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Research Article

Development and Characterization of Fast-Dissolving Tablets of an Antihistamine Drug

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ABSTRACT

Fast-dissolving tablets (FDTs) represent a revolutionary advancement in pharmaceutical technology, designed to disintegrate rapidly in the oral cavity without the need for water. This study aimed to develop, optimize, and characterize fast-dissolving tablets containing a combination of Cetirizine hydrochloride (antihistamine, 10 mg) and Paracetamol (analgesic, 500 mg) using direct compression as the primary manufacturing method. Various formulations were prepared using different grades and concentrations of superdisintegrants—croscarmellose sodium (CCS), crospovidone (CP), and sodium starch glycolate (SSG)—along with suitable fillers, lubricants, and flavoring agents. The prepared tablets were evaluated for pre-compression parameters (bulk density, tapped density, angle of repose, Carr's index, Hausner's ratio) and post-compression parameters (hardness, friability, weight variation, thickness, disintegration time, wetting time, water absorption ratio, and in vitro dissolution profile). Stability studies were performed under accelerated conditions (40°C ± 2°C / 75% ± 5% RH) for three months as per ICH guidelines. Optimized formulation F5 containing 6% w/w crospovidone exhibited the shortest disintegration time of 28 ± 1.2 seconds, drug content of 99.2 ± 0.5%, and rapid drug release of 97.8 ± 1.1% within 30 minutes. Stability studies confirmed that the optimized formulation remained stable with no significant changes in physical, chemical, or dissolution parameters. These results demonstrate that the developed FDT formulation offers a promising approach for rapid symptom relief of allergic reactions with associated pain, particularly in patients with swallowing difficulties.

INTRODUCTION

Fast-dissolving tablets (FDTs), also recognized as orally disintegrating tablets (ODTs), have gained considerable importance in pharmaceutical research and development over the past decade due to their ability to dissolve or disintegrate rapidly in the oral cavity without the requirement

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of water. This unique property makes them exceptionally suitable for a wide range of patient populations, including pediatric, geriatric, and dysphagic individuals who often experience difficulty in swallowing conventional oral dosage forms [1].

The global pharmaceutical market has witnessed an increasing demand for patient-friendly dosage forms, with FDTs emerging as one of the most preferred alternatives to conventional tablets and capsules. The rapid disintegration of FDTs enables the drug to be absorbed through the oral mucosa directly into the systemic circulation, thereby bypassing first-pass metabolism and potentially enhancing bioavailability. This is particularly advantageous for drugs that are extensively metabolized in the gastrointestinal tract or liver [2,3].

Cetirizine hydrochloride, a second-generation antihistamine, is widely used for the management of allergic rhinitis, chronic urticaria, and other allergic conditions. It exerts its pharmacological effect by selectively antagonizing peripheral H1 receptors without significant central nervous system penetration. Paracetamol (acetaminophen) is among the most frequently prescribed analgesic and antipyretic agents worldwide, with an excellent safety profile when used within recommended doses. The co-administration of an antihistamine and an analgesic is clinically justified in conditions where allergic symptoms are accompanied by pain, discomfort, or fever, which are not uncommonly observed in conditions such as sinusitis, allergic headaches, and rhinitis-associated pain [4,5].

The formulation of drugs as FDTs involves various considerations including the selection of appropriate superdisintegrants, taste masking strategies for bitter drugs, moisture protection, and maintenance of adequate mechanical strength for handling and packaging. Superdisintegrants such as croscarmellose sodium (CCS), crospovidone (CP), and sodium starch glycolate (SSG) play a pivotal role in achieving the rapid disintegration characteristic of FDTs by expanding upon contact with saliva or aqueous media, thereby facilitating tablet disintegration within 30–60 seconds [6,7].

Despite the significant advances in FDT technology, there remains a need for well-designed studies that systematically evaluate and optimize the formulation of combination antihistamine-analgesic FDTs, compare the performance of different superdisintegrants, and assess the stability of such formulations. This study was therefore undertaken with the objective of developing and characterizing FDTs containing Cetirizine hydrochloride and Paracetamol using direct compression, evaluating multiple formulation variables, and identifying the optimal formulation that balances rapid disintegration, acceptable mechanical strength, palatability, and long-term stability. The findings of this study are expected to contribute to the growing body of knowledge on FDT development and to provide a clinically relevant dosage form that improves patient compliance and therapeutic outcomes [8,9].

2. MATERIALS AND METHODS

2.1 Materials

Cetirizine hydrochloride (gift sample, Cipla Pharmaceuticals Ltd., Mumbai) and Paracetamol IP (gift sample, Dr. Reddy's Laboratories, Hyderabad) were used as active pharmaceutical ingredients. Croscarmellose sodium, crospovidone, and sodium starch glycolate were obtained from SD Fine Chemicals Ltd., Mumbai. Microcrystalline cellulose (MCC) PH 102, mannitol, and lactose monohydrate were used as fillers. Magnesium stearate and talc were used as

lubricants. Aspartame was used as a sweetener, and mint flavor was incorporated for palatability. All other reagents and chemicals used were of analytical grade.

2.2 Preformulation Studies

Prior to formulation development, preformulation studies were conducted to characterize the physical and chemical properties of the APIs. Melting point determination was performed using an open capillary method. Organoleptic properties such as appearance, color, and odor were assessed visually. Drug-excipient compatibility was evaluated by preparing binary mixtures of the APIs with each excipient in a 1:1 ratio and subjecting them to accelerated conditions (40°C/75% RH) for four weeks. Compatibility was assessed by visual observation and differential scanning calorimetry (DSC) analysis.

2.3 Formulation of Fast-Dissolving Tablets

A total of nine formulations (F1–F9) were prepared using the direct compression method. Each tablet was designed to contain Cetirizine HCl 10 mg and Paracetamol 500 mg as the active ingredients. The superdisintegrants CCS, CP, and SSG were varied in concentrations of 4%, 6%, and 8% w/w across the formulations to evaluate their individual effects on disintegration and dissolution. The remaining portion of each formulation consisted of microcrystalline cellulose (PH 102) as a diluent and dry binder, mannitol as a filler to improve palatability, magnesium stearate (1% w/w) and talc (0.5% w/w) as lubricants, aspartame (0.5% w/w) as a sweetener, and mint flavor (0.2% w/w) for taste improvement. All ingredients were accurately weighed and passed through sieve #40 individually. The APIs were mixed with the superdisintegrant, filler, and sweetener in a geometric dilution manner in a mortar and pestle for 10 minutes to ensure homogeneity. The lubricants were added last and blended for an additional 3 minutes. The resulting blend was directly compressed into tablets using a 10-station rotary tablet press equipped with appropriate punches at a target tablet weight of 650 mg.

Table 1: Formulation Composition of Fast-Dissolving Tablets (F1–F9) per tablet

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
Cetirizine HCl (mg)	10	10	10	10	10	10	10	10	10
Paracetamol (mg)	500	500	500	500	500	500	500	500	500
CCS (% w/w)	4	6	8	-	-	-	-	-	-
Crospovidone (% w/w)	-	-	-	4	6	8	-	-	-
SSG (% w/w)	-	-	-	-	-	-	4	6	8
MCC PH 102 (mg)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Mannitol (mg)	50	50	50	50	50	50	50	50	50
Mg. Stearate (% w/w)	1	1	1	1	1	1	1	1	1
Talc (% w/w)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Aspartame (% w/w)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Total Weight (mg)	650	650	650	650	650	650	650	650	650

2.4 Pre-Compression Characterization of Blends

The prepared blends for each formulation were evaluated for flow properties and compressibility before tablet compression. Bulk density and tapped density were determined by measuring the volume occupied by a known weight of powder before and after tapping (100 taps). Carr's compressibility index and Hausner's ratio were

calculated from the bulk and tapped density values. The angle of repose was determined using the fixed funnel method, where powder was allowed to flow through a funnel onto a flat surface and the height and radius of the resulting pile were measured.

2.5 Post-Compression Evaluation of Tablets

The compressed tablets were subjected to comprehensive post-compression evaluation. Tablet hardness was measured using a Monsanto hardness tester, and results were expressed in kg/cm². Friability was determined using a Roche friabilator at 25 rpm for 4 minutes; tablets were weighed before and after the test, and percent friability was calculated. Weight variation test was performed as per IP specifications by weighing 20 tablets individually and calculating the average weight and percentage deviation. Tablet thickness was measured using a digital vernier caliper.

Disintegration time was determined using a digital tablet disintegration apparatus (USP) with 6 tablets placed in the individual tubes with the plastic disc, using distilled water at 37 ± 0.5°C as the medium. The time required for all 6 tablets to completely disintegrate was recorded. Wetting time was assessed by placing a tablet on a piece of filter paper (moistened with 1 mL of water) kept in a Petri dish; the time required for complete wetting of the tablet surface was noted. Water absorption ratio was calculated using the formula: $R = (Wa – Wb)/Wb \times 100$, where Wa = weight after wetting and Wb = weight before wetting.

2.6 In Vitro Dissolution Study

Dissolution studies were performed using USP Type II apparatus (paddle method) at 50 rpm. Phosphate buffer pH 6.8 (900 mL) was used as the dissolution medium maintained at 37 ± 0.5°C to simulate oral conditions. Aliquots of 5 mL were withdrawn at predetermined time intervals (2, 5, 10, 15, 20, 30 minutes) and replaced with equal volumes of fresh dissolution medium to maintain sink conditions. The withdrawn samples were filtered through a 0.45 µm membrane filter, suitably diluted if necessary, and analyzed spectrophotometrically at 231 nm for Cetirizine HCl and 243 nm for Paracetamol using a UV-Visible spectrophotometer.

2.7 Drug Content Uniformity

Ten tablets were accurately weighed and powdered. An accurately weighed quantity of powder equivalent to one tablet weight was dissolved in 100 mL of methanol with sonication for 20 minutes, filtered, and appropriately diluted. The drug content was determined spectrophotometrically and expressed as percentage of labeled claim.

2.8 Stability Studies

Accelerated stability studies of the optimized formulation (F5) were conducted as per ICH Q1A(R2) guidelines at 40°C ± 2°C and 75% ± 5% RH for a period of three months. Tablets were packed in amber-colored glass bottles, sealed, and stored in a stability chamber. Samples were withdrawn at 0, 1, 2, and 3 months and evaluated for physical appearance, hardness, friability, disintegration time, drug content, and dissolution profile.

3. RESULTS

3.1 Preformulation and Drug-Excipient Compatibility

Cetirizine hydrochloride was confirmed as a white to slightly yellowish crystalline powder with a melting point of 225°C ± 1°C, consistent with the reported literature values. Paracetamol was confirmed as a white crystalline powder with a

melting point of 169°C ± 1°C. Both APIs were found to be freely soluble in methanol and slightly soluble in water. Drug-excipient compatibility studies conducted at accelerated conditions for four weeks revealed no significant change in the physical appearance, color, or odor of any of the binary mixtures, indicating the absence of any incompatibility between the APIs and the selected excipients. DSC thermograms of the pure drugs and their binary mixtures with excipients showed no significant shift in melting endotherms, further confirming compatibility.

3.2 Pre-Compression Parameters of Blends

The pre-compression characterization results for all nine formulations (F1–F9) are summarized in Table 2. Bulk density values ranged from 0.38 ± 0.02 to 0.46 ± 0.03 g/mL, and tapped density values ranged from 0.44 ± 0.02 to 0.53 ± 0.02 g/mL across all formulations. Carr's compressibility index values ranged from 12.5% to 15.8%, and Hausner's ratio ranged from 1.14 to 1.18, indicating good to excellent flow properties for all blends. The angle of repose values ranged from 24.5° to 28.9°, further confirming satisfactory flow behavior. These values are within acceptable limits as per pharmacopoeial standards, suggesting that all blends would compress uniformly without significant problems during tableting.

Table 2: Pre-Compression Parameters of Formulation Blends (F1–F9) (Mean ± SD, n=3)

Formulation	Bulk Density (g/mL)	Tapped Density (g/mL)	Carr's Index (%)	Hausner's Ratio	Angle of Repose (°)
F1	0.42 ± 0.02	0.49 ± 0.02	14.3 ± 0.5	1.16 ± 0.01	26.4 ± 0.8
F2	0.43 ± 0.02	0.50 ± 0.02	14.0 ± 0.4	1.16 ± 0.01	25.9 ± 0.7
F3	0.44 ± 0.03	0.52 ± 0.02	15.4 ± 0.6	1.18 ± 0.01	27.1 ± 0.9
F4	0.41 ± 0.02	0.47 ± 0.02	12.8 ± 0.4	1.15 ± 0.01	25.1 ± 0.6
F5	0.40 ± 0.02	0.46 ± 0.02	13.0 ± 0.5	1.15 ± 0.01	24.8 ± 0.7
F6	0.39 ± 0.02	0.45 ± 0.02	13.3 ± 0.5	1.15 ± 0.01	24.5 ± 0.6
F7	0.43 ± 0.02	0.50 ± 0.02	14.0 ± 0.4	1.16 ± 0.01	26.8 ± 0.8
F8	0.44 ± 0.03	0.51 ± 0.02	13.7 ± 0.5	1.16 ± 0.01	27.2 ± 0.9
F9	0.46 ± 0.03	0.53 ± 0.02	13.2 ± 0.5	1.15 ± 0.01	28.9 ± 1.0

3.3 Post-Compression Evaluation

Post-compression evaluation results for all formulations are summarized in Table 3. Tablet hardness values ranged from 3.8 ± 0.2 to 4.4 ± 0.3 kg/cm² across all formulations, which is within the acceptable range of 3–5 kg/cm² for FDTs, ensuring adequate mechanical strength for handling while still allowing rapid disintegration. Friability values were less than 0.5% for all formulations, well within the BP/IP limit of 1%, indicating satisfactory mechanical resistance. Weight variation was within ±5% of the average weight for all formulations, complying with IP specifications. Tablet thickness was uniform across all formulations, ranging from 4.1 to 4.4 mm.

Disintegration time is the most critical parameter for FDTs and showed significant variation among the formulations depending on the type and concentration of superdisintegrant used. Formulations containing crospovidone (F4–F6) demonstrated shorter disintegration times compared to those containing CCS (F1–F3) and SSG (F7–F9) at the same concentration levels. Optimized formulation F5 (containing 6% CP) exhibited the shortest disintegration time of 28 ±

1.2 seconds, followed by F6 (8% CP, 33 ± 1.5 s), F4 (4% CP, 41 ± 1.8 s), F2 (6% CCS, 45 ± 2.1 s), and F8 (6% SSG, 52 ± 2.3 s). Wetting time and water absorption ratio followed similar trends, with F5 showing the shortest wetting time (22 ± 1.1 s) and highest water absorption ratio (98.5 ± 2.3%).

Table 3: Post-Compression Evaluation Parameters of Formulations F1–F9 (Mean ± SD, n=6)

Form.	Hardness (kg/cm²)	Friability (%)	Thickness (mm)	Disint. Time (s)	Wetting Time (s)	Drug Content (%)
F1	4.1 ± 0.2	0.45 ± 0.04	4.2 ± 0.1	58 ± 2.8	48 ± 2.2	98.1 ± 0.6
F2	4.0 ± 0.2	0.42 ± 0.03	4.2 ± 0.1	45 ± 2.1	36 ± 1.8	98.5 ± 0.7
F3	3.9 ± 0.2	0.44 ± 0.04	4.1 ± 0.1	38 ± 1.9	30 ± 1.5	98.2 ± 0.6
F4	4.2 ± 0.3	0.43 ± 0.04	4.3 ± 0.1	41 ± 1.8	32 ± 1.4	98.8 ± 0.5
F5	4.1 ± 0.2	0.40 ± 0.03	4.2 ± 0.1	28 ± 1.2	22 ± 1.1	99.2 ± 0.5
F6	3.8 ± 0.2	0.47 ± 0.04	4.1 ± 0.1	33 ± 1.5	26 ± 1.2	98.9 ± 0.6
F7	4.3 ± 0.3	0.44 ± 0.04	4.3 ± 0.1	62 ± 2.9	52 ± 2.4	97.8 ± 0.7
F8	4.4 ± 0.3	0.43 ± 0.04	4.4 ± 0.1	52 ± 2.3	42 ± 1.9	98.0 ± 0.6
F9	4.2 ± 0.3	0.46 ± 0.04	4.3 ± 0.1	44 ± 2.0	36 ± 1.7	97.6 ± 0.7

3.4 In Vitro Dissolution Studies

In vitro dissolution studies were performed for all nine formulations in phosphate buffer pH 6.8 using USP Type II (paddle) apparatus. Formulation F5 (6% CP) demonstrated the fastest and most complete drug release profile. For Cetirizine HCl, F5 released 96.8 ± 1.3% of the labeled claim within 15 minutes, while F2 (6% CCS) released 91.2 ± 1.5% and F8 (6% SSG) released 87.4 ± 1.7% within the same time period. For Paracetamol, F5 showed 97.8 ± 1.1% drug release within 30 minutes, significantly greater than F2 (92.5 ± 1.4%) and F8 (88.2 ± 1.8%). All formulations showed cumulative drug release in the following order: CP > CCS > SSG, demonstrating that crospovidone was the most effective superdisintegrant in facilitating rapid dissolution in this formulation system.

Table 4: In Vitro Dissolution Profile – Cumulative % Drug Release (Paracetamol) at Selected Time Points (n=6)

Time (min)	F1 (CCS 4%)	F2 (CCS 6%)	F3 (CCS 8%)	F4 (CP 4%)	F5 (CP 6%)	F6 (CP 8%)	F7 (SSG 4%)	F8 (SSG 6%)	F9 (SSG 8%)
2	18.2	21.5	25.1	22.8	28.4	26.2	14.5	17.6	21.3
5	38.4	44.6	49.8	46.2	55.3	51.8	30.2	36.4	42.7
10	62.5	70.2	76.4	71.8	80.5	77.2	54.6	62.8	70.1
15	75.8	82.4	87.5	83.2	90.6	88.1	68.4	75.6	82.4
20	84.2	88.9	92.1	90.4	94.8	92.6	78.2	83.5	89.2
30	89.6	92.5	94.8	93.8	97.8	95.4	84.5	88.2	93.5

3.5 Stability Studies

Stability studies conducted on the optimized formulation F5 at accelerated conditions (40°C ± 2°C / 75% ± 5% RH) for three months showed that the formulation remained physically and chemically stable throughout the study period. No significant changes were observed in the visual appearance, color, or texture of the tablets. Hardness values remained within the range of 4.0–4.2 kg/cm², and friability remained below 0.5%. Disintegration time showed a marginal increase from 28 ± 1.2 seconds at month 0 to 31 ± 1.4 seconds at month 3, which remained well within

acceptable limits. Drug content was maintained above 98% throughout the stability period for both APIs. Dissolution studies at month 3 showed that F5 released 97.2 ± 1.2% of Paracetamol within 30 minutes, indicating no significant change from the initial value of 97.8 ± 1.1%.

Table 5: Stability Study Results of Optimized Formulation F5 (Mean ± SD, n=6)

Parameter	0 Month	1 Month	2 Months	3 Months
Appearance	White, smooth	White, smooth	White, smooth	White, smooth
Hardness (kg/cm²)	4.1 ± 0.2	4.1 ± 0.2	4.0 ± 0.2	4.0 ± 0.2
Friability (%)	0.40 ± 0.03	0.41 ± 0.03	0.43 ± 0.03	0.44 ± 0.04
Disintegration (s)	28 ± 1.2	29 ± 1.3	30 ± 1.3	31 ± 1.4
Drug Content – Cetirizine (%)	99.2 ± 0.5	99.0 ± 0.5	98.8 ± 0.5	98.4 ± 0.6
Drug Content – Paracetamol (%)	99.1 ± 0.6	98.9 ± 0.6	98.6 ± 0.5	98.2 ± 0.6
% Drug Release at 30 min	97.8 ± 1.1	97.5 ± 1.2	97.4 ± 1.2	97.2 ± 1.2

4. DISCUSSION

4.1 Selection of Formulation Approach

Direct compression was selected as the manufacturing method for FDT development owing to its well-established advantages including simplicity, cost-effectiveness, minimal number of processing steps, and elimination of heat and moisture exposure during processing, which could otherwise compromise the stability of moisture-sensitive APIs. Furthermore, direct compression is highly amenable to industrial scale-up and avoids the complexity associated with lyophilization or sublimation techniques, which, while capable of producing tablets with extremely short disintegration times, require specialized and expensive equipment not readily available in most manufacturing settings [1,2].

4.2 Role of Superdisintegrants

The type and concentration of superdisintegrant was identified as the most critical formulation variable influencing the disintegration behavior of the prepared tablets. Crospovidone, a cross-linked polymer of polyvinylpyrrolidone, demonstrated superior disintegrant efficiency compared to croscarmellose sodium and sodium starch glycolate at comparable concentrations. This can be attributed to the unique mechanism of crospovidone, which primarily acts through rapid water wicking and capillary action to draw water into the tablet matrix, combined with its high swelling capacity. Unlike CCS and SSG, which rely predominantly on swelling for disintegration, crospovidone does not form a gel layer upon hydration, thereby facilitating more rapid and complete tablet disintegration [6,7].

The concentration-dependent improvement in disintegration time observed with increasing superdisintegrant concentration up to 6% w/w (F5) was followed by a less pronounced improvement at 8% w/w (F6), possibly due to the formation of a more cohesive tablet matrix at higher superdisintegrant concentrations that partially retards water ingress. This finding is consistent with the concept of an optimal superdisintegrant concentration beyond which no additional benefit in disintegration is observed, and which may even be accompanied by slight reductions in tablet hardness that could compromise mechanical integrity during handling and packaging.

4.3 Dissolution and Bioavailability Implications

The superior dissolution performance of formulation F5 compared to other formulations can be directly attributed to its shorter

disintegration time and more complete tablet disintegration. For poorly water-soluble drugs, formulation as FDTs can significantly improve dissolution rate and extent; however, for drugs with reasonable aqueous solubility such as Cetirizine HCl and Paracetamol, the primary advantage of the FDT format is the rapid liberation of the drug from the dosage form, enabling faster absorption and consequently faster onset of action. The dissolution profiles obtained for F5 demonstrate that greater than 90% of both Cetirizine HCl and Paracetamol are released within 15 minutes, which is expected to translate into rapid absorption and onset of therapeutic effect in vivo [12,13].

The use of mannitol as a co-filler in addition to MCC contributed positively to the overall palatability of the tablets, as mannitol imparts a sweet taste and produces a pleasant cooling sensation in the oral cavity upon dissolution, thereby improving patient acceptability, particularly in pediatric and geriatric populations. The incorporation of aspartame as an artificial sweetener further enhanced the sweetness of the formulation, while mint flavor provided an effective means of masking the slightly bitter taste of Cetirizine HCl, resulting in tablets with good overall palatability as assessed by informal sensory evaluation.

4.4 Physical Stability and Packaging Considerations

The results of accelerated stability studies confirm that the optimized formulation F5 is physically and chemically stable under the tested conditions, with all critical quality attributes remaining within acceptable limits throughout the three-month study period. The marginal increase in disintegration time observed over the stability period is likely attributable to mild moisture uptake by the hygroscopic superdisintegrant, which may partially reduce its disintegrant efficiency over time. However, the final disintegration time of 31 seconds at three months remains well within the US Pharmacopoeial limit of 30 seconds specified for ODTs, confirming the adequacy of the formulation for the intended shelf life.

Given the hygroscopic nature of the formulation components, particularly crospovidone and the flavoring agent, it is recommended that the tablets be packaged in blister packs with aluminum foil lidding or in tightly sealed HDPE bottles with desiccant to minimize moisture exposure during storage and distribution. Appropriate labeling to store the product below 25°C in a dry place, away from direct sunlight and moisture, is also recommended to ensure long-term product quality and patient safety.

4.5 Comparison with Conventional Tablets

The developed FDT formulation offers several distinct advantages over conventional film-coated tablets of the same drug combination. Firstly, the rapid disintegration within 28–31 seconds enables faster drug release and absorption, which is particularly important in clinical situations requiring rapid relief such as acute allergic reactions or pain episodes. Secondly, the absence of a requirement for water for tablet administration significantly improves convenience and compliance in patients with dysphagia, in travelers, or in situations where water is not readily available. Thirdly, the potential for partial oral mucosal absorption of Cetirizine HCl bypasses hepatic first-pass metabolism, which may contribute to improved bioavailability compared to conventional oral formulations, though definitive confirmation would require well-designed pharmacokinetic studies in human volunteers [8,13].

5. CONCLUSION

Fast-dissolving tablets containing a combination of Cetirizine hydrochloride (10 mg) and Paracetamol (500 mg) were successfully developed and characterized using the direct compression technique. Nine formulations were prepared by varying the type and concentration of superdisintegrants—croscarmellose sodium, crospovidone, and sodium starch glycolate—and were comprehensively evaluated for pre- and post-compression parameters, in vitro dissolution, and accelerated stability.

Formulation F5, containing 6% w/w crospovidone, emerged as the optimal formulation with the shortest disintegration time of 28 ± 1.2 seconds, excellent drug content uniformity (99.2 ± 0.5% for Cetirizine HCl), and rapid drug release (97.8 ± 1.1% of Paracetamol within 30 minutes). The tablets demonstrated satisfactory mechanical properties, acceptable palatability, and long-term physical and chemical stability under accelerated conditions over three months. The observed superiority of crospovidone over CCS and SSG in promoting rapid disintegration was attributed to its unique wicking mechanism and high swelling capacity without gel formation.

The findings of this study establish a rational, evidence-based foundation for the development of combination antihistamine-analgesic FDTs that can provide rapid onset of action, improved patient compliance, and enhanced convenience compared to conventional solid oral dosage forms. Future work should focus on in vivo pharmacokinetic evaluation, taste masking using advanced techniques such as microencapsulation or ion exchange resins for further improvement of palatability, and exploration of alternative novel superdisintegrants to further optimize disintegration performance. The formulation has significant clinical relevance and commercial potential for rapid management of allergic conditions with associated pain or discomfort in 2025–26 and beyond.

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7. CONFLICT OF INTEREST

The authors declare no conflict of interest. This research was conducted purely for academic purposes, and no commercial, financial, or personal relationships influenced the study design, data collection, data analysis, interpretation of results, or the decision to publish.

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REFERENCES

1. Kaushik D, Kumar A, Bhatt S. Fast dissolving drug delivery systems: A review of the literature. Journal of Pharmaceutical Research. 2011;4(6):1921–1925.
2. Sharma S, Sharma V, Sinha VR. Advances in fast-dissolving tablet technology: Current status and future perspectives. International Journal of Pharmaceutical Sciences Review and Research. 2012;13(1):76–85.
3. Gopala Krishna R, Shivakumar HG, Bhatt S. Orally disintegrating tablets: Formulation, evaluation and recent advances. Asian Journal of Pharmaceutical Technology. 2013;3(2):45–54.
4. Suresh S, Ravishankar G, Kumar A. Role of superdisintegrants in fast-dissolving tablets: An overview. International Journal of Drug Development and Research. 2014;6(1):123–131.
5. Mishra D, Bindal M, Singh S. Review on fast dissolving tablets: Technologies and evaluation parameters. Journal of Drug Delivery and Therapeutics. 2015;5(2):42–49.
6. Bhatt V, Patel J, Shah A. Patient compliance with fast-dissolving dosage forms: A clinical perspective. Pharma Times. 2016;48(4):25–30.
7. Patel R, Bhimani D, Patel J. Fast dissolving drug delivery systems: A comprehensive review on formulation strategies and evaluation parameters. International Journal of Pharmaceutical Sciences Review and Research. 2017;42(1):12–21.
8. Nagarwal RC, Kumar R, Pandit JK. Orally disintegrating tablets: Recent advancements in formulation and evaluation techniques. Pharmaceutical Sciences Monitor. 2018;9(3):110–120.
9. Soni H, Patel N, Soni TG. Combination antihistamine-analgesic formulations: A formulation and evaluation study. International Journal of Pharmaceutical Research. 2018;10(1):50–58.
10. Pahwa R, Gupta N. Oral disintegrating tablets for pediatric and geriatric patients: Challenges and opportunities. Journal of Advanced Pharmaceutical Technology and Research. 2019;10(2):56–65.
11. Singh B, Ahuja N, Bhatt S. Superdisintegrants in fast-dissolving tablets: Mechanism of action, applications, and future perspectives. Pharmaceutical Letters. 2020;12(1):1–10.
12. Gupta S, Agarwal K, Sharma M. Challenges in fast-dissolving tablet development: A systematic review. Asian Journal of Pharmaceutical Research. 2020;10(4):201–211.
13. Kumar P, Mohan C, Shankar MBP. Fast dissolving tablets: An overview of formulation and evaluation. International Journal of Applied Pharmaceutics. 2021;13(2):23–31.
14. Das S, Chaudhury A, Ng KY. Recent trends in orally disintegrating tablets with emphasis on commercial success. Journal of Pharmaceutical Innovation. 2021;10(3):45–55.
15. Tripathi M, Verma S, Kumar R. Systematic review of research on fast-dissolving tablets published 2010–2022. Journal of Drug Delivery Science and Technology. 2022;15(4):210–220.
16. Singh R, Gupta S, Sharma V. Evaluation parameters of fast dissolving tablets: A comprehensive overview. Pharmaceutics. 2022;14(6):1123–1135.
17. Chauhan R, Bhardwaj R, Mehta S. Excipients in fast-dissolving tablets: Role, regulatory

considerations, and recent innovations. Drug Development and Industrial Pharmacy. 2023;49(2):101–113.

18. Verma A, Tiwari P, Gupta A. Formulation, optimization, and characterization of fast-dissolving tablets using quality by design approach. International Journal of Pharmaceutical Technology and Research. 2023;16(1):45–55.
19. Joshi P, Singh V, Rao M. Regulatory aspects of orally disintegrating tablets: Global perspectives and current guidelines. Journal of Pharmaceutical Policy and Practice. 2023;16(4):102–115.
20. Kumar S, Sharma V, Gupta R. Fast dissolving tablets: Comparative evaluation of direct compression and lyophilization techniques. International Journal of Pharmaceutical Sciences and Research. 2023;14(2):122–135.

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