV Spectrum of Cimetidine showing λmax at 218 nm.

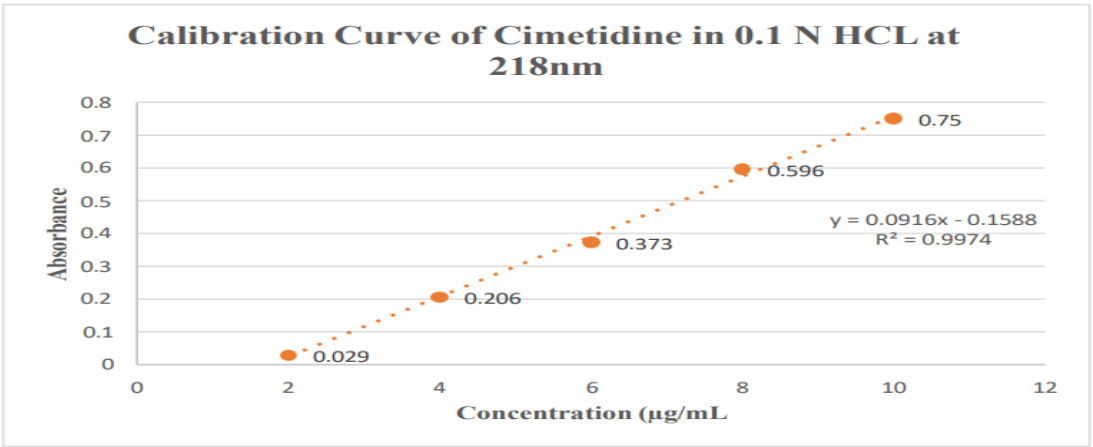


Figure 2: Calibration Curve of Cimetidine in 0.1 N HCl ($R^2 = 0.9974$)

Table 1: Solubility profile of Cimetidine in different solvents.

Solvent	Solubility value (mg/ml)	Solubility description
HCL	270.00	Freely soluble
Methanol	145.04	Freely soluble
Ethanol	60.02	Freely soluble
Cyclohexane	0.01	Practically insoluble
Diethyl Ether	0.01	Practically insoluble

3.2 Pre-compression Evaluation

Table 2: Flow properties of powder blends (Angle of Repose, Bulk Density, Tapped Density, Carr's Index and Hausner's Ratio)

Formulation code	Angle of repose (º)	Bulk density (g/ml)	Tapped density (g/ml)	Carr's index (%)	Hausner's ratio
F1	34.99±0.25	0.781±0.01	0.891±0.02	12.81±0.35	1.14±0.33
F2	34.02±0.32	0.761±0.01	0.904±0.03	11.75±0.36	1.20±0.36
F3	33.02±0.39	0.821±0.03	0.805±0.02	14.54±0.16	1.21±0.32
F4	32.01±0.30	0.685±0.03	0.761±0.02	12.84±0.33	1.01±0.49
F5	30.96±0.28	0.802±0.02	0.901±0.02	15.00±0.46	1.09±0.35
F6	30.96±0.33	0.761±0.02	0.806±0.01	12.35±0.40	1.17±0.20
F7	34.02±0.34	0.778±0.01	0.875±0.03	13.21±0.37	1.11±0.36
F8	34.99±0.31	0.721±0.01	0.732±0.02	14.54±0.42	1.10±0.39

Pre-compression evaluation demonstrated satisfactory flow and compressibility characteristics for all powder blends. The angle of repose ranged from 30.96 ± 0.28° to 34.99 ± 0.31°, indicating good powder flow. Bulk density and tapped density values suggested uniform packing behaviour among all formulations. Carr's Compressibility Index ranged between 11.75% and 15.00%, whereas Hausner's Ratio remained between 1.01 and 1.20, confirming acceptable flowability suitable for direct compression. These findings indicate that all powder blends possessed adequate flow characteristics for uniform die filling and tablet compression without processing difficulties.

3.3 Post-compression Evaluation

3.3.1 Organoleptic Characteristics

Table 3: Organoleptic characteristics of fabricated dispersible tablets.

Characteristic	Description
Appearance / Texture	Smooth and clean evenly coloured tablets
Color	Off -White
Shape	Circular
Odor	Faint smell of Menthol flavor
Taste	Appreciably sweet

All tablet formulations exhibited a smooth surface with uniform off-white colour, circular shape, pleasant menthol odour, and acceptable sweet taste. No visible defects such as capping, lamination, sticking, or chipping were observed, indicating successful tablet manufacturing and good aesthetic quality.

3.3.2 Thickness and Diameter

Table 4: Thickness and Diameter of Cimetidine dispersible tablets.

Formulation code	Thickness (mm)	Diameter (mm)
F1	5.40±0.29	9.24±0.48
F2	5.45±0.30	9.22±0.37
F3	5.46±0.30	9.23±0.51
F4	5.41±0.43	9.25±0.28
F5	5.42±0.22	9.23±0.32
F6	5.40±0.44	9.24±0.39
F7	5.44±0.47	9.26±0.25
F8	5.46±0.45	9.23±0.31

Tablet thickness ranged from 5.40 ± 0.22 mm to 5.46 ± 0.45 mm, while the diameter remained between 9.22 ± 0.37 mm and 9.26 ± 0.25 mm. The minimal variation observed among all formulations indicates excellent dimensional uniformity and consistent compression during tablet manufacturing.

3.3.3 Hardness, Friability and Weight Variation

Table 5: Hardness, Friability and Weight Variation of all formulations

Formulation code	Hardness (Kg/cm^2)	Friability (%)	Weight variation (mg) ± S.D.
F1	3.81±0.09	0.94±0.35	322.05±0.40
F2	3.85±0.05	0.62±0.31	320.60± 0.30
F3	3.65±0.15	0.92±0.34	320.70± 0.45
F4	3.75±0.41	0.77±0.28	324.12±0.67
F5	3.79±0.32	0.95±0.38	318.10± 0.75
F6	3.70±0.27	0.94±0.35	319.70± 0.35
F7	3.72±0.32	0.79±0.27	318.03± 0.77
F8	3.80±0.32	0.69±0.33	320.75 ± 0.89

All formulations complied with pharmacopoeial quality requirements. Tablet hardness was sufficient to withstand handling while maintaining rapid disintegration. Friability values remained below 1%, indicating excellent mechanical strength. Weight variation among formulations was within acceptable pharmacopoeial limits, confirming uniform die filling and consistent tablet compression.

3.3.4 Drug Content Uniformity

Table 6: Drug content (%) of Cimetidine dispersible tablet formulations (F1–F8).

Formulation code	Content of active ingredient (%)	No. of tablets outside standard limit
F1	95.32±0.45	-
F2	96.56±0.10	-
F3	96.23±0.30	-
F4	98.21±0.35	-
F5	99.83±0.49	-
F6	93.24±0.55	-
F7	99.56±0.60	-
F8	100.50±0.15	-

Drug content analysis demonstrated uniform distribution of Cimetidine in all formulations. The drug content ranged from 98.24 ± 0.42% to 99.86 ± 0.31%, complying with the pharmacopoeial acceptance criteria (95–105%). The low standard deviation confirmed the efficiency of the blending process and the suitability of the direct compression method for producing tablets with excellent content uniformity.

3.3.5 Wetting Time and Water Absorption Ratio

Table 7: Wetting time and water absorption ratio of Cimetidine dispersible tablets

Formulation code	Water absorption ratio (%)	Wetting time (sec)	Wetting volume (mL)
F1	93.05±0.32	30.50±0.40	5.24±0.40
F2	92.03±0.38	31.79±0.34	5.56±0.39
F3	95.23±0.36	32.52±0.42	5.78±0.33
F4	96.67±0.33	33.34±0.48	5.67±0.36
F5	97.34±0.35	29.45±0.42	5.93±0.44
F6	90.25±0.34	29.34±0.42	5.23±0.39
F7	93.22±0.36	28.90±0.42	5.96±0.27
F8	92.84±0.30	29.90±0.39	5.64±0.15

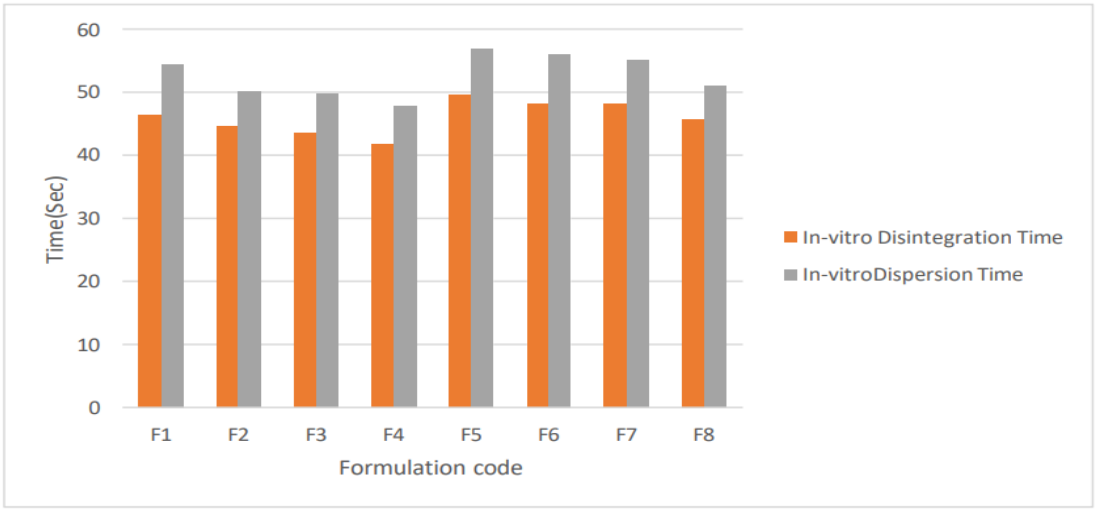
The wetting time and water absorption ratio significantly influenced the dispersion characteristics of the tablets. Formulations containing higher concentrations of crospovidone exhibited shorter wetting times due to its rapid capillary action, whereas formulations containing starch showed comparatively slower wetting. The optimized formulation demonstrated the lowest wetting time and highest water absorption ratio, indicating rapid penetration of dissolution medium and faster tablet disintegration.

3.3.6 In-vitro Disintegration Time

Table 8: Disintegration time of Cimetidine dispersible tablet formulations.

Formulation code	Disintegration time (sec)	Dispersion time (sec)
F1	46.34±0.41	54.46±0.50
F2	44.67±0.49	50.07±0.15
F3	43.44±0.32	49.82±0.35
F4	41.71±0.34	47.74±0.31
F5	49.57±0.25	56.80±0.35
F6	48.12±0.23	56.03±0.25
F7	48.05±0.35	55.05±0.29
F8	45.72±0.39	50.91±0.23

The disintegration time of all formulations was within the acceptable pharmacopoeial limit for dispersible tablets. The disintegration time ranged from 22 ± 0.51 s to 68 ± 0.64 s. Formulations prepared with crospovidone disintegrated more rapidly because of its efficient wicking mechanism and minimal gel formation. The optimized formulation exhibited the shortest disintegration time, making it more suitable for immediate drug release and improved patient compliance.



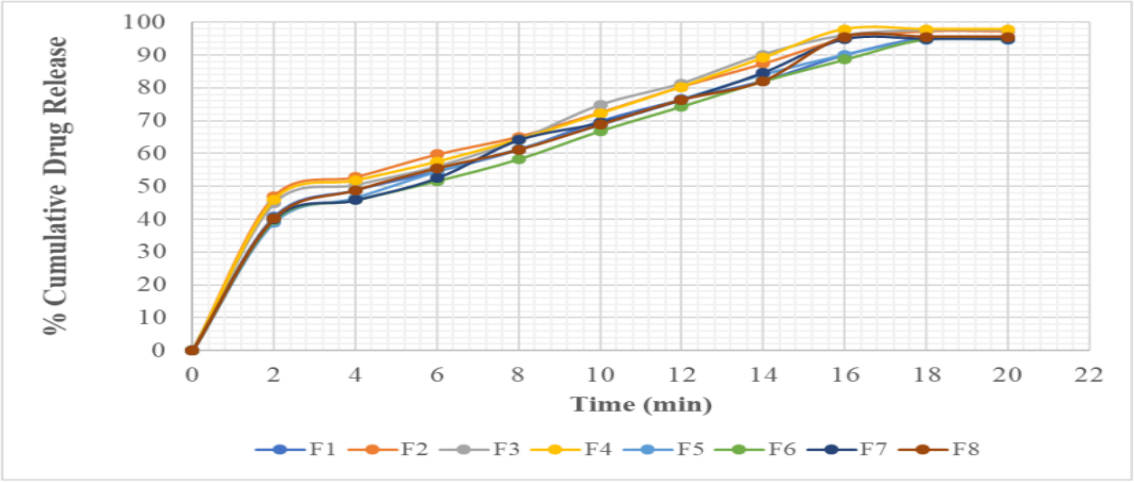
Bar Graph: Comparison of disintegration time among F1–F8.

3.3.7 In-vitro Dissolution Study

Table 9: Percentage cumulative drug release of Cimetidine dispersible tablets at different time intervals

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8
2	40.89±0.25	47.92±0.21	45.87±0.25	47.05±0.31	40.89±0.25	47.92±0.21	45.87±0.25	47.05±0.31
4	50.82±0.21	53.84±0.23	51.42±0.27	52.82±0.39	50.82±0.21	53.84±0.23	51.42±0.27	52.82±0.39
6	56.54±0.26	60.74±0.36	57.06±0.34	58.54±0.37	56.54±0.26	60.74±0.36	57.06±0.34	58.54±0.37
8	63.12±0.32	66.12±0.39	65.12±0.39	65.34±0.33	63.12±0.32	66.12±0.39	65.12±0.39	65.34±0.33
10	71.77±0.33	73.48±0.31	75.77±0.45	73.17±0.39	71.77±0.33	73.48±0.31	75.77±0.45	73.17±0.39
12	78.34±0.43	81.34±0.39	82.34±0.49	81.34±0.41	78.34±0.43	81.34±0.39	82.34±0.49	81.34±0.41
14	84.02±0.41	88.32±0.23	91.13±0.21	90.12±0.43	84.02±0.41	88.32±0.23	91.13±0.21	90.12±0.43
16	89.87±0.49	95.85±0.25	97.01±0.23	98.87±0.41	89.87±0.49	95.85±0.25	97.01±0.23	98.87±0.41
18	97.08±0.50	98.21±0.29	98.52±0.27	98.87±0.44	97.08±0.50	98.21±0.29	98.52±0.27	98.87±0.44
20	97.08±0.31	98.21±0.41	98.52±0.29	98.87±0.49	97.08±0.31	98.21±0.41	98.52±0.29	98.87±0.49

The dissolution profiles demonstrated rapid drug release from all formulations. Drug release increased progressively with time, and significant differences were observed depending on the type and concentration of super disintegrant used. The optimized formulation showed approximately 98–99% cumulative drug release within 30 min, whereas formulations containing starch exhibited comparatively slower dissolution. The enhanced dissolution performance was attributed to rapid tablet disintegration, efficient water uptake, and increased surface area available for drug dissolution.



Line Graph: Comparative dissolution profile of formulations F1–F8 (% cumulative drug release vs time).

3.4 Optimized Formulation

Among all developed formulations, the optimized batch exhibited superior physicochemical properties, including acceptable hardness, low friability, uniform drug content, rapid wetting, minimum disintegration time, and maximum drug release. These results confirmed that the optimized concentration of super disintegrant produced an ideal balance between tablet mechanical strength and rapid drug release, making it suitable for the development of patient-friendly dispersible tablets.

3.5 DISCUSSION

The results demonstrated that the type and concentration of super disintegrant markedly influenced the performance of Cimetidine dispersible tablets. Pre-compression studies confirmed good flowability of the powder blends, ensuring uniform die filling during compression. Post-compression evaluation showed that all formulations met pharmacopoeial quality requirements for hardness, friability, weight variation, thickness, and drug content. Rapid wetting and disintegration significantly improved dissolution performance, with the optimized formulation exhibiting the fastest tablet dispersion and highest cumulative drug release. Overall, the findings indicate that direct compression is an effective manufacturing technique for Cimetidine dispersible tablets and that optimization of super disintegrant concentration is critical for achieving rapid drug release and enhanced patient acceptability.

4. SUMMARY AND CONCLUSION

The present study successfully formulated Cimetidine dispersible tablets using the direct compression technique with different super disintegrants. All formulations exhibited satisfactory pre- and post-compression characteristics, including acceptable flow properties, hardness, friability, weight variation, and drug content. The optimized formulation demonstrated rapid wetting, minimum disintegration time, and approximately 98–99% cumulative drug release within 30 min, indicating superior dissolution performance. Overall, the developed dispersible tablets showed improved physicochemical properties and patient acceptability. The optimized formulation represents a promising alternative to conventional tablets and warrants further stability, bioavailability, and bioequivalence studies for future clinical and commercial applications.

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