RESEARCH ARTICLE

ISSN: 0331 - 670X

https://doi.org/10.51412/psnnjp.2023.11

The Nigerian Journal of PHARMACY

AS MEN OF HONOUR WE JOIN HANDS

THE OFFICIAL ORGAN OF THE PHARMACEUTICAL SOCIETY OF NIGERIA FOUNDED 1927

Application of ISO 17025 Standards in the Validation of a Spectrophotometric Method for Quality Assessment of Generic Brands of Cetirizine Tablets marketed in Nigeria.

Nneka Nwamaka Ibekwe[1]*, Isa Hayatu Galadima[1], Judith Eloyi Okoh[2], Martins Emeje[2]

[1]Department of Medicinal Chemistry and Quality Control, National Institute for Pharmaceutical Research and Development, Abuja, Nigeria

[2]Department of Pharmaceutical Technology and Raw Materials Development, National Institute for Pharmaceutical Research and Development, Abuja, Nigeria

ARTICLE INFO

Article history:

Received 20 February 2023
Revised 4 March 2023
Accepted 29 March 2023
Online Published 31 March 2023

Keywords:

Cetirizine dihydrochloride,
quality control,
method validation,
UV spectrophotometry,
assay.

* *Corresponding Author:*

nnekaibekwe@yahoo.com
+234 805 893 9488
https://orcid.org/0009-0009-4283-3418

ABSTRACT

Background: The concern for the quality of medicines is to ensure efficacious clinical outcomes and quality health care. The World Health Organization (WHO) estimates that 10–20 % of medicines in developing country markets are sub-standard. Continuous monitoring of the quality of medicines requires both competent analysts and well-equipped drug quality control laboratories with international accreditation. The objective of the study was to evaluate the quality control parameters of the generic cetirizine dihydrochloride 10 mg tablets marketed in Abuja metropolis of Nigeria and to validate and apply a UV spectrophotometric method to the assay of the commercial tablet formulations.

Method: Nine brands of cetirizine dihydrochloride tablets were randomly selected from retail pharmacy stores and quality control tests of weight variation, friability, hardness, disintegration, and dissolution parameters were conducted per United States Pharmacopoeia (USP) standards. Thickness and diameter were also evaluated by standard methods. A UV spectrophotometric method was adopted and validated according to ICH guidelines and applied for the drug assay of the tablet dosage units.

Results: The thickness, diameter, hardness and disintegration tests for the drug samples ranged from 2.81–3.76 mm, 3.88–8.11 mm 1.65–7.50 KgF and 0.44–4.90 min, respectively. All the samples met the compendial specifications for the weight variation test and also for the friability and dissolution tests which ranged 0.18–0.56 % and 90.15–109.18 % at 30 min, respectively. The studies for validation of the UV method demonstrated good linearity with a correlation coefficient of r^2 = 0.9989 in the concentration range of 2.5–25 µg/mL of cetirizine dihydrochloride (CTZ) reference standard and the limit of detection (LOD) and limit of quantitation (LOQ) were 0.42 µg/mL and 1.29 µg/mL, respectively. The % RSD of the precision studies was less than the 2 % standard limit and the accuracy (recovery) ranged from 100.9–103.4 %. The percentage contents of the generic brands were determined and ranged from 99.12–103.21 % and were within the official specifications.

Conclusion: The UV method was simple, sensitive and rapid and successfully applied to the assay of nine commercial brands of CTZ tablets. All the drugs met the compendial specifications on the quality parameters.

1. Introduction

Although the cost of building quality into any product is capital intensive at the initial stage, it is ultimately cheaper and yield better results than testing for quality in the final product. This is because it reduces deviations and costly investigations, and also avoids regulation compliance problems. Adherence to standards of the International Organization for Standardization (ISO) helps to minimize defects or prevent mistakes which might lead to disastrous expenses by an organization.[1] We recognize that organizations are set up to either fill a need, solve actual problems and/or satisfy the needs of their customers, and this is achieved through adherence to international standards epitomized by total quality management, which demands that quality be built into the product rather than waiting to check the quality of the outcome, however,

testing the final products using ISO 17025 standards is key to producing internationally acceptable data on the quality of medicines circulating in Nigeria. Unfortunately, with the continually increasing number of pharmaceutical products being imported into Nigeria, ensuring the quality of those products becomes even more important and challenging. According to the World Health Organization (WHO), 10-20 % of medicines in developing country markets are sub-standard,[2–5] and the consequences of such sub-standard or counterfeit medicines are extremely serious and detrimental to public health. Among the strategies required to combat drug counterfeiting, well equipped drug quality control laboratories in Nigeria are key, but, this is not the case at the moment. In fact, even where minimal equipment exist, necessary laboratory accreditation such as ISO 17025 required to handle the drug quality tests and international proficiency tests to confer competency on analysts as well as global acceptability of results are lacking.

One of the most frequently employed analytical tools in the pharmaceutical industry in developing countries, including Nigeria, is the Ultraviolet-Visible (UV-Vis) spectrophotometry. Of the various spectrophotometric methods[6] used for estimating drugs in pharmaceutical preparations, spectrophotometry has proven to be selective, precise, rapid, reproducible, and economical for many drugs. This has generated interest among pharmaceutical analysts, and efforts at developing UV method for more drugs have continued to increase; one of such drug of importance is cetirizine dihydrochloride.

Cetirizine dihydrochloride (CTZ), chemically named [(±)-(2-[4-[(4-chlorophenyl) phenylmethyl)-1-piperazinyl] ethoxy) acetic acid dihydrochloride] and with the molecular formula $C_{21}H_{25}ClN_2O_3.2HCl$, is a racemic mixture composed of equal amounts of two enantiomers, levocetirizine, and dextrocetirizine (Figure 1). It is a second-generation antihistamine used in the treatment of allergic rhinitis, allergic skin itching, conjunctivitis, and minimizes or eliminates the symptoms of perennial and seasonal allergic rhinitis, chronic idiopathic urticaria, allergic asthma, physical urticaria, and atopic dermatitis.[7,8] With the recent outbreak of COVID-19, the administration of CTZ in combination with another antihistamine, famotidine demonstrated reductions in ventilation dependence and inpatient fatality.[9] CTZ acts by inhibiting the H1-receptors primarily on respiratory smooth muscle cells, vascular endothelial cells, immune cells, and the gastrointestinal tract.[10] Unlike first-generation antihistamines, cetirizine does not cross the blood-brain barrier to a large extent, avoiding the neurons of the central nervous system. As a result, it does not cause side effects such as sedation, dry mouth, or blurred vision, making it an antihistamine of choice in the management of allergy-related conditions.[7] It is one of the most used drugs in children, accounting for about 9% of all pediatric prescriptions.[8]

The most commonly administered dosage forms are tablets and the official tests for evaluation of tablets found in most pharmacopeias are weight variation, friability disintegration, dissolution, and assay. These tests aim to ensure that the tablets have the correct nominal drug content and that the drug is released into the solution within a specified time.[11] Appearance, size, shape, thickness, and hardness of the tablets are the non-official tests. Quality control parameters also assure the manufacturer that the tablets meet the acceptance limits within the same and across different production lots.

Assay is very important in the pharmaceutical analysis as it determines that the drug product has the same quantity as the labeled claim. Several methods have been developed to assay CTZ in pharmaceutical preparations including derivative and ion-pair spectrophotometry,[12,13] spectro-flourimetry,[14] emission spectrophotometry,[15] high-performance liquid chromatography (HPLC) [16] and thin layer chromatography (TLC) densitometry.[17] Quality control studies have also been carried out on CTZ[18,19,20] and ultraviolet (UV) spectrophotometry has also been used to evaluate the content uniformity of CTZ dosage form.[21] Our literature search resolved very scanty reports on the application of UV spectrophotometry for the assay of CTZ formulations in quality control studies.[22] In this paper, we report the validation of a simple and sensitive spectrophotometric method, which is selective, precise, rapid, reproducible, and economical, and most importantly without using organic solvents, costly reagents or other tedious procedures. The validated method was used to evaluate the quality of nine generic brands of CTZ 10 mg tablets marketed in Abuja metropolis of Nigeria.

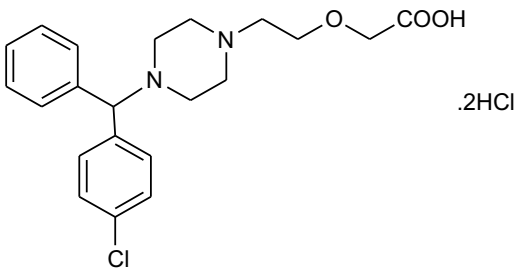

Figure 1: Chemical structure of cetirizine dihydrochloride

1. Materials and methods

2.1 Materials

Equipment: Ultraviolet-visible spectrophotometer (Agilent technologies, Cary 60 UV-Vis, Malaysia), friability test apparatus (Erweka®, Germany), hardness tester (Erweka®, Germany), vernier caliper, analytical weighing balance (Mettler Toledo®, Germany), dissolution test apparatus (RC-6, China), disintegration apparatus (Erweka® ZT Disintegration Tester, China), *Reagents and chemicals*: Hydrochloric acid (Analar grade, Sigma-Aldrich, Germany), distilled-deionized water, cetirizine dihydrochloride reference standard (USP, Rockville, USA).

2.2 Methods

2.2.1 Sample Collection

Nine (9) commercial brands of CTZ were purchased from community pharmacies within the Federal Capital Territory (FCT), Abuja, between July and August 2022. Although the pharmacies were randomly selected, all the brands in circulation were procured. The label information on the packets was examined for batch numbers, manufacturing date, expiry date, National Agency for Food Drug Administration and Control (NAFDAC) number, manufacturer's name, and country of manufacture. The brands were coded as samples A to I and the study was carried out before the expiry dates for the products.

2.2.2 Non-compendial methods of evaluation

2.2.2.1 Thickness and Diameter

The thickness and diameter of each sample were determined using the thickness and diameter gauge (vernier caliper). Results obtained are tabulated as the mean of 10 readings with standard deviation.[23]

2.2.3 Compendial methods of evaluation

Weight variation, disintegration, dissolution, friability and hardness tests were carried out according to the ISO 17025 standards in the USP General Chapters 2091, 701, 711, 1216, 1217, respectively.[24-28]

2.2.3.1 Weight variation

Twenty tablets of each sample were randomly selected and the individual weight of each tablet was measured on an analytical weighing balance (Mettler Toledo®, Germany). The average weight was calculated and the variation of each tablet from the mean was evaluated, including the standard deviation.

2.2.3.2 Friability test:

Ten (10) tablets from each sample were randomly selected, collectively weighed (W1), placed into the friabilator (Erweka®, Germany), and set to rotate at 25 rpm for 4 min. The tablets were de-dusted, and re-weighed (W2) and the percentage loss in weight was calculated.

2.2.3.3 Hardness test

Ten randomly selected tablets from each sample were subjected to a hardness test using the Erweka® hardness tester, the force (KgF) required to break each tablet was recorded and the average force was calculated.

2.2.3.4 Disintegration test:

Six (6) randomly selected tablets from each sample were placed in each of the six compartments of the disintegration tester (Type ZT4 Erweka®, Germany) containing distilled water maintained at 37 ± 2 ℃. The time taken for all the tablet particles to pass through the compartment's mesh was noted and the average time was calculated as the disintegration time.

2.2.3.5 Dissolution test

One tablet from each sample was placed in the dissolution vessel containing 900 mL matrix solution maintained at 37 ± 0.5 ℃. The dissolution apparatus type 11 (RC-6, China, paddle apparatus) was set to rotate at 50 rpm and aliquots of five (5) mL were withdrawn at intervals of 5, 10, 20, and 30 min and filtered (0.45µm membrane filter). The equivalent volume of the medium was replaced to maintain sink conditions. The absorbance of the sample was thereafter measured in triplicates at 231 nm using the UV-Visible spectrophotometer, and the percentage release of the drug was determined.

2.2.4 Assay

2.2.4.1 Pre-experimental conditions for method validation and assay of CTZ

The six major standard clauses[29] of the ISO-17025 guided this procedure; briefly, Performance Verification Tests (PVT) and calibration of the UV-Vis spectrophotometer and the analytical balance were carried out according to USP standards. The temperature and humidity of the environment were routinely monitored and recorded in the control chart record form by the Instrument Maintenance

Team (IMT). A routine daily check for the analytical balance with different standard weights was performed by the IMT before weighing was done. The checks were confirmed by the Quality Assurance (QA) team in order to ensure the quality and reliability of the generated results.

2.2.4.2 Method

A UV-Visible spectrophotometric UV method by LGC, Pharmassure Pharmaceutical Proficiency Testing Scheme was adopted for the estimation of CTZ.[29]

2.2.4.2a Preparation of matrix solution: The matrix solution was prepared at a concentration of 10.3 g/L HCl by adding 23.39 mL of 37 % HCl to 500 mL of deionized water in a 1 L volumetric flask. The final solution was made up to the mark with deionized water, and the solution was well mixed.

2.2.4.2b Preparation of stock solution: A 100 µg/mL stock solution of CTZ in matrix solution was prepared by dissolving 10 mg of the reference standard (USP, Rockville, USA) in 50 mL of matrix solution in a 100 mL volumetric flask. The mixture was swirled thoroughly and made up to the mark using the matrix solution. An aliquot was scanned from 400 to 200 nm with a UV spectrophotometer and showed maximum absorption at 231 nm against the reagent blank.

2.2.4.3 Method Validation

Method validation was carried out to determine the suitability of the adopted UV spectrophotometric method for the assay of commercial brands of CTZ. The method was validated for linearity, precision, accuracy, the limit of quantification (LOQ), and the limit of detection (LOD) following International Conference for Harmonization (ICH) guidelines.[30] Standard solutions for testing the linearity of calibration plots were prepared in triplicates by diluting accurate volumes of 0.25, 0.5, 1.0, and 2.5 mL of the 100 µg/mL CTZ stock solution to 10 mL with the matrix solution to obtain different concentrations within the range of 2.5–25 µg/mL. Linearity was determined by plotting the concentration against the corresponding absorbance. Linearity was evaluated by linear regression analysis and calculated by the least square regression method. The limit of detection (LOD) and limit of quantification (LOQ) were estimated from the calibration curves of CTZ using the standard deviation of the response and slope approach. Repeatability was tested by preparing 5, 10, and 15 µg/mL of CTZ in triplicates and the absorbance was measured at three different times (10.00, 13.00, 16.00 h) on the same day. Freshly prepared solutions of the same concentrations were analyzed daily by the same analyst for three consecutive days for the intermediate precision study. The precision was expressed as relative standard deviation (RSD).

2.2.4.4 Determination of content of commercial samples of CTZ

The adopted and validated method was used in the determination of the content of CTZ in the nine commercial brands of CTZ tablets (10 mg)**.** Twenty (20) tablets from each sample were weighed and crushed to a fine powder in a clean porcelain pestle and mortar. An amount of the finely powdered sample equivalent to one tablet (10 mg) of CTZ was weighed and transferred into a clean 500 mL volumetric flask and dissolved with approximately 250 mL matrix solution. The solution was swirled to fully combine and the final solution was made up to the mark with the matrix solution and filtered. The sample solutions were analyzed at a wavelength of 231 nm.

2. Results

The results of the quality control test (thickness, diameter, hardness, friability, weight, disintegration, and dissolution) for the nine different brands of CTZ tablets labeled A–I are presented in Tables 1 and 2. The thickness and diameter varied from 2.81 to 3.76 mm and 3.88 to 8.11 mm, respectively. The results for the hardness test of the cetirizine tablets ranged from 1.65–7.50 KgF, in the order H > F > G > E > C > D > A > B > I, with the lowest value being for sample I and the highest value for sample H. The friability of the samples ranged from 0.24–0.56 %. The weight of the different brands of cetirizine tablets ranged from 118.71–184.66 mg. The disintegration time of the samples ranged from 0.44–4.90 min with sample E having the least disintegration time and sample G having the highest time. The *in-vitro* dissolution profile (Figure 2) of the samples ranged from 90.15–109.18 % at 30 min. Results of the linearity, precision, and accuracy studies are summarized in Tables 3 and 4, respectively. The validated UV method was applied to the assay of cetirizine in the commercially available samples as shown in Table 5.

Table 1. Non-compendial quality control tests for CTZ tablets

Sample code	Thickness (mm)	Diameter (mm)
A	2.94 ± 0.02	4.66 ± 0.01
B	3.25 ± 0.02	3.88 ± 0.06
C	3.35 ± 0.07	5.09 ± 0.01
D	2.81 ± 0.03	4.04 ± 0.01
E	3.76 ± 0.11	8.11 ± 0.06
F	3.12 ± 0.01	4.08 ± 0.01
G	2.93 ± 0.02	4.11 ± 0.01
H	3.28 ± 0.02	3.94 ± 0.01
I	3.10 ± 0.02	4.02 ± 0.01

Data are presented as mean ± standard deviation (n=10)

Table 2. Compendial quality control tests for CTZ tablets

Sample code	Weight variation* (mg)	Hardness** (KgF)	Friability Test (%)	Disintegration*** time (min)	Dissolution @ 30 min
A	120.86 ± 0.00	2.45 ± 1.34	0.27	0.53 ± 0.07	103.53
B	134.84 ± 0.00	1.65 ± 0.49	0.24	3.17 ± 0.05	108.44
C	184.66 ± 0.01	3.35 ± 1.06	0.35	2.40 ± 1.23	105.13
D	119.85 ± 0.00	2.70 ± 0.14	0.55	4.40 ± 0.14	108.45
E	183.37 ± 0.00	3.35 ± 0.21	0.18	0.44 ± 0.17	106.74
F	119.10 ± 0.00	5.10 ± 0.14	0.56	1.55 ± 0.05	91.92
G	118.71 ± 0.00	5.00 ± 0.85	0.56	4.90 ± 2.19	90.15
H	120.60 ± 0.00	7.50 ± 0.42	0.50	2.76 ± 0.44	97.82
I	124.84± 0.01	1.40 ± 0.14	0.28	2.14 ± 0.06	109.18

Data are presented as mean ± standard deviation (*n=20, **n=10, ***n=6)

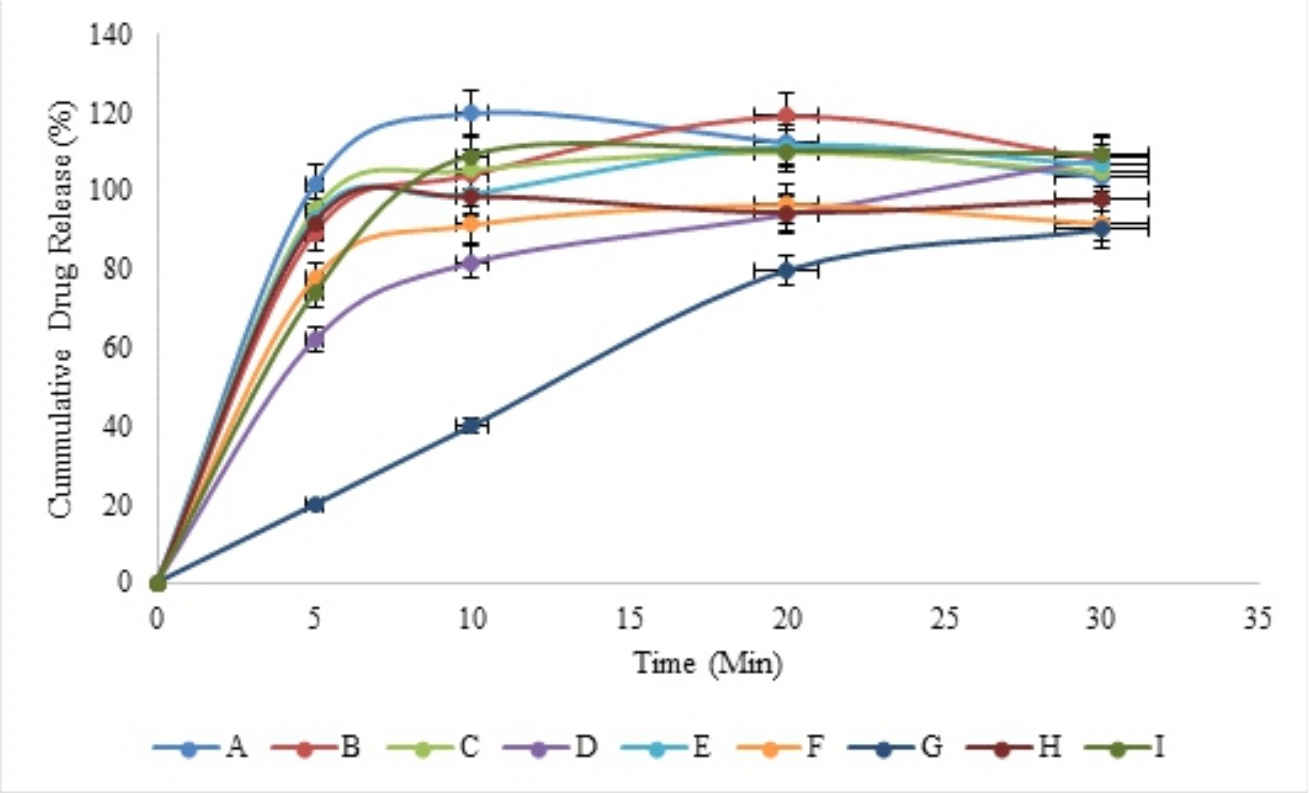

Figure 2: *In vitro* release profile of brands of cetirizine dihydrochloride tablets

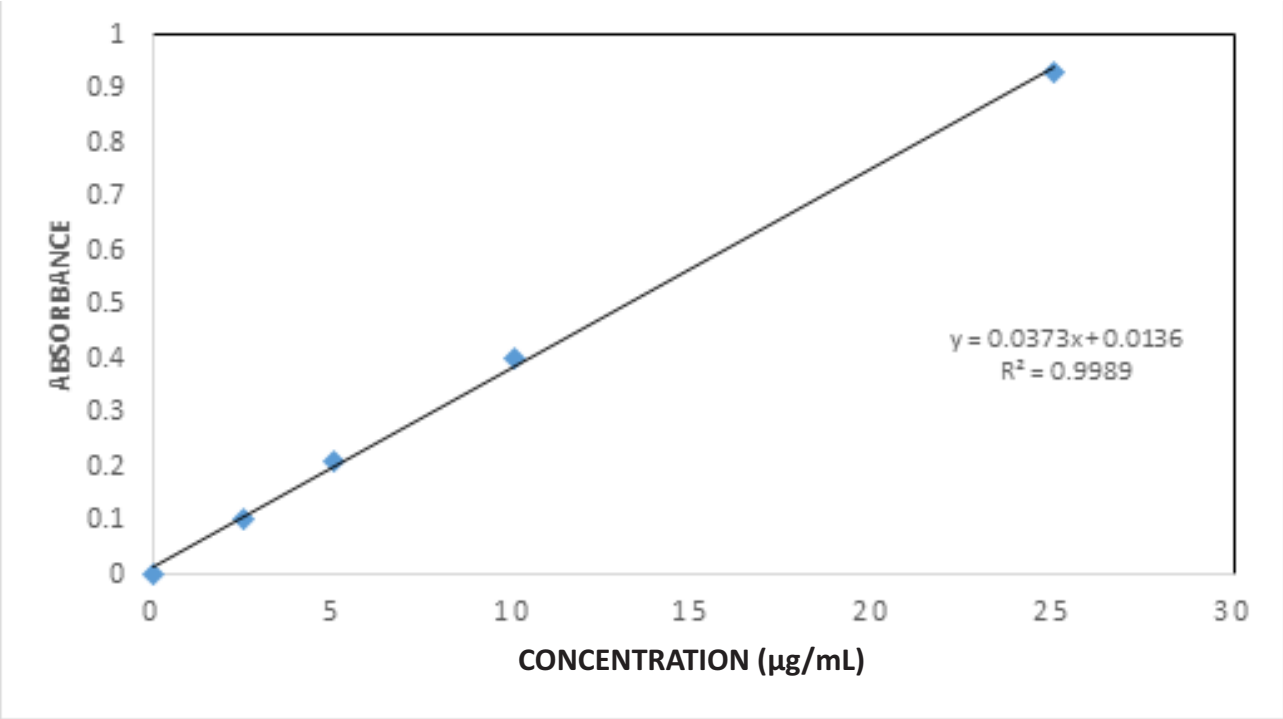

Figure 3: Standard calibration plot of cetirizine dihydrochloride at 231 nm

Table 3. Linear Regression Parameters

Parameter	Result
λ-max (nm)	231
Beer's law linearity range (µg/mL)	2.5–25.0
Regression equation	$y = 0.0373x + 0.0136$
Intercept	0.0136
Slope	0.0373
Correlation coefficient (r^2)	0.9989
Standard deviation of the intercept	0.01288
Limit of detection (µg/mL)	0.42
Limit of quantification (µg/mL)	1.29

Table 4. Precision and accuracy results of CTZ reference standard

Nominal Conc. (µg/mL)	No of replicates	Found concentration (µg/mL)			Mean conc. ± SD (µg/mL)	Precision (% RSD)	Accuracy* (%)
Intra-day		**10.00 h**	**13.00 h**	**16.00 h**			
5.00	3	5.10	5.08	5.11	5.10 ± 0.02	0.39	102.0
10.00	3	10.11	10.19	10.18	10.16 ± 0.04	0.39	101.6
15.00	3	15.14	15.12	15.16	15.14 ± 0.02	0.13	100.9
Inter-day							
5.00	3				5.17 ± 0.02	0.38	103.4
10.00	3				10.18 ± 0.04	0.40	101.8
15.00	3				15.41 ± 0.03	0.19	102.7

Data are presented as mean ± standard deviation (n=3), * expressed as recovery

Table 5. Assay results of marketed CTZ tablets

Sample code	Assay (% content)
A	103.21 ± 1.07
B	100.26 ± 1.38
C	99.11 ± 1.57
D	100.21 ± 1.04
E	101.20 ± 1.07
F	99.06 ± 1.45
G	101.16 ± 0.52
H	99.12 ± 0.12
I	100.31 ± 0.05

Data are presented as mean ± standard deviation (n=3)

4. Discussion

Nine commercial CTZ 10 mg tablet formulations sold in the Nigerian market were assessed for quality. The brands were coded as samples A, B, C, C, D, E, F, G, H, and I. The samples had varying results for hardness which ranged from 1.4–7.5 KgF. Hardness also known as breaking force, is an important quality parameter as it imparts on the friability and disintegration of the tablets. An immediate-release uncoated tablet dosage form is recommended to have a minimum hardness of 4 KgF.[31] In our study, only three samples F, G, and H had values of the hardness test greater than 4 KgF. Similar studies on CTZ by and reported hardness values greater than 4 KgF.1[8,21] The authors proposed that hardness should not be so low that the tablets are soft and friable.[21] That was not the case in our study as the friability values of all the samples were less than 1.0 % which is the acceptance limit according to the USP standard. Previous quality tests on CTZ also met the official specifications.[18,19,20,21] The friability test measures the tablet's resistance to abrasion or fracture. The goal of the friability test is to simulate the types of forces experienced by a tablet during coating, packaging, handling, and shipping, which includes collisions and sliding of tablets towards each other in order to assess the possible damage due to wear and tear that the tablet can withstand. In the weight variation test, all the samples had average weights of 130 mg or less except samples B, C, and E which had average weights greater than 130 mg, but less than 325 mg (Table 2). The results for weight variation showed that all the samples complied with the USP specification as no tablet from a sample deviated from the average weight by 10 % for weights 130 mg or less, or by 7.5 % for weights 130–324 mg. It was also observed that the average weights obtained for the samples could be related to the thickness and diameter of the tablets where the highest average weights also had the highest dimensions as seen with samples C and E. Weight variation imparts directly on the assay of the tablets as it demonstrates uniformity in the dosage units of tablets.[32] The rate of disintegration has an effect on the release of active ingredient from the dosage form. The results obtained in this study were comparable to the time ranges demonstrated in the studies by and Odeniran et al. at 4.00–14.33 min, 0.38–19.04 min and 0.34–3.98 min, respectively.[18,20,21] It has also been postulated that disintegration time is directly related to hardness, that is, as the breaking strength of the tablet is increased, there is also an increase in disintegration time.[33] This study did not follow that trend as the disintegration time was arbitrarily distributed amongst the different brands. Another plausible explanation by Gwaziwa et al. was that excipients such as binders used play a major role in the rate at which a tablet breaks down into smaller particles.34 However, a relationship was observed between the tablet dimensions and the disintegration time. Sample E (diameter 8.11 mm, thickness 3.76 mm) had the fastest disintegration time at 0.44 min. A probable reason as provided by Molavi et al. was that the larger tablets provided more surface area for their pharmacological performance, as was corroborated in their study.35 The rate of dissolution of a tablet is directly correlated with the oral bioavailability of the drug. Cetirizine hydrochloride tablets are defined by the USP to contain between 90.0 % and 110.0 % of cetirizine hydrochloride. The tolerance for CTZ according to USP is that not less than 80% is dissolved at the maximum time of 30 min. All the samples released over 80% of cetirizine in 30 min.36 The in-vitro dissolution profile (Figure 2) of selected cetirizine tablets at 30 min ranged from 90.15 % to 109.18 %. All the brands released over 50 % of cetirizine in 5 min except G which had a 19.89 % release of active ingredient within the same time frame. Samples A (119.83 %) and H (98.61 %) had their peak release at 10 min; samples B (119.20 %), C (110.11 %), E (111.49 %), F (96.65 %), and I (110.13 %) had their maximum release at 20 min, while D (108.45 %) and G (90.15 %) had their maximum release at 30 min. Generally speaking, sample G had the lowest dissolution rate as seen in Figure. 1. In their studies , Hasan et al., Anjum et al. and Odeniran et al. reported that the maximum cetirizine release at 30 min was 106.63% 90.09% and 103.36 % respectively.18,20,21 The factors that may be responsible for the differences in the in vitro release of API from formulation include the type of excipients used, nature of the excipients, the aqueous solubility of the Active Pharmaceutical Ingredient (API) and the media used.37 The validation studies aimed to demonstrate the suitability of the adopted method for the assay of the drug in dosage preparations. Beer's law was obeyed in the concentration range of 2.5–25 μg/mL. The correlation coefficient obtained for the line was 0.9989 indicating good linearity (Figure 3, Table 3). The % RSD values of the intra-day and inter-day precision studies were found to be in the range 0.13–0.40 % while the % accuracy (recovery) ranged 100.9–103.4 % (Table 4). The low relative standard deviation values (<2 %) were indicative of good precision. The method was found to be sensitive, reliable, and satisfactory and was applied to the assay of cetirizine tablets in generic brands. The percentage contents of cetirizine estimated from the samples were within the range of 99.11–103.21 % as shown in Table 5. The percent

content of all the samples was within the USP monograph specification of 90.0–110.0 %, and as such, all the brands met the acceptance criteria.[36] The findings of this study suggest that the interchangeable use of the brands may probably result in a similar clinical outcome due to comparable values of the quality parameters of the assessed samples. In their study, Odeniran et al. determined the assay of five brands of CTZ by HPLC and found all to be within the pharmacopeial limits.[20] Hasan and his colleagues had also employed the UV spectrophotometry as an analytical tool in the quality control of CTZ but to determine the content uniformity only.[21] In a related study but employing different reagents, Urs and co-workers developed a UV spectrophotometric method and adopted it for the determination of CTZ in marketed formulations.[22] Assay is a critical test in the quality assessment of pharmaceutical products. It determines the amount, concentration, or percentage content of a drug compared to its labeled amount. It is one of the quality control parameters for detecting counterfeit or substandard pharmaceutical products as the failure to meet standard specifications is suggestive of poor quality.

5. Conclusion

For the first time, ISO 17025 Standards, including environmental temperature, calibration, validation, storage, and personnel audit such as proficiency test results and outcome of inter-laboratory audits were applied to check the quality of cetirizine tablets using UV-Vis spectrophotometer as the analytical tool. Compared with the HPLC method provided by the official monograph for this drug, the UV method requires less skill to operate, it is cheaper, more affordable, while still retaining its simplicity, and reliability, making it a better alternative testing method in resource-starved nations. All the samples interrogated passed the individual and corporate tests for quality in accordance with total quality management principles.

References

1. Emeje M, Ekere K, Olayemi O, Isimi C, Gamaniel K. (2019). Total quality management in a resource-starved nation. Available at: https://10.5772/intechopen.82759 Accessed January 08, 2023
2. World Health Organization (2003). WHO releases new tool to boost access to quality medicines and detect counterfeits [Online]. Available at: https://www.who.int/news/item/19-03-2003-who-releases-new-tool-to-boost-access-to-quality-medicines-and-detect-counterfeits. Accessed January 10, 2023
3. World Health Organization (2005). Combating counterfeit drugs: A concept paper for effective international cooperation [Online]. Available at: http://www.who.int/medicines/services/counterfeit/CombatingCounterfeitDrugs_Conceptpaper.pdf
4. World Health Organization (2007). Good governance for medicines. Curbing corruption in medicines regulation and supply [Online]. Available at: http://www.who.int/medicines/policy/goodgovernance/home/en/index.html
5. World Health Organisation (2017). WHO global surveillance and monitoring system for substandard and falsified medical products [Online]. Available from https://apps.who.int/iris/handle/10665/326708 Accessed January 10, 2022.
6. Beckett AH, Stenlake JB (2005). Practical Pharmaceutical Chemistry. 4th ed.–Part One. New Delhi, India: CBS Publishers and Distributors, 133–136.
7. Chen C (2008). Physicochemical, pharmacological and pharmacokinetic properties of the zwitterionic antihistamines cetirizine and levocetirizine. Current Medicinal Chemistry 15(21): 2173–2191.
8. Parisi GF, Leonardi S, Ciprandi G, Corsico A, Licari A, Giudice M, Peroni DG, Salpietro C, Marseglia GL (2020). Cetirizine use in childhood: an update of a friendly 30-year drug. Clinical and Molecular Allergy 18:2.
9. Hogan RB, Hogan III RB, Cannon T, Rappai M, Studdard J, Paul D, Dooley TP (2020). Dual-histamine receptor blockade with cetirizine - famotidine reduces pulmonary symptoms in COVID-19 patients. *Pulmonary Pharmacology and Therapeutics 63: 101942*.
10. Portnoy JM, Dinakar C (2004). Review of cetirizine hydrochloride for the treatment of allergic disorders. Expert Opinion on Pharmacotherapy 5:125–135.
11. Gupta M, Khoorban A, Ali A, Ramlogan O, Talukdar D (2020). Comparative quality control study of different brands of diclofenac sodium tablet available in local and government pharmacies by in-vitro testing. Cureus 12(11): e11348.
12. Ulu ST (2010). Extractive spectrophotometric determination of cetirizine dihydrochloride in pure and

pharmaceutical preparations. Journal of Food and Drug Analysis 18(6): 440–446.

13. El Walily AFM, Korany MA, El Gindy A, Bedair MF (1998). Spectrophotometric and high performance liquid chromatographic determination of cetirizine dihydrochloride in pharmaceutical tablets. Journal of Pharmaceutical and Biomedical Analysis 17: 435–442.
14. Abd-AlGhafar WN, Aly FA, Sheribah ZA, Saad S (2022). Synchronous fluorescence as a green and selective method for the simultaneous determination of Cetirizine and Azelastine in aqueous humor. Journal of Fluorescence 32: 1199–1210.
15. Li-sheng W, Xiao-ling W, Qi G, Zhi-liang J, Dong-mei L, Qing L (2011). Indirect determination of cetirizine hydrochloride by ICP-AES. Bulletin of Korean Chemical Society 32(2): 595–598.
16. Jaber AMY, Al Sherife HA, Al Omari MM, Badwan AA(2004). Determination of cetirizine dihydrochloride, related impurities and preservatives in oral solution and tablet dosage forms using HPLC. Journal of Pharmaceutical and Biomedical Analysis 36: 341–350.
17. Kristiningrum N, Martyanti EN (2013). Validated TLC-densitometry method for determination of cetirizine dihydrochloride in tablet dosage form. International Current Pharmaceutical Journal 3(1): 208–210.
18. Anjum F, Razvi N, Ghazal L (2012). A comparative study of different brands of cetirizine hydrochloride tablets available in Karachi, Pakistan. Jordan Journal of Pharmaceutical Sciences 5(3): 165–170.
19. Xhafaj D, Malaj L, Mileti M Md(2015). A comparative quality control study of cetirizine hydrochloride 10mg tablets on the Albanian pharmaceutical market. International Journal of Pharmacy and Pharmaceutical Sciences 7(1): 504–507.
20. Odeniran OA, Ekere KE, Galadima IH, Kirim RA, Tarfa FD, Mustapha KB (2022). Evaluation of some quality parameters of five brands of cetirizine hydrochloride tablets marketed in Abuja, Nigeria. Journal of Phytomedicine and Therapeutics 21(2): 922–930.
21. Hasan A, Dewan SMR, Ahamed SK, Kaisar M (2013). Quality control studies on cetirizine hydrochloride tablets available in Bangladeshi drug market. International Journal of Pharmacy and Biological Sciences 3(1): 349–354.
22. Urs SSR, Bindu M, Ramyashree D, Sowmya KN (2020). Spectrophotometric method for the estimation of cetirizine hydrochloride in pharmaceutical preparation. Asian Journal of Pharmaceutical Analysis 10(4): 185–188.
23. Srivastava P, Malviya R, Kulkarni, G T (2010). Formulation and evaluation of paracetamol tablets to assess binding property of orange peel pectin. International Journal of Pharmaceutical Sciences Review and Research 3(1): 30–34.
24. USP (2020). General Chapters <2091> Weight variation of dietary supplements. In: USP 43 NF 38. Twinbrook Parkway, Rockville, MD: The United States Pharmacopeial Convention.
25. USP (2020). General Chapters <701> Disintegration. In: USP 43 NF 38. Twinbrook Parkway, Rockville, MD: The United States Pharmacopeial Convention.
26. USP (2020). General Chapters <711> Dissolution. In: USP 43 NF 38. Twinbrook Parkway, Rockville, MD: The United States Pharmacopeial Convention.
27. USP (2020). General Chapters <1216> Tablet friability. In: USP 43 NF 38. Twinbrook Parkway, Rockville, MD: The United States Pharmacopeial Convention.
28. USP (2020). General Chapters <1217> Tablet breaking force. In: USP 43 NF 38. Twinbrook Parkway, Rockville, MD: The United States Pharmacopeial Convention.
29. Pharmassure (2022). Pharmaceutical products proficiency testing scheme. Issue 23 (Applicable to PH082, sample 6B–UV).
30. International Conference on Harmonisation (2005). Validation of analytical procedures: text and methodology. Available at http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html. Accessed 29 July 2022.
31. Ofoefule SI (2002). A Textbook of Pharmaceutical Technology and Industrial Pharmacy. 2nd edn. Lagos, Nigeria: Samakin Enterprises, 57–66.
32. Alam K, Shareef H, Bushra R (2013). Formulation development and evaluation of caffeine tablets (200mg) by direct compression. International Journal of Drug Development and Research 5(3): 371-376.
33. Ahmed A, Ali SA, Hassan F, Ayub S, Haque N (1998). Effect of disintegrants and hardness on the disintegration time of acetaminophen tablets. Pakistan

Journal of Pharmaceutical Sciences 11(1): 41–46.

34. Gwaziwa NN, Dzomba P, Mupa M (2017). A quality control study of ibuprofen tablets available in the formal and informal market in Harare, Zimbabwe. African Journal of Pharmacy and Pharmacology 11(16): 195–203.

35. Molavi F, Hamishehkar H, Nokhodchi A (2020). Impact of tablet shape on drug dissolution rate through immediate released tablets. Advanced Pharmaceutical Bulletin 10(4): 656-661.

36. USP (2020). Cetirizine hydrochloride tablets. In: USP 43 NF 38. Twinbrook Parkway, Rockville, MD: The United States Pharmacopeial Convention.

37. Zarmpi P, Flanagan T, Meehan E, Mann J, Østergaard J, Fotaki N (2020). Biopharmaceutical implications of excipient variability on drug dissolution from immediate release products. European Journal of Pharmaceutics and Biopharmaceutics 154:195–209.