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In-Vitro Quality Assessment of Selected Marketed Cetirizine Tablets Products in Iraq

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Abstract

This investigation aimed to evaluate the quality of specific cetirizine HCL products available in pharmacies in Iraq. Various measures can ensure their quality and efficacy, such as utilizing quality control metrics, specifically the variability of weight, friability, content, disintegration time, and release. Allercet, Allereset, Ceritec, and Cetirizine-Ozon were categorized according to their weight range. Depending on the formulation, the disintegration time for Allercet, Allereset, Ceritec, and Cetrizine-Ozon was 4.5, 5.5, 6, and 12 minutes, respectively. All products had released more than 80% of their content after 30 minutes, and the content homogeneity was within the limit. The disintegration rate of Allercet was the quickest, whereas that of Cetrizine-Ozon was the slowest. Moreover, Allercet tablets revealed the quickest disintegration and release 81% after 10 min and may exhibit the quickest response after administration. The results indicated that all products met the specified requirements of the United States and British Pharmacopeia. However the best brand was Allercet which had the fastest release (81% after 10 minutes) and the least disintegration time.

Keywords: Cetrizine, assessment, hardness, dissolution, disintegration.

1. Introduction

Cetirizine is a potent second-generation histamine H-1 antagonist that effectively treats allergic rhinitis, chronic urticaria, pollen-induced asthma, and runny nose [1-3]. Unlike other conventional antihistamines, it does not induce somnolence. Moreover, cetirizine Has a half-life of eleven hours. Also, It is used to relieve allergy symptoms such as runny nose and watery eyes [4-5]]

Due to the significant cost savings that generic medicines offer to healthcare systems, various governments have promoted using generic medicines to solve the increasing healthcare expenses, especially for medicine, achieved through implementing different policies and strategies [6]. Concerns regarding reducing healthcare expenditures have led to a significant surge in the utilization

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of generic pharmaceutical items. Nevertheless, the introduction of generic drugs from various origins into the healthcare system to decrease healthcare expenses is linked to the presence of inferior, fraudulent, inaccurately labeled, falsified, and counterfeit medications [7].

Pharmaceutical brands are considered equivalent if they have the same strength and dosage form and meet the same standards. However, they may differentiate in characteristics like shape and excipients, expiration time, and labeling requirements within certain limits [8,9]. Manufacturers and law enforcement authorities should ensure that pharmaceutical products with the same active ingredient and dosage forms are consistent, safe, and effective. Ensuring the reliability and consistency of medication product quality across different batches is crucial for guaranteeing their safety and effectiveness [10, 11]. In order to guarantee the necessary standard, pharmaceutical producers must conduct testing on their goods both before and after the production process, as well as at regular intervals throughout the product's shelf life. Consequently, monitoring and verifying some brands' quality is imperative [12-14].

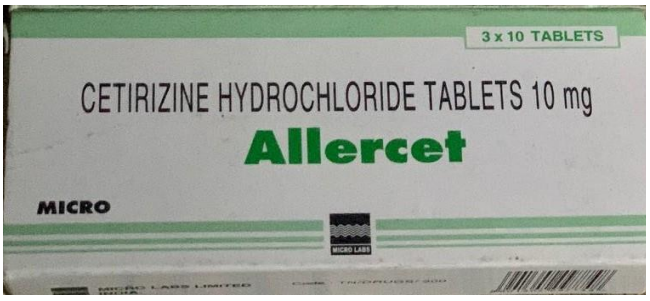
This study examined and assessed the pharmaceutical characteristics of four distinct brands of cetirizine tablets available in Iraq. In vitro methods, following the guidelines of the USP and official standards, were employed to emphasize that all brands are equivalent in terms of pharmaceutical quality. The tablets were assessed by evaluating weight, disintegration time, release, and assay using the U.V. spectrophotometric.

2. Materials and Methods

2.1 Marketed Tablets Products

Allercet tablets, Micro Labs LTD, India; Allereset tablets, Santa Farma, Turkey.; Ceritec tablets, S, N, Pharmaceutical Ltd, Bangladesh, Cetrizine – Ozon, Ozon pharmaceuticals, Russia.

Allercet tablets



Allereset tablets

Ceritec tablets

Cetrizine – Ozon

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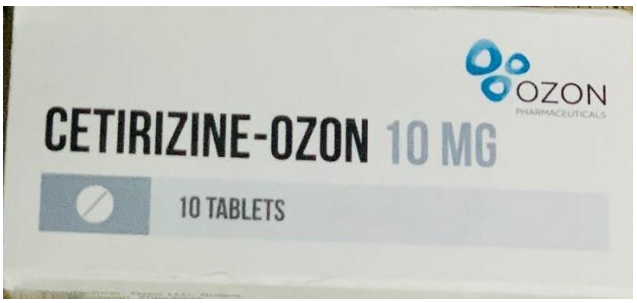

2.2 Analytical Method

The cetirizine HCL was precisely measured and dissolved in water using a 100 ml volumetric flask, diluted as required, and filtered and scanned (UV-Spectrophotometer AVI-2700, labtech, Ined) in the range of 200-400 nm measuring the absorbance using a U.V. spectrophotometer and a wavelength of 230 nm was selected as the maximum λ max.

2.3 Calibration Curve

An accurate 50 mg amount of cetirizine HCL was placed in a 250 ml volumetric flask. 100 ml of water was added, and the mixture was shaken until the cetirizine HCL dissolved. The flask was then filled to the volume with water, ensuring thorough mixing. The solution was diluted to obtain a series of cetirizine concentrations ranging from 6-14 µg/ml in water and measured at 230 nm against water as a blank.

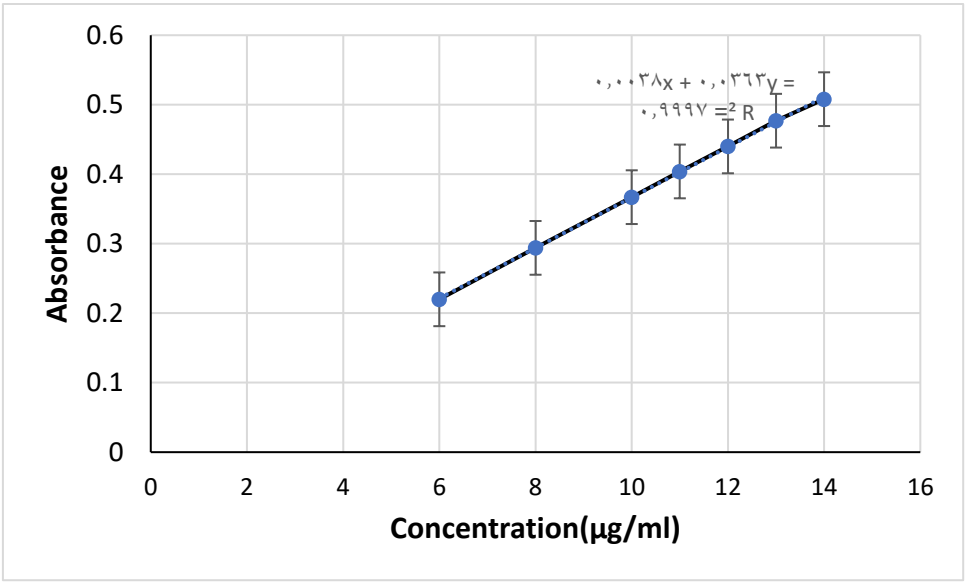

Figure 1. Calibration curve of cetirizine HCL

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2.4 Evaluation Tests

2.4.1 Weight Variation

Ten tablets were chosen randomly from each brand and individually weighed (Electronic Balance, China). The mean weights were computed. Subsequently, the calculation of the standard deviation and the determination of the percentage of the related standard deviation (RSD) were performed [15-17].

2.4.2 Assay

The weight of 10 tablets was measured, and the average weight was determined milled. An equivalent weight of 10 mg cetirizine HCL was then placed into a 100 ml volumetric flask and 50 ml of water, diluted, and the measurement was taken at a wavelength of 230 nm.

2.4.3 Hardness Test

Tablet hardness is the measurement of the force needed to break a tablet. If the tablet is excessively rigid, it may fail to disintegrate within the specified time frame, therefore not meeting the disintegration requirement [18]. On the other hand, the tablets should not have such a low hardness that they become soft and easily crumble [19]. In order to get a desirable level of tablet hardness, it is recommended that the hardness falls within the range of 4 to 8 kg 6. The hardness test results for the branded products (Table 2) were deemed satisfactory using the Erweka hardness tester from Germany.

2.4.4 Disintegration Time (DT)

Disintegration aids the formulator in developing an acceptable tablet formula by serving as a control test for the manufacturing process. Hence, the D.T. test holds excellent significance in guaranteeing consistency of product quality across different batches [20-22]. The disintegration device, manufactured by Erweka in Germany, consists of six glass tubes, and the disintegration time was measured [23].

2.4.5 Friability

Weighing 10 tablets of every formulation was performed, and they were introduced in the friablator [Veego, India] at 25 rpm for 4 min. After brushing the tablets and weighing them again, friability was determined [15].

2.4.6 Content Uniformity

To check for consistency, we crushed 10 tablets of each formula to determine the drug content of each tablet separately [23].

2.4.7 In Vitro Release

The dissolution test is an in vitro procedure to assess the quality of oral pharmaceutical solid dosage forms, such as tablets and capsules. It is both qualitative and quantitative. The test, as mentioned above, provides significant insights into the biological accessibility of a pharmaceutical compound, as well as the uniformity of products across different batches [24, 25]. The dissolution studies were conducted using the USP paddle method. The agitation speed was 50 revolutions per minute (rpm) at 37 ± 0.5 °C. The solvent used for dissolution was 900 cc of water [23]. The samples, consisting of 12 units, were analyzed using spectrophotometry at a wavelength of 230 nm after a 30-minute interval. The percentage of medication dissolution for each tablet was determined.

3. Results and Discussion

The current study assessed the various quality criteria of multiple brands of cetirizine HCL. The research used the USP and B.P. pharmacopeia protocols for each test. Four brands of cetirizine HCL marketed in Iraq were assessed for weight variation, hardness, disintegration time, friability, solubility, and content.

Allercet, Allereset, Ceritec, and Cetrizine-Ozon had weight ranges of 0.187-0.194 g, 0.12-0.125 g, 0.171-0.181 g, and 0.199-0.213 g, respectively. The disintegration times for Allercet, Allereset, Ceritec, and Cetrizine-Ozon were 4.5, 5.5, 6, and 12 minutes, respectively. After 30 minutes, all brands had an adequate amount of active ingredient released; however, Allercet had the fastest release (81% after 10 minutes), and Cetrizine-Ozon had the slowest release (29.7%) after 10 min. Every one of the four brands' weight variations results fell within the permitted range of 5% [23], with RSDs ranging from 1.31 to 1.88%. According to the test, all the samples have successfully passed the weight variation. None of the brands differed by more than 5% from the average weight. Any deviation over the established limits of Pharmacopeia shows inappropriate pharmaceutical items and a corresponding variance in the drug content. Tables 1 and 2 display the results below.

Table 1. Weight variation (n = 10)

Brand	*Minimum weight/tab (g)*	*Maximum weight/tab (g)*	*Average weight/tab (g)*	*Standard Deviation (SD)*	*%Relative Standard deviation (RSD)*
Allercet	0.187	0.194	0.190	0.003	1.31

Allereset	0.120	0.125	0.122	0.002	1.39
Ceritec	0.171	0.181	0.175	0.003	1.66
Cetrizine - Ozon	0.199	0.213	0.205	0.004	1.88

Tablets may be able to withstand abrasion caused by collisions and sliding against each other and other solid objects, which can lead to the removal of minute fragments from the surface of the tablets. The friability test found that several brands of cetirizine HCL tablets had friability levels between 0.06 and 0.10%. Each of the four cetirizine HCL brands has satisfied the USP requirement, which specifies that no brand should lose more than 1% of its beginning weight and has also passed the friability test [15]. The outcome may also demonstrate the tablets' durability to external pressure encountered throughout production, shipping, and transportation. Simultaneously, ensuring that the drug's strength does not hinder its ability to dissolve in the stomach is crucial. Its strength must not interfere with the stomach disintegration process to ensure the drug is released quickly from the tablet.

The investigation revealed that the mean compression force measured fell between 9.4 and 15.3 kg/cm3. The tablet's hardness must be within the permissible range. Tablets with higher hardness levels often take longer to break apart, while tablets with lower hardness are more easily crumbled and disintegrate faster. The disintegration time was measured to assess the duration it takes for a medication to break down in the stomach. The cetirizine tablets were anticipated to undergo disintegration within 15 to 30 minutes [15], and based on this investigation, the average disintegration time varied between 4.5 and 12 minutes, which is shorter than the typical disintegration period of 15 minutes for uncoated tablets and 30 minutes for coated tablets [15].

Table 2: Results of quality tests (All values are reported as mean ± standard deviation (SD)**)**.

Brand	***Assay (%)***	***Content uniformity (%)***	***Hardness (kg/cm^3)***	***Friability (%)***	***Disintegration time* (min)***
Allercet	99.5%± 0.3	98.6% ± 0.5	12.7±1.6	0.07	4.5± 0.01

Allereset	98.6%± 0.2	97.5%± 0.1	13.9±0.75	0.10	5.5± 0.04
Ceritec	100.2%± 0.4	99.1%± 0.3	9.4±0.85	0.06	6± 0.01
Cetrizine - Ozon	99.7%± 0.1	98.9%± 0.1	15.3±1.29	0.08	12± 0.05

Dissolution is a parameter directly linked to the absorption and bioavailability of the medicine. Inadequate absorption means that the body will not get the therapeutic benefit from medications with poor dissolving characteristics. Different brands of cetirizine HCL have different release rates, ranging from 29.7% to 81.1% after 10 min. Allercet exhibited the highest drug release percentage among the entire sample, with a value of 81%. Allerset followed closely with a drug release percentage of 79.3%, while Certic tablets showed a lower drug release percentage of 45%. Cetirizine ozone had the lowest drug release percentage at 29.7%. However, all of these formulations met the USP Pharmacopeia requirements for drug release after 30 minutes, with values ranging from 91.6% to 104.9%.

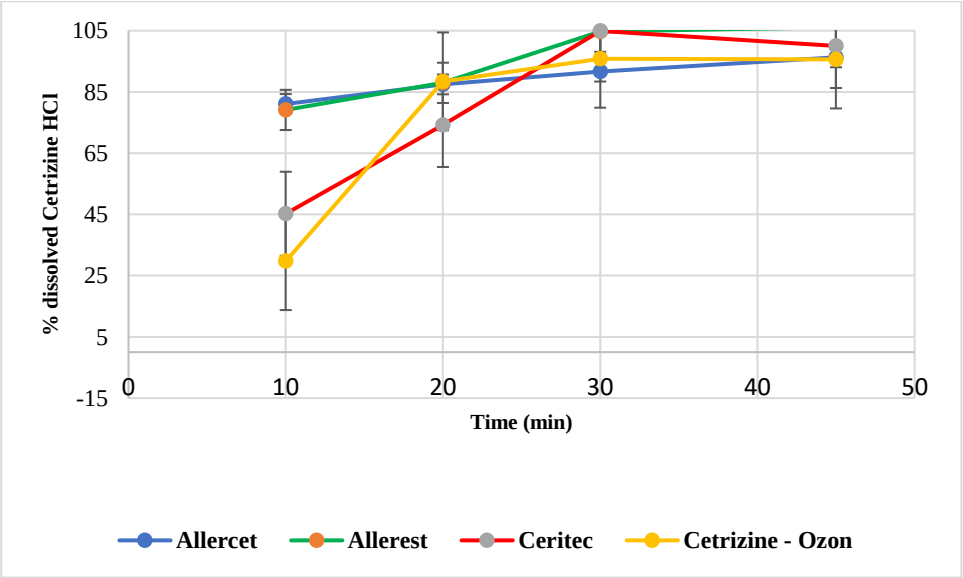

Figure 2. release of cetirizine HCL from tablets.

The assay results for cetirizine (Table 2) of four brands of cetirizine HCL showed that Ceritec had the highest amount (100.2) while Allereset had the lowest (98.5). All items contained cetirizine hydrochloride within a range of 100% ±10% of the amount stated on the label. As to the USP pharmacopeia, the cetirizine HCL content must be within the range of 90% to 110% [15]. Thus, all the brands that were examined adhered to the pharmacopeial requirements set by the USP.

Thus, the four marketed products of cetirizine HCL are deemed safe and meet the quality standards set by the Pharmacopeia [15, 23]. Hence, the study demonstrates that most examined brands

had favorable outcomes. The appropriate governing body must implement additional measures to ensure the ongoing maintenance of product quality.

According to the World Health Organization (WHO), around 700 deaths occur each year as a result of fake pharmaceuticals, which indicates that the overall yearly fatality rate associated with this treatment is likely to be far higher [26,27]. Hence, it is imperative to conduct quality control assessments for all pharmaceutical products, including cetirizine HCL.

4. Conclusions

The results indicate that all of the tested products meet the specified requirements of the United States and British Pharmacopeia.

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