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Research Article

Preparation and Characterization of Cetirizine Fast-Dissolving Tablets

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ABSTRACT

This research aimed to prepare and characterize the properties of cetirizine fast-dissolving tablets (FDTs) for improving patient compliance, especially among the elderly or individuals with swallowing difficulties. The effects of disintegrant type and concentration, including Kollidol®CL, Kollidol® CL-SF, and Explotab®, were evaluated on the characteristics of blank FDTs at concentrations of 5%, 7%, and 10% w/w. Additionally, the effect of compaction force was also investigated. The prepared tablets were evaluated regarding their properties in terms of thickness and hardness, weight variation, wetting time, and disintegration time (DT). The results revealed that the type and concentration of disintegrants significantly influenced tablet hardness, wetting time, and DT, with minimal impact on thickness and weight. Tablets formulated with 7% w/w of various disintegrants and compressed at a force of 12 kN demonstrated optimal physical properties and were selected for the preparation of cetirizine FDTs. Three formulations of cetirizine FDTs were prepared, with an average tablet weight of 307.34±2.57 mg. The weight fluctuation among the tablets was within 5%, adhering to the acceptability standards for the target weight. All FDT formulations exhibited complete wetting and full disintegration within 3 minutes. As a result, the prepared cetirizine FDTs conformed to the standards specified in the European Pharmacopoeia (EU). After one month of stability testing, all cetirizine FDTs retained satisfactory physical properties. However, further studies are required to evaluate their chemical stability. Future studies should focus on long-term stability and the evaluation of cetirizine FDT palatability in human volunteers.

Keywords: Cetirizine, Compaction force, Disintegrants, Stability, Wetting time

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Introduction

Among various drug delivery technologies, the oral route remains the most preferred for administering therapeutic agents due to its precise dosing, ease of self-administration, pain-free delivery, high patient compliance, and cost-effectiveness [1, 2]. Fast-dissolving tablets (FDTs) are designed to rapidly disintegrate and dissolve in saliva within seconds, even in the absence of water [3]. According to the European Pharmacopoeia, FDTs must disintegrate on the tongue before swallowing and should disperse within three minutes [4]. In tablet formulation, essential excipients include binders, diluents, disintegrants, glidants, and lubricants. In the development of FDTs, the impact of disintegrant concentration on tablet hardness, friability, and disintegration time (DT) was evaluated to determine the optimal formulation. Incorporating disintegrants is a widely recognized strategy for FDT formulation [5, 6]. Disintegrants play a critical role in the disintegration and dissolution of FDTs, with their effectiveness dependent on both type and optimal concentration [5]. Additionally, disintegrants impact tablet hardness, which is further influenced by compression force [5, 6]. Since compaction force directly affects disintegrant efficiency and tablet integrity, optimizing the type and concentration of disintegrants, along with the appropriate compression force, is essential for achieving the desired FDT properties.

Cetirizine is a long-acting, non-sedative antihistamine commonly prescribed to treat a range of allergic symptoms, including hay fever and chronic urticarial [7]. Cetirizine dihydrochloride is a white powder that is freely soluble in water but practically insoluble in acetone and methylene chloride [7, 8]. Kollidon® CL (crospovidone) is a water-insoluble, cross-linked homopolymer of N-vinyl-2-pyrrolidone, widely utilized as an effective disintegrant in tablet formulations. Kollidon® CL-SF, with its ultra-fine particle size, enhances the mouthfeel in fast-disintegrating tablet (FDT) formulations [9]. While Kollidon® CL has an average particle size ranging from 110 to 130 μm, Kollidon® CL-SF features a significantly smaller particle size range of 10 to 30 μm [9]. Explotab® (sodium starch glycolate) is the sodium salt of a carboxymethyl ether of starch. Its properties are defined by the degree of substitution and cross-linking [10]. It facilitates disintegration through rapid water absorption, leading to significant and rapid swelling. Kollidon® CL and Explotab® are widely used commercial disintegrants in FDT formulations. They promote tablet disintegration by rapidly expanding in volume and creating hydrostatic pressure [9, 10]. Subramanian *et al*. reported that a 1:3 weight ratio of mannitol to camphor was used as a disintegrant combination in cetirizine FDTs, producing tablets with good physical properties and a short disintegration time of 16 seconds [11]. However, Kukati *et al*. later reported that camphor could increase tablet thickness and porosity, leading to physical changes in the tablets during storage [12]. Radke *et al.* reported that cetirizine FDTs formulated with 6% w/w Kollidon® as a disintegrant exhibited the shortest DT and fastest drug release, compared to formulations containing 2% or 4% w/w Kollidon® and low-substituted hydroxypropyl cellulose (L-HPC) [13]. Furthermore, the 6% w/w Kollidon® tablets remained physically stable for three months; however, their chemical stability was not assessed. Other studies have indicated that formulations containing 13–17% w/w Kollidon® also resulted in shorter DT compared to those with 3–10% w/w [14]. Patro *et al*. reported that cetirizine FDTs with 2.5% w/w Explotab® showed the shortest disintegration time and fastest drug release, outperforming formulations

with higher concentrations (5–10% w/w) of Explotab® and Kollidon® [15]. Sharma *et al.* reported that cetirizine FDTs containing 4% w/w Explotab® exhibited the shortest disintegration time, outperforming formulations with both lower and higher concentrations (1–10% w/w) [16]. Additionally, the tablets maintained physicochemical stability after one month of storage at 40 °C and 75% relative humidity (RH). Studies have shown that increasing the compression force improves the mechanical strength of tablets but may also slow down drug release [10, 17]. The results demonstrated that higher compression force significantly reduced tablet thickness and friability while enhancing hardness and extending DT. The disintegration of tablets is optimized by selecting the appropriate type and concentration of disintegrants, as well as adjusting the compression force. Douroumis *et al.* reported that the use of Kollidon® CL-SF at a high concentration (20% w/w) combined with low compression forces (4–8 kN) had a significantly negative impact on the friability of cetirizine FDTs [18]. Therefore, Kollidon® CL and Kollidon® CL-SF at concentrations of 5–10% w/w were selected for evaluation in combination with high compression forces (10–15 kN). Moreover, there is limited comparative data on the effects of Kollidon® CL, Kollidon® CL-SF, and Explotab® at these concentrations on tablet properties and their stability. This study aimed to formulate and characterize cetirizine FDTs to enhance patient compliance, particularly for the elderly and individuals with swallowing difficulties. Three widely used commercial disintegrants including Kollidon® CL, Kollidon® CL-SF, and Explotab® were evaluated for their effects on tablet properties. Additionally, the effect of compaction force was examined. The physicochemical stability of the selected cetirizine FDTs was assessed under accelerated conditions (40 °C and 75%RH) for one month.

Materials and Methods

Materials

Cetirizine dihydrochloride and Explotab® were generously provided by Bangkok Lab and Cosmetic Co, Ltd (Ratchaburi, Thailand). Kollidol® CL and Kollidol® CL-SF were received as a gift from VIV Interchem Co., Ltd. (Bangkok, Thailand). Mannitol, microcrystalline cellulose (MCC), and acetonitrile (high-performance liquid chromatography (HPLC) grade) were sourced from TTK Science (Bangkok, Thailand), while magnesium stearate and talcum were obtained from Union Science Co., Ltd. (Chiang Mai, Thailand). Other chemical reagents used were of analytical grade.

Pre-formulations composition of the fast-dissolving tablets (FDTs) mixtures

Nine pre-formulated blank FDT mixtures were prepared as follows. The pre-formulation compositions included mannitol as a sweetening agent and MCC as a diluent. Additionally, magnesium stearate and talcum were incorporated as lubricants and glidants. The detailed composition of the pre-formulated blank FDT mixtures is presented in Table 1. The nine formulations were labeled as FD1, FD2, FD3, FD4, FD5, FD6, FD7, FD8, and FD9, respectively.

Table 1 The composition of the pre-formulated fast-dissolving tablet (FDTs) mixtures.

Compositions	Amount (%w/w)								
	FD1	**FD2**	**FD3**	**FD4**	**FD5**	**FD6**	**FD7**	**FD8**	**FD9**
Mannitol	25%	25%	25%	25%	25%	25%	25%	25%	25%
Kollidol® CL	5%	7%	10%	-	-	-	-	-	-
Kollidol® CL-SF	-	-	-	5%	7%	10%	-	-	-
Explotab®	-	-	-	-	-	-	5%	7%	10%
Magnesium stearate	1% w/w of dried mixture weight								
Talcum	3% w/w of dried mixture weight								
MCC add to	100%	100%	100%	100%	100%	100%	100%	100%	100%

MCC: Microcrystalline cellulose; Kollidol® CL and Kollidol® CL-SF: crospovidone; Explotab®: sodium starch glycolate.

Pre-formulation evaluation of powder mixtures

In this study, FDTs were developed using the direct compression method. Before tablet compression, the powder mixtures were prepared, with their compositions detailed in Table 1. Subsequently, the powder properties were analyzed, including bulk density, tapped density, compressibility index, Hausner's ratio, and angle of repose as previously described [19]. The bulk density of the mixtures was assessed as follows. Briefly, 20 grams of mixtures were placed into a measuring cylinder. The cylinder was then tapped three times, and the bulk volume of the mixtures was recorded. To determine the tapped density, the measuring cylinder containing the mixtures was tapped mechanically until no significant change in volume or mass was visually noted. The bulk and tapped densities of the granules were calculated using the following equations:

$$\text{Bulk density } (\rho_{\text{Bulk}}) = \frac{\text{weight of the mixtures}}{\text{bulk volume of mixtures}}$$

$$\text{Tapped density } (\rho_{\text{Tapped}}) = \frac{\text{weight of the mixtures}}{\text{tapped volume of mixtures}}$$

The compressibility index (%CI) was calculated by measuring the difference between the tapped density (ρ_{Tapped}) and bulk density (ρ_{Bulk}), relative to the tapped density (ρ_{Tapped}), using the following equation:

$$(\%)\text{CI} = \left(\frac{\rho_{\text{Tapped}} - \rho_{\text{Bulk}}}{\rho_{\text{Tapped}}} \right) \text{x } 100$$

Hausner's ratio of the granule was calculated by comparing the tapped density (ρ_{Tapped}) to the bulk density (ρ_{Bulk}) using the following equation:

$$\text{Hausner's ratio} = \frac{\rho_{Tapped}}{\rho_{Bulk}}$$

The angle of repose was measured by allowing the powders (20 g) to flow freely through a funnel and accumulate at the base. The height and radius of the resulting powder pile were recorded. The angle of repose (θ) was then calculated using the following equation:

$$\text{Tan } \theta = \frac{\text{height of the mixture pile (cm)}}{\text{radius of the mixture pile (cm)}}$$

Preparation and characterization of blank FDTs Tablet

Tablet compression was carried out using a hydraulic press (PerkinElmer, IL, USA). Pre-formulated mixtures, each weighing approximately 300 mg, were compressed at forces of 10, 12, and 15 kN using a flat-faced round punch with a diameter of 12.73 mm. The physical properties of the formulated tablets were evaluated, including weight variation, thickness and hardness, and disintegration time (DT). Additionally, the wetting time of the formulated FDTs was assessed as follows:

Weight variation

Twenty tablets were individually weighed with precision using an analytical balance (ADAM, United Kingdom), and their respective weights were documented. The permissible weight variation was set within ±5%.

Thickness and hardness

The thickness and hardness of ten tablets were assessed individually using a hardness and thickness tester (Erweka, Germany). The results were expressed as mean±standard deviation (SD), with thickness measured in millimeters (mm) and hardness in kiloponds (KP).

Wetting time (WT)

A single tablet was placed in a Petri dish (12 cm in diameter) containing 10 mL of distilled water, and the time taken for the tablet to become completely wetted was recorded.

Disintegration time (DT)

Six tablets were evaluated for disintegration time using an Erweka ZT-322 disintegration tester (Erweka, Germany). The test was conducted in distilled water maintained at 37±2°C. The duration required for the tablet to fully disintegrate into fine particles was recorded.

Preparation and characterization of cetirizine FDTs

The optimal concentration of disintegrant and the appropriate compaction force were determined based on the characterization results of blank FDT tablets. These parameters were then used to formulate cetirizine FDTs to achieve the desired balance of hardness and DT. Cetirizine was incorporated into the FDT mixture to ensure each tablet contained 5 mg of the active ingredient. The prepared cetirizine FDTs were evaluated for weight variation, thickness, hardness, wetting time, and DT as previously described.

Drug content analysis

After preparing the cetirizine FDTs, their drug content was analyzed as follows. Ten tablets were randomly selected from each batch, crushed, and an amount of the blend equivalent to 5.0 mg of cetirizine was accurately weighed. This weighed sample was then transferred to a 100 mL volumetric flask. Under continuous stirring, 20 mL of phosphate buffer (pH 6.8) was added, and the volume was adjusted to 100 mL using the same buffer. The resulting solution was then filtered and analyzed using the high performance liquid chromatography (HPLC) analysis as previously described by kamchai *et al*. [20]. A Shimadzu LC 2050C system with an isocratic pump, autosampler, and UV−vis detector was used. Separation was performed on a Hypersil BDS C18 column (4.6 mm × 150 mm, 5 μm). The mobile phase consisted of 50 mM KH_2PO_4 and acetonitrile (60:40 v/v, pH 3.5) at a 1 mL/min flow rate. The injection volume was 20 μL, and UV detection was set at 230 nm.

Dissolution test

The *in vitro* dissolution tests for the formulated FDTs were conducted using USP apparatus II (paddle method) (Erweka®, Heusenstamm, Germany). The dissolution medium consisted of 900 mL of purified water, maintained at a temperature of 37±0.5 °C. The paddles were set to rotate at 50 rpm. For each formulation, six tablets were tested. At predetermined time intervals, aliquots of the dissolution samples were manually withdrawn and replaced with an equal volume of fresh dissolution medium to maintain sink conditions. The collected samples were then filtered and diluted with the dissolution medium to achieve the appropriate working concentration. Drug release was quantified using HPLC analysis, as previously described [20]. The amount of drug released was calculated using an equation derived from the standard curve, and the percentage of cumulative drug release was reported.

Stability study

Physicochemical stability was assessed at 40°C and 75% relative humidity for one month. Their physical properties were assessed as previously described, while cetirizine content was determined using HPLC analysis.

Statistical analysis

Data were presented as mean±SD. Statistical analysis was conducted using one-way ANOVA followed by a post hoc LSD test in Sigma Stat software (version 3.5, Systat Software Inc., San Jose, CA, USA). A p-value <0.05 was considered statistically significant.

Results and Discussion

Pre-formulation evaluation of FDT mixtures

The evaluation parameters for the pre-formulated FDT mixtures are presented in Table 2. The constituent powder mixture had poor flowability, as seen by its Hausner's ratio, which exceeded 1.25, except for FD2, which had a Hausner's ratio of 1.18. The compressibility index for most formulations

ranged between 15% and 26%. Additionally, all powder blends demonstrated poor flowability, as proven by angle of repose values greater than 30 [21]. Given these qualities, the formulation's flowability could be improved by using the granulation process before tablet compression.

Table 2 Evaluation parameters of the pre-formulated fast-dissolving tablet (FDTs) mixtures.

Formulation	Bulk density (g/mL)	Tapped density (g/mL)	Hausner's ratio	Carr's index (%)	Angle of repose (°)
FD1	0.45±0.01	0.59±0.02	1.25±0.02	23.12±1.85	45.98±0.85
FD2	0.50±0.01	0.59±0.00	1.18±0.01	15.82±0.98	48.57±1.54
FD3	0.46±0.02	0.61±0.00	1.32±0.05	25.14±3.41	44.67±2.00
FD4	0.43±0.00	0.57±0.01	1.33±0.02	24.99±0.75	47.39±0.54
FD5	0.40±0.02	054±0.00	1.36±0.06	26.41±3.10	45.94±2.39
FD6	0.39±0.01	0.52±0.01	1.34±0.04	26.08±2.04	48.77±0.82
FD7	0.50±0.00	0.66±0.01	1.31±0.02	23.84±1.32	46.00±1.74
FD8	0.51±0.00	0.67±0.00	1.30±0.00	23.08±0.00	44.46±1.51
FD9	0.52±0.01	0.66±0.01	1.27±0.04	21.08±2.71	42.76±2.04

Properties of the formulated FDT tablets

The formulated blank FDT tablets had a flat surface and a round shape with a diameter of 12.73 mm. As illustrated in Figure 1, the tablets appeared white and demonstrated desirable physical characteristics. With compaction forces of 10, 12 and 15 kN, the tablet weight ranged from 298 to 305 mg, aligning closely with the target weight of 300 mg. The formulated FDT tablets showed a narrow weight variation range with a percentage weight variation of less than 5%. The thickness of the tablets averaged 1.92±0.07 mm, influenced by the die size. Tablet hardness varied between 5.15 and 12.92 KP, suggesting sufficient mechanical strength to resist friability during packaging and transportation. Also, the formulated tablets were completely wet and could disintegrate within a minute. The formulated FDTs incorporating different types of disintegrants exhibited varying physicochemical properties (Figure 2). Among the formulations, those containing Kollidon® CL-SF demonstrated the highest tablet hardness, followed by formulations with Kollidon® CL and Explotab® (Figure 2A). In terms of wetting time, FDTs formulated with Explotab® exhibited a significantly longer wetting time compared to those containing Kollidon® CL and Kollidon® CL-SF ($p < 0.05$) (Figure 2B). Similarly, the DT of the FDTs formulated with Explotab® was longer than that of formulations incorporating Kollidon® CL and Kollidon® CL-SF (Figure 2C). FDTs formulated with Explotab® at a concentration of 7% w/w exhibited a significantly longer DT compared to those containing Kollidon® CL and Kollidon® CL-SF (p <0.05). Our findings are consistent with a previous study that reported a longer DT for FDTs formulated with Explotab® compared to those containing Kollidon® CL [22]. Moreover, studies have reported that Kollidon® CL

reaches 90% of its maximum swelling pressure in less than 10 minutes, whereas Kollidon® CL-SF requires less than 30 minutes [9]. Additionally, formulations containing more than 8% Explotab® may exhibit increased disintegration time due to its gelling properties and the resulting rise in viscosity [16]. When various disintegrants were incorporated at concentrations of 5%, 7%, and 10% w/w, both wetting time and DT decreased as the concentration increased (Figure 2B and Figure 2C). However, variations in disintegrant concentration had minimal impact on tablet hardness (Figure 2A). When compaction forces of 10, 12, and 15 kN were applied, tablet hardness, wetting time, and DT increased proportionally with the compaction force. This increase in DT with higher compression force is likely due to reduced liquid penetration, leading to greater tablet strength and density, as noted by Marais *et al.* [6]. The results indicated that changes in disintegrant type and concentration had a significant impact on tablet hardness, wetting time, and DT, while their effect on thickness and weight remained minimal.

Figure 1 The physical appearance of the blank fast-dissolving tablet (FD2: 7% w/w Kollidol® CL).

Properties of the formulated cetirizine FDT tablets

Tablets formulated with 7% w/w of three disintegrants and compressed at a force of 12 kN demonstrated optimal physical properties and were selected for the preparation of cetirizine FDTs. Cetirizine FDTs were formulated using the wet granulation method to enhance the flow properties of the blended FDT mixtures. Ethanol (95%) was employed as a binder. The flow properties of the three FDT granules were assessed, indicating fair to good flowability. This was evidenced by a Hausner's ratio ranging from 1.18 to 1.23, a compressibility index of 15% to 20% for most formulations, and angle of repose values below 30. Three cetirizine FDTs were prepared and characterized their physicoproperties as described above. Furthermore, the friability test was conducted by measuring the tablet weight before and after friability test. During the test, tablets were placed in a rotating drum operating at 25 rpm for a total of 100 revolutions. A weight loss of no more than 1.0% is generally considered acceptable for most pharmaceutical products (USP41) [21]. All formulated cetirizine FDTs exhibited friability exceeding 1.0%. Consequently, the compaction force was increased to 20 kN to achieve optimal tablet hardness and reduce friability. Three formulations of cetirizine FDTs were prepared, with an average tablet weight of 307.34±2.57 mg. Cetirizine FDTs exhibited a physical appearance similar to that of the blank FDTs, featuring a flat surface, a round shape, and a diameter of 12.73 mm. The weight fluctuation among the tablets was within 5%, adhering to the acceptability

standards for the target weight as shown in Table 3. All FDT formulations exhibited complete wetting and full disintegration within 3 minutes. As a result, the prepared cetirizine FDTs conformed to the standards specified in the European Pharmacopoeia (EU). All formulated cetirizine FDTs demonstrated friability below 1.0%.

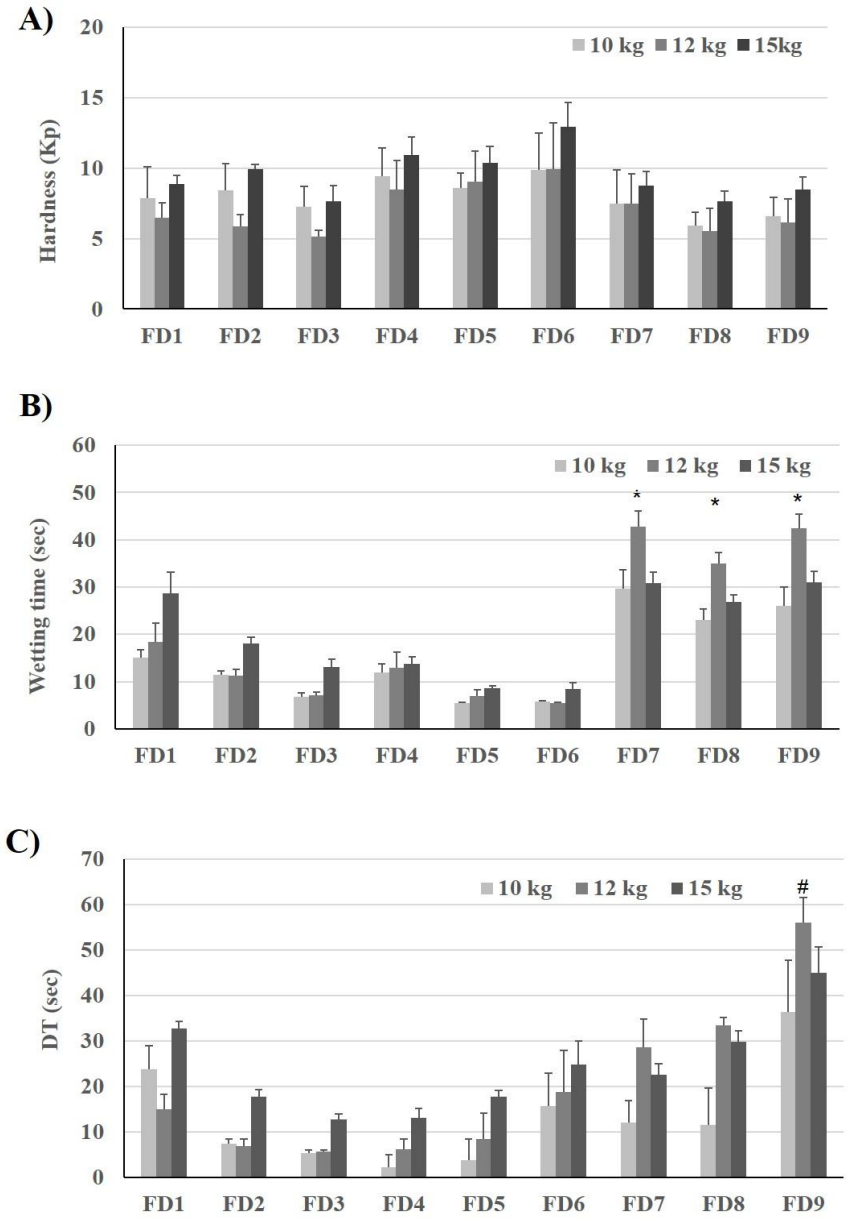

Figure 2 Effect of the type and concentration of disintegrants and compression force on tablet hardness (A) wetting time (B) and disintegration time (DT) (C). A statistically significant difference (p <0.05) in wetting time was observed between FD7-FD9 (formulated with Explotab®) and both FD1-FD3 (formulated with Kollidon® CL) and FD4-FD6 (formulated with Kollidon® CL-SF), as indicated by an asterisk (*). A significant difference (p <0.05) in disintegration time was noted between FD7-FD9 and FD1-FD8, as indicated by a hash (#).

Table 3 Evaluation parameters of cetirizine fast-dissolving tablet (FDTs) before stability test.

Formulation	Thickness (mm)	Hardness (KP)	Weight variation (mg)	%Friability	Wetting time (sec)	Disintegration time (sec)
FD2	2.03±0.01	23.90±0.17	307.77±0.02	0.81	21.34±2.28	60.30±3.38
FD5	1.90±0.05	62.90±0.89	307.34±0.01	0.75	28.32±1.56	85.06±9.07
FD8	1.83±0.00	27.90±0.02	309.91±0.05	0.52	51.49±1.98	105.09±5.68

Drug content analysis

The drug content of cetirizine FDTs was analyzed using HPLC. The chromatographic peak for cetirizine appeared at 3.9 minutes (Figure 3). A standard calibration curve was established using cetirizine concentrations ranging from 1 to 20 μg/mL. The analysis showed that each tablet contained 3.40 mg, 3.15 mg, and 2.98 mg of cetirizine in formulations FD2, FD5, and FD8, respectively. The corresponding drug recovery rates were 68.0%, 63.0%, and 59.6%. As a result, the cetirizine content in the FDTs fell outside the United States Pharmacopeia (USP 41) [21] acceptance range of 85–115% of the labeled amount. This discrepancy may be attributed to incomplete extraction of cetirizine from the FDTs or the entrapment of the active drug within certain tablet components. Consequently, the detected cetirizine content was below the acceptable threshold. The extraction efficiency of the active drug from cetirizine FDTs will be further investigated in future studies. The drug content of cetirizine FDTs in our study was lower than the 94–100% reported by Sharma *et al*. likely due to their use of a longer extraction time combined with sonication [16]. Additionally, Baniya *et al*. reported a drug content of 98–108% in cetirizine fast-dissolving films when using 0.1 N HCl as the extraction solvent, highlighting the impact of extraction conditions on drug content determination [23].

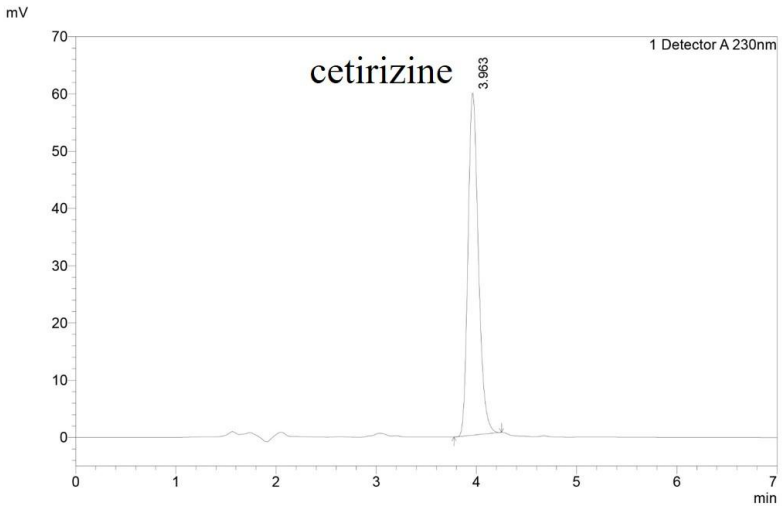

Figure 3 Chromatograms obtained from cetirizine standard solution (10 μg/mL).

Dissolution test

As shown in Figure 4, the cetirizine release from the prepared FDTs formulated with Kollidon® CL (FD2), Kollidon® CL-SF (FD5), and Explotab® (FD8) was approximately 73%, 72%, and 67%, respectively. A delay in drug release was observed with FD8, which was formulated using Explotab®. In contrast, FD2 exhibited a faster cetirizine release compared to FD5 and FD8. At 30 and 45 minutes, FD2 demonstrated a significantly higher drug release than FD8 (p <0.05). However, by 60 minutes, there was no statistically significant difference in the cumulative drug release among the formulations.

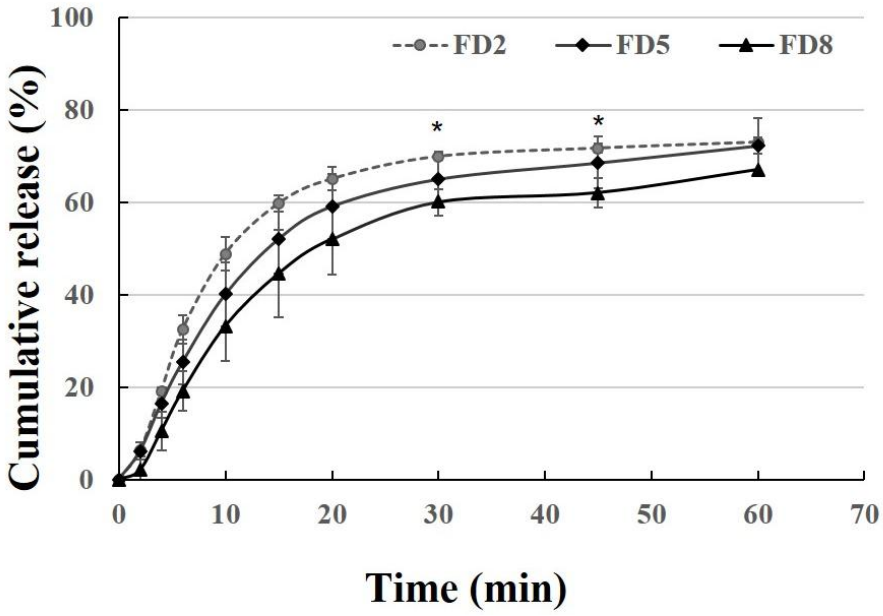

Figure 4 Dissolution profiles of cetirizine from the prepared fast-dissolving tablets formulated with Kollidon® CL (FD2), Kollidon® CL-SF (FD5), and Explotab® (FD8). A statistically significant difference (p <0.05) was observed between the dissolution profile of FD2 (formulated with Kollidon® CL) and FD8 (formulated with Explotab®), as indicated by an asterisk (*).

Stability studies

After one month of stability testing, all cetirizine FDTs maintained acceptable physical properties. All cetirizine FDTs successfully achieved complete wetting and full disintegration within 3 minutes. The decrease in tablet hardness was observed across all cetirizine FDTs, while increases were observed in thickness, weight variation, %friability, wetting time, and DT (Table 4). However, these changes were not statistically significant compared to the initial values, which may be attributed to the relatively short duration of the stability study. The observed variations may be attributed to moisture absorption within the storage condition, which contributed to increased tablet thickness and weight, as well as higher %friability, wetting time, and DT. Based on its optimal physical properties and the shortest wetting and disintegration times, FD2 was selected for HPLC analysis to determine the remaining cetirizine content in the FDTs. The results indicated that 80% of the cetirizine remained in FD2.

Table 4 Evaluation parameters of cetirizine fast-dissolving tablet (FDTs) after stability test.

Formulation	Thickness (mm)	Hardness (KP)	Weight variation (mg)	%Friability	Wetting time (sec)	Disintegration time (sec)
FD2	2.17±0.12	20.50±3.21	310.75±2.08	0.92	25.37±1.93	65.30±4.80
FD5	2.05±0.11	59.42±1.98	312.34±5.23	0.88	30.15±0.98	94.01±2.38
FD8	1.93±0.10	24.57±2.90	315.52±6.54	0.70	55.06±2.18	120.09±8.74

Conclusions

In this study, FDTs were successfully developed. The findings demonstrated that variations in the type and concentration of disintegrants significantly influenced tablet hardness, wetting time, and DT, whereas their impact on tablet thickness and weight was minimal. Cetirizine FDTs were prepared with 7% w/w of (Kollidon® CL, Kollidon® CL-SF, and Explotab®) and compressed at a force of 20 kN. After one month of stability testing, all cetirizine FDTs retained satisfactory physical properties. However, further studies are required to evaluate their chemical stability. The cetirizine FDT formulation with Kollidon® CL (FD2) was chosen for long-term stability testing and future evaluation of palatability in human volunteers because it is physically stable and has the shortest DT.

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