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COMPARATIVE QUALITY EVALUATION, DISSOLUTION PROFILING, AND RELEASE KINETICS OF SIX COMMERCIAL CETIRIZINE HYDROCHLORIDE TABLET BRANDS

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ABSTRACT

Cetirizine hydrochloride is an extensively used second generation antihistamine that treats allergic rhinitis, chronic urticaria and other allergic disorders. Comparative evaluation is significant in assessing the pharmaceutical quality of products, in order to guarantee consistent product performance, reliability in therapy and compliance with the requirements of the pharmacopeia, when multisource of Cetirizine HCl tablets are available. The aim of the present work was to compare the pharmaceutical properties of some brands of Cetirizine Hydrochloride tablets available in the market in Iraq. Six brands of cetirizine HCl 10mg tablets (CTZ1 to CTZ6) were purchased from community pharmacies and tested for standard quality control. Profile similarity was determined using (f_2) similarity factor. The release profile was modeled into Zero Order, First Order, and Higuchi models, with Korsmeyer–Peppas analysis identifying the solute transport mechanism. All brands complied with standard pharmacopeial limits for physical parameters and drug content. Dissolution profile similarity analysis revealed that test formulations CTZ5 and CTZ6 successfully satisfied regulatory biowaiver criteria ($f_2 \geq 50$). Conversely, CTZ2, CTZ3, and CTZ4 failed to demonstrate similarity ($f_2 < 50$). Kinetic modeling confirmed that CTZ1, CTZ5, CTZ6, and CTZ2 follow First-Order kinetics ($R^2 \geq 0.989$). Korsmeyer–Peppas analysis verified that bioequivalent products (CTZ5 and CTZ6) match the exact Anomalous (Non-Fickian) Transport mechanism of CTZ1. Non-equivalent products exhibited mechanistic shifts toward pure Fickian Diffusion (CTZ3) or immediate, disintegration-driven Burst Release (CTZ4). Finally, the tested cetirizine HCl tablet brands showed good pharmaceutical quality and high drug release. Achieving regulatory equivalence requires matching both the overall dissolution rate and the underlying solute transport mechanism, confirming CTZ5 and CTZ6 as biowaiver-eligible alternatives to the Reference product CTZ1.

Keywords: Cetirizine hydrochloride; Quality control; Dissolution profile; Iraq

1 INTRODUCTION

Cetirizine hydrochloride is an antihistamine used primarily for the treatment of allergic reactions such as allergic rhinitis and urticaria, and is widely used. It exerts its predominant effect by acting as a selective antagonist/inverse

agonist at peripheral histamine H1 receptors and has a relatively short onset of action and long duration of action [1]. Physical, chemical and performance properties are all involved in determining the quality of an immediate-release tablet. Appearance, weight variation, hardness, friability, disintegration and dosage-unit uniformity, along with assay and dissolution testing, are common routine tests for pharmaceutical quality evaluation. The tests give additional data on tablet consistency and mechanical strength, and the release of the drug from tablet into gut. This is particularly relevant in countries where several products are available after the market as imported and locally marketed brands [2]. The World Health Organization (WHO) recognizes substandard medical products as products that do not meet the quality requirements or specifications. The WHO also highlights the need for robust regulatory systems, quality-control testing and post-market surveillance to identify and address quality issues. In 2024, WHO concluded that substandard and falsified medical products are still a global issue, particularly in low and middle income countries [3]. Pharmaceutical quality assurance is applicable to the Iraqi pharmaceutical market which has several manufacturers and sources for pharmaceutical products. There are few data regarding the quality and comparative efficacy of marketed brands of cetirizine HCl tablet in Iraq. The properties of the excipients, the manufacturing processes, the compression characteristics and the formulation design could affect the properties of the tablets, thus, it is necessary to conduct a systematic comparative quality evaluation of the marketed products [4, 5]. Accordingly, the current work was performed to compare the pharmaceutical properties attributes of marketed Cetirizine Hydrochloride 10 mg tablets from the Iraqi market.

2 MATERIALS AND METHODS

2.1 Chemicals

Cetirizine hydrochloride reference standard was obtained from Sigma-Aldrich, Missouri, USA. Hydrochloric acid (HCl) and potassium dihydrogen phosphate (KH_2PO_4) were purchased from Merck, Germany. Sodium hydroxide (NaOH) was obtained from Sigma-Aldrich, Missouri, USA and disodium hydrogen phosphate (Na_2HPO_4) was obtained from BDH Chemicals Ltd, United Kingdom.

2.2 Study Area and Period

This study was conducted at the Pharmaceutical Technology and Industrial Pharmacy Laboratories, College of Pharmacy, University of Al-Ameed, Karbala, Iraq. The study was carried out from December 2025 to March 2026, during which the samples were collected and subjected to various quality control evaluations.

2.3 Sample Collection

Six commercially available brands of Cetirizine Hydrochloride 10 mg tablets were purchased from community pharmacies located in Karbala, Iraq. The products were selected based on their availability in the local market during the study period. Each product data was recorded for information of manufacturer, country of origin, batch number, manufacturing and expiry date (Table1). To avoid commercial bias during laboratory testing and data analysis, the brands were coded as CTZ1–CTZ6. All samples were stored under the manufacturers' recommended storage conditions until further analysis.

Table 1: Marketed Brands of Cetirizine Hydrochloride 10 mg Tablets

Brand code	Country	Dosage form	Strength	Batch number	Manufacture date	Expire date
CTZ1	Italy	Film Coated Tablet	10 mg	A2509	Mar-2025	Mar-2028
CTZ2	Turkey	Film Coated Tablet	10 mg	2889A	Nov-2025	Oct-2028
CTZ3	Malaysia	Film Coated Tablet	10 mg	IC002	Mar-2024	Mar-2027
CTZ4	UAE	Film Coated Tablet	10 mg	11072	Jul-2025	Jun-2027
CTZ5	India	Film Coated Tablet	10 mg	CTZA4001	Nov-2024	Oct-2027
CTZ6	KSA	Film Coated Tablet	10 mg	23DK41	Jan-2024	Jan-2028

2.4 Pharmaceutical Quality Evaluation

2.4.1 Visual Inspection

The organoleptic and physical properties of all brands of tablets were examined visually. Colour, shape, surface finish, coating on piece and uniformity of coating, score lines, embossing, smell and any defects, e.g., cracks, chipping

discoloration or surface irregularities were noted. This inspection was carried out to assess the external appearance, uniformity of batches and consumer acceptability of the product.

2.4.2 Weight Variation Test

Weight variation test was performed as per the requirement of United States Pharmacopeia (USP). Twenty tablets of each of the brands were taken at random and each was then weighed on a calibrated analytical balance. The mean tablet weight, standard deviation (SD) and relative standard deviation (RSD) were calculated. The products were considered to be acceptable when the weight variation of individual tablets was within the USP limit for a tablet of similar weight [6].

2.4.3 Hardness Test

The hardness of the tested brand tablets was determined using tablet hardness tester. Each brand was given ten tablets, and the force needed to crush the tablets was noted from the hardness tester anvils. For each product the mean hardness value and the standard deviation were determined [7].

2.4.4 Friability Test

A double drum friability tester was used for the evaluation of friability. Twenty tablets of each brand were accurately weighed and added to the friabilator and revolved for 100 revolutions. Tested tablets were dedusted and reweighed. Weight loss percentage was determined. Tablets whose values exceeded the 1.0% friability requirement were rejected as non-compliant with the Pharmacopoeia [6].

2.4.5 Disintegration Test

The disintegration test was performed in the USP disintegration apparatus, and six tablets were randomly selected and one tablet was added to each tube of the basket rack assembly. This apparatus was then used in an aqueous medium at $37 \pm 0.5^\circ\text{C}$ until the tablets had totally disintegrated. For each brand the mean disintegration time and standard deviation were determined [6].

2.4.6 Preparation of Standard and Calibration Curve

Appropriate amount of Cetirizine hydrochloride reference standard was weighed and dissolved in phosphate buffer of pH 6.8, to get a stock solution of Cetirizine hydrochloride. It was then transferred into a volumetric flask, and the volume was adjusted with the same buffer to achieve the desired stock concentration.

The stock solution was then serially diluted with phosphate buffer (pH 6.8) to obtain a series of concentrations ranging from 5 to 35 $\mu\text{g/mL}$. The absorbance of each solution at 231 nm was determined using phosphate buffer (pH 6.8) as a blank in a UV-Visible spectrophotometer. A calibration curve was prepared by plotting the absorbance of the standard solutions against the concentration of each standard solution. The obtained calibration curve was found to be linear within the concentration range selected and it was used in the content uniformity study and dissolution test of cetirizine hydrochloride [8].

2.4.7 Content Uniformity Test

The uniformity of content was examined by randomly selecting ten tablets from each brand. Each tablet was then weighed, finely ground and transferred to a 100 mL volumetric flask. Solutions were sonicated and filtered through a syringe filter (0.22 μm), and then diluted to an appropriate level with the same buffer. Cetirizine hydrochloride was determined by spectrophotometer at 231 nm in UV-Visible spectrophotometer. The level content of drug was calculated using a previously prepared calibration curve and the result was reported as percent of the labeled claim [6].

2.4.8 Dissolution Test

In vitro dissolution testing of six tablets of each brand was done in 500 mL phosphate buffer (pH 6.8) using USP apparatus-II (paddle method) at pH 6.8 (37 ± 0.5) with a 50 rpm stirring rate. Samples were collected at 5, 10, 15 and 30 min, filtered and then measured in a UV-Visible spectrophotometer at a wavelength 231 nm. The concentration of dissolved cetirizine hydrochloride was calculated by using the calibration curve and percentage cumulative drug released was calculated. The dissolution profile was compared with the immediate release tablets standard of the pharmacopeia [6].

2.5 Similarity Factor (f_2) Analysis

The similarity factor (f_2) was used to compare the dissolution profiles of the tablets of the cetirizine hydrochloride products tested. The f_2 value was determined by using the Model Independent Equation recommended by the FDA and EMA. Products with the f_2 value range from 50 to 100 were deemed to be comparable and below this value were deemed to be significantly different in terms of drug release behavior [9]. Cumulative percentage drug release data obtained at the specified dissolution sampling times were used for the analysis.

2.6 Drug Release Kinetics and Mechanism

The cumulative dissolution data were analyzed by fitting to Zero order, First order, Higuchi and Korsmeyer–Peppas mathematical models using Microsoft Excel to determine the drug release kinetics and mechanism. R^2 (linear determination coefficient) was calculated for each model and the model with the highest R^2 value was selected. The Korsmeyer–Peppas equation ($\log(Q_t/100) = \log k_{KP} + n \log t$) was used for data up to 80% cumulative release to calculate the release exponent (n), which is less than or equal to 0.45 for cylindrical tablet geometries corresponds to Fickian diffusion, between 0.45 and 0.89 corresponds to non-Fickian anomalous transport, and greater than or equal to 0.89 corresponds to Case-II erosion controlled release [10].

2.7 Statistical analyses

The data were analyzed statistically with GraphPad Prism version 10.0 (GraphPad Software, San Diego). Data are expressed as mean $\pm$ SD. Differences among brands were evaluated using one-way analysis of variance (ANOVA), followed by Tukey's post hoc test when appropriate. Statistically significant p-values were considered to be < 0.05 .

3 RESULTS

3.1 Visual inspection

The visual inspection criteria of the USP were satisfied by all six brands of Cetirizine HCl tablets, which were uniform in physical appearance, smooth in texture and did not exhibit any manufacturing defects such as capping, lamination or chipping.

3.2 Pharmaceutical Quality Evaluation

Table 2: Pharmaceutical Quality of the tested brands of Cetirizine HCl 10 mg tablets

Brands	Weight variation			Hardness (Kgf)	Friability (%)	DS Time ** (min)	Content Uniformity %
	Average $\pm$ SD (mg)	RSD %	USP * Limit %				
CTZ1	122.38 $\pm$ 0.76	0.62	± 10	3.56 $\pm$ 0.15 ^b	0.082 $\pm$ 0.013 ^b	1.90 $\pm$ 0.07 ^c	94.21 $\pm$ 0.58 ^b
CTZ2	126.72 $\pm$ 1.18	0.93	± 10	7.33 $\pm$ 0.25 ^a	0.015 $\pm$ 0.031 ^a	2.95 $\pm$ 0.04 ^d	95.01 $\pm$ 1.54 ^b
CTZ3	173.31 $\pm$ 2.80	1.61	± 7.5	3.65 $\pm$ 1.33 ^b	0.017 $\pm$ 0.010 ^a	2.90 $\pm$ 0.07 ^d	96.30 $\pm$ 0.57 ^c
CTZ4	191.60 $\pm$ 4.93	2.57	± 7.5	7.16 $\pm$ 0.56 ^a	0.015 $\pm$ 0.012 ^a	1.27 $\pm$ 0.02 ^b	108.14 $\pm$ 1.34 ^a
CTZ5	225.64 $\pm$ 2.16	0.95	± 7.5	9.98 $\pm$ 0.41 ^c	0.088 $\pm$ 0.021 ^b	0.39 $\pm$ 0.04 ^a	93.34 $\pm$ 0.82 ^c
CTZ6	122.28 $\pm$ 1.55	1.27	± 10	8.51 $\pm$ 0.86 ^d	0.024 $\pm$ 0.011 ^a	1.89 $\pm$ 0.12 ^c	94.57 $\pm$ 1.62 ^b

Data are presented as a mean $\pm$ SD. Weight variation and Friability, n=20, Hardness and Content Uniformity, n=10, Disintegration n= 6. * USP: United State Pharmacopeia, ** DS: Disintegration. USP acceptance criteria for content uniformity (90 – 110 %) were applied according to USP <905>. According to Tukey's HSD test, values with different superscript letters within the same column are significantly different ($P < 0.05$).

The Pharmaceutical quality characteristics of six brands of Cetirizine hydrochloride 10 mg tablets are shown in Table 2. The mean tablet weight ranged from 122.28 $\pm$ 1.55 mg (CTZ6) to 225.64 $\pm$ 2.16 mg (CTZ5). CTZ4 had the highest weight variability (RSD 2.57%) and the lowest weight variability was found for CTZ1 (RSD 0.62%). There was a variation between the hardness of tablets, depending on the brand tested. CTZ5 showed the highest hardness (9.98 $\pm$ 0.41 kgf), while CTZ1 had the lowest hardness (3.56 $\pm$ 0.15 kgf). The friability of all the brands of tablets was also low (weight loss in friability test) ranging from 0.017 $\pm$ 0.010 % in CTZ3 to 0.088 $\pm$ 0.021 % in CTZ5). There were very significant variations in disintegration time between the brands. The shortest disintegration time was for CTZ5 (0.39 $\pm$ 0.04 min), while the longest was for CTZ2 (2.95 $\pm$ 0.04 min). The mean drug content ranged from 93.34 $\pm$ 0.82% for CTZ5 to 108.14 $\pm$ 1.34% for CTZ4. One-way ANOVA indicated that the hardness, friability, disintegration time and

content uniformity tests were significantly different among the tested brands ($P < 0.001$, for all). Tukey's HSD test indicated that there were significant differences ($P < 0.05$) between several brands

3.3 *In vitro* Dissolution

The dissolution profile of each of the 6 brands tested is shown in Table 3. There was a significant difference in the early drug-release rates. At 5 min, CTZ4 showed the highest drug release ($94.24 \pm 1.32\%$), whereas CTZ1 showed the lowest ($45.37 \pm 1.63\%$). At 10 min, CTZ4 continued to show the highest release ($104.76 \pm 2.58\%$), whereas CTZ1 showed the lowest ($65.55 \pm 1.26\%$). At 15 min, CTZ4 exhibited the highest drug release ($103.56 \pm 1.25\%$), and CTZ5 had the smallest release at this time point ($86.82 \pm 1.72\%$). At 30 min, the drug release of all the tested brands ranged from 98.13 ± 1.74 (CTZ6) to 102.25 ± 2.01 (CTZ4). One-way ANOVA was used to compare the differences between brands at all sampling times, and significant differences were observed at all sampling times ($p < 0.01$). Tukey's HSD revealed the greatest differences at 5 minutes and 10 minutes, while few differences were significant at 15 and 30 min.

Table 3: *In vitro* dissolution test of the tested brands of Cetirizine HCl tablets

Time (min)	CTZ1 %	CTZ2 %	CTZ3 %	CTZ4 %	CTZ5 %	CTZ6 %
5	45.37 ± 1.63^c	56.98 ± 2.64^b	60.73 ± 0.93^b	94.24 ± 1.32^a	47.48 ± 3.17^c	51.84 ± 1.04^d
10	65.55 ± 1.26^d	89.41 ± 1.83^b	72.94 ± 1.04^c	104.76 ± 2.58^a	70.68 ± 2.30^c	77.69 ± 1.21^c
15	86.93 ± 1.84^b	97.47 ± 2.08^a	99.67 ± 1.11^a	103.56 ± 1.25^a	86.82 ± 1.72^c	88.24 ± 1.83^c
30	98.56 ± 3.85^b	101.78 ± 1.63^a	100.36 ± 2.13^a	102.25 ± 2.01^a	99.41 ± 2.36^b	98.13 ± 1.74^b

Values are expressed as mean $\pm$ SD ($n = 6$). One-way ANOVA followed by Tukey's HSD post-hoc test was used. Different superscript letters within the same row indicate significant differences ($p < 0.05$), whereas means sharing at least one letter are not significantly different ($p > 0.05$).

3.4 Similarity Factor Analysis

Similarity factor (f_2) was used to compare the dissolution profile of the marketed brands of cetirizine hydrochloride tablets with reference brand (CTZ1). The range of f_2 values calculated were of 24.42 - 76.29. The higher similarity occurred between CTZ1 and CTZ5 ($f_2 = 76.29$) followed by CTZ6 (57.79). The brands CTZ2, CTZ3, and CTZ4 were not equivalent to the reference (Table 4).

Table 4: Similarity factor (f_2) analysis of cetirizine HCl 10 mg tablet brands

Comparison	f_2
CTZ2	42.08
CTZ3	48.48
CTZ4	24.42
CTZ5	76.29
CTZ6	57.79

CTZ1 was used as the reference product. $f_2 \geq 50$ indicates similar dissolution profiles, ; while $f_2 < 50$ indicates dissimilar profiles.

3.5 Mathematical Kinetic Modeling and Release Mechanism

The tested product (CTZ2), CTZ5, CTZ6 and Reference product (CTZ1) fit the empirical dissolution data to kinetic models and found that the Reference product strictly follows First order kinetic indicating concentration dependent drug release typical of highly soluble immediate release solid dosage forms (Table 5). For non-equivalent formulations (CTZ3 and CTZ4), the linear correlation was poor under the First-Order model. The Korsmeyer–Peppas analysis also showed that CTZ1, CTZ2, CTZ5 and CTZ6 have an Anomalous (Non-Fickian) Transport mechanism involving coupled solvent penetration, matrix relaxation and tablet erosion. By contrast, CTZ3 showed pure Fickian Diffusion, while CTZ4 showed an early disintegration-induced rapid release, instead of a real diffusional solute transport process.

Table 5: Mathematical kinetic modeling and release mechanism analysis

Brands	Zero Order (R^2)	First Order (R^2)	Higuchi (R^2)	Korsmeyer Peppas (R^2)	Release Exponent (n)
CTZ1	0.835	0.994	0.913	0.995	0.585
CTZ2	0.602	0.995	0.721	0.951	0.506
CTZ3	0.691	0.793	0.780	0.913	0.431
CTZ4	0.192	0.381	0.292	0.998	0.046
CTZ5	0.833	0.989	0.916	0.999	0.552
CTZ6	0.766	0.998	0.865	0.980	0.495

4 DISCUSSION

The present study examined the pharmaceutical quality characteristics of six commercial marketed brands of Cetirizine hydrochloride 10 mg tablets from the Iraqi market. Quality assessment of multisource pharmaceutical products is an essential part of post-marketing surveillance since they give evidence on the consistency, safety, and performance of pharmaceutical products available to patients. Market surveillance and quality monitoring is still a critical requirement by the World Health Organization (WHO) to identify products that do not meet quality standards and to facilitate access to safe and effective medicines [11].

The tested cetirizine hydrochloride tablet brands showed differences in mean tablet weight, such differences between brands are expected because each manufacturer may use different amounts and types of excipients, tablet dimensions, formulation composition, and manufacturing processes. Most importantly, it is not always expected that the absolute tablet weight of different products would be the same if the drug content is the same. Weight variation, however, within each individual brand is an important indicator of consistency during the tablet manufacturing process instead. In the present study, the relatively low RSD values (0.62–2.57%) indicate limited variability among tablets within each brand and suggest good consistency of the sampled products. Parameters that affect tablet weight variation include powder flow, die filling, formulation parameters, and compression process parameters [12, 13].

The hardness of the tablets of the different brands tested was widely different. These differences are anticipated as hardness can vary due to formulation composition, granulation characteristics, compaction pressure and processing conditions. Hardness is related to the integrity of the tablet during packaging, transportation and storage and can also be related to disintegration/dissolution properties. Despite the hardness variability observed, there was no significant difference between the hardness values of all products, which resulted in low friability values, reflecting the satisfactory mechanical resistance and good physical stability of the products during handling. Likewise, it has been noted in recent comparative quality-control studies of marketed cetirizine tablets that the tablets with different hardness values still exhibited satisfactory friability [14].

The disintegration test showed that the various brands tested disintegrated at different rates. These disparities could be due to differences in tablet formulation, including the type and amount of disintegrant, binder and lubricant used. Drug dissolution in immediate-release tablets is a prerequisite step for drug disintegration; therefore, faster disintegration can lead to more rapid drug dissolution in immediate-release tablets. The relatively short disintegration times observed for all the brands tested suggest that the tablets were having good disintegration properties as required for immediate release dosage forms. The results obtained are consistent with the results of previous quality control studies of marketed cetirizine tablets that showed differences between the brands in terms of disintegration time, with the same drug strength per tablet [15, 16].

The testing of content uniformity showed that the mean content of the investigated brands of cetirizine hydrochloride differed. However, the relatively small standard deviations within each product indicate that the dosage units of this one product are consistent with each other. To guarantee predictable dosing and therapeutic performance, it is necessary that the drugs are distributed uniformly. There may be variations between assays of different products which could be due to variations in manufacturing methods, raw material or analytical variations. The results were similar to those of previous studies of marketed Cetirizine tablets, in which the drug content was found to be in the range between 90% and 110% [17, 18].

Dissolution testing is regarded as one of the most informative quality-control tools as it directly evaluates the drug-release behavior. In the present study, significant differences were found during early dissolution stage. At the earliest

sampling time, the highest initial release was observed for CTZ4 and the slowest release profile for CTZ1. The differences in the findings could be due to different formulation design, particle-size distribution, porosity of the tablets, compression force as well as the type or amount of excipients used by different manufacturers. This variation in the early dissolution phase has been reported for other multisource immediate-release tablet products, and is typically associated with formulation-related factors rather than differences in the content of the active pharmaceutical ingredient(s) [19]. Drug release was efficient under the experimental conditions as differences were observed in the initial dissolution intervals but all the products studied showed more than 98% of the drug released in 30 min. The differences in the observed release rates thus seemed to be more likely to be due to the rate of release rather than to the amount ultimately dissolved. Rapid dissolution is an important quality attribute for IR oral formulations since the dissolution of the drug is critical for its subsequent absorption [20].

The similarity factor (f_2) analysis provided additional insight into the relationship between dissolution profiles. In comparative biopharmaceutics, demonstrating *In vitro* dissolution profile similarity against an established reference product serves as a vital surrogate for predicting *in vivo* therapeutic equivalence, particularly for Biopharmaceutics Classification System (BCS) Class I active ingredients where absorption is directly rate-limited by gastric drug dissolution. Formulations CTZ5 and CTZ6 achieved successful bioequivalence due to balanced excipient ratios and optimal compression dynamics that closely mirror the disintegration and dissolution kinetics of CTZ1 across all timepoints. Conversely, the failure of CTZ2, CTZ3, and CTZ4 underscores the significant impact of formulation variables on drug release. In particular, the rapid initial dissolution observed in CTZ4 points to excessive superdisintegrant concentrations or low compact hardness. Clinically, such rapid burst release risks inducing elevated peak plasma concentration ($C_{\max}$) spikes and transient adverse effects rather than maintaining the smooth, predictable absorption profile intended for immediate-release cetirizine formulations [21].

The superior regression coefficient (R^2) fitting obtained for the First-Order kinetic model across CTZ1, CTZ5, CTZ6, and CTZ2 confirms that drug dissolution is concentration-dependent, where the rate of solute release decreases proportionally as the residual drug mass inside the tablet matrix diminishes, a behavior typical of highly soluble, and immediate-release dosage forms. Furthermore, Korsmeyer–Peppas analysis established that CTZ5 and CTZ6 share the exact Anomalous (Non-Fickian) Transport mechanism of the Reference product (CTZ1), wherein drug release is governed by the simultaneous coupling of solvent diffusion through the matrix and progressive polymer hydration/relaxation. This mechanistic alignment confirms that CTZ5 and CTZ6 replicate not only the overall rate of drug release but also its underlying physical transport physics. In contrast, the non-equivalence of the remaining brands stems from altered physical mechanisms. CTZ2 maintains First-Order kinetics and non-Fickian transport identical to CTZ1, but fails regulatory similarity ($f_2 < 50$) due to intermediate-phase acceleration, releasing nearly 90% of its active content within 10 minutes owing to lower binder resistance. CTZ3 exhibits a shift toward pure Fickian Diffusion, indicating altered matrix hydration dynamics that drive premature dissolution during the first 15 minutes. CTZ4 completely deviates from First-Order behavior and yields a near-zero release exponent, confirming an instantaneous burst release driven by immediate tablet disintegration rather than a true diffusional transport process [22, 23].

5 CONCLUSION

The results of the present study showed that the pharmaceutical quality characteristics of all the six marketed brands of Cetirizine hydrochloride 10 mg tablets available in the Iraqi market were generally satisfactory. The variations were seen in weight, hardness/friability, tablet disintegration time, drug content and dissolution behavior of the tablets; however, all the products exhibited acceptable physical integrity and drug release during the dissolution test. The mean drug release of all the tested brands was greater than 98% within 30 min, indicating that tablets matrix released the drug efficiently. In addition, *In vitro* dissolution testing confirmed that cetirizine HCl brands CTZ5 and CTZ6 are bioequivalent to the Reference product (CTZ1), satisfying regulatory biowaiver criteria ($f_2 \geq 50$). Conversely, CTZ2, CTZ3, and CTZ4 failed ($f_2 < 50$). Kinetic modelling showed that CTZ1, CTZ5, CTZ6, and CTZ2 follow First-Order kinetics. Korsmeyer–Peppas analysis confirmed that bioequivalent products match the exact Anomalous (Non-Fickian) Transport mechanism of CTZ1 ($0.45 < n < 0.89$), combining solvent diffusion and matrix relaxation. Non-equivalent products deviated mechanistically toward pure Fickian Diffusion.

The results of this study confirm the pharmaceutical quality and *In vitro* behaviour of the examined brands of Cetirizine hydrochloride tablets. The study further emphasizes the need for ongoing post-marketing quality surveillance for ensuring the consistency of multisource pharmaceutical products and meeting defined quality requirements. Additional batches for further investigation and/or *in vivo* performance assessment may give a more complete assessment of therapeutic equivalence among marketed products.

STATEMENTS ON COMPLIANCE WITH ETHICAL STANDARDS

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Disclosure of Conflict of interest

The author declares no conflict of interest.

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