

In-vitro Comparative Study of Leading Brands of Ciprofloxacin Tablets 500mg in Taiz City, Yemen

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Abstract

Ciprofloxacin is commonly used in Yemen and widely available in both imported and locally manufactured tablet forms. Although these products contain the same labeled dosage, differences in manufacturing quality may influence their therapeutic efficacy. This study aimed to perform an in-vitro comparative analysis of ten brands of ciprofloxacin 500 mg tablets (six imported and four local), collected from pharmacies in Taiz city, using pharmacopeial quality control tests. Physicochemical parameters assessed included appearance, weight variation, hardness, thickness, friability, disintegration time, dissolution profile, and drug content. Results were evaluated against United States Pharmacopeia (USP) and British Pharmacopeia (BP) standards. All brands complied with USP specifications for weight uniformity, friability, and disintegration time. Assay results ranged from 90.34% to 101.30%; while all brands met USP requirements, four brands (F3, F5, F8, and F10) did not satisfy the BP minimum limit. Dissolution testing revealed that only four brands (F1, F2, F6, and F9) released more than 80% of the drug within 45 minutes, in accordance with USP standards. Overall, the in-vitro evaluation showed that most brands, including locally produced tablets, met key pharmacopeial quality standards. These findings support the use of local products as cost effective alternatives to imported brands. Further in-vivo studies are recommended to confirm bioequivalence and therapeutic consistency.

Keywords: Quality control, Leading brands, Ciprofloxacin, In-vitro release, Pharmacopoeial specifications.

1. Introduction

In today's pharmaceutical world, it's crucial to ensure that medicines are high-quality and consistent. This is important because it affects patient health and safety, as well as the trust of people in pharmaceutical companies manufacturing these drug products. Many developing countries (including Yemen), lack the laboratories and resources to effectively monitor the quality of generic drug products (either registered or counterfeited) available on the market. The tests of quality control of pharmaceutical preparations consists certain tests of investigation began through manufacturing process by inspection tests and after manufacturing through finished product quality control tests according to official pharmacopoeias and various regulatory agencies [1]. These investigations aid in prevention the problems associated with safety, potency, efficacy and stability of pharmaceutical products. Most of drugs that imported into the Arabic countries had not evaluated for quality and safety especially in Yemen that make these products do not meet pharmacopoeial standards. Based on this fact, it is necessary to evaluate these drugs to support the health agencies in country in this field and provide them with these results. One study conducted to analyze amoxicillin capsules in many Arab countries showed that 56 % of these products did not meet USP standards. On the other hand, based on in vivo investigations in the Italian market showed that some generic amoxicillin capsules were not bioequivalent to the original product [2].

Quinolone antibiotics, especially ciprofloxacin, are essential medicines used in Yemeni market and dispensed as OTC drug in pharmacies, hospitals and clinics. Ciprofloxacin is an antibiotic related to fluoroquinolone class and has a structure in Figure (1) [3]. It was discovered by Germanic company in 1981 and approved by Food and Drug Administration in 1987 and became first antibiotic in United States in this period and included in the

World Health Organization's (WHO) list of essential medicines [4]. It became a very cheap drug and included in generic lists of most common drugs that should be pharmaceutically equal to the modernizer final product [5]. The safety and effectiveness of common products are in uncertainty specially in situation of underprivileged and developing areas.

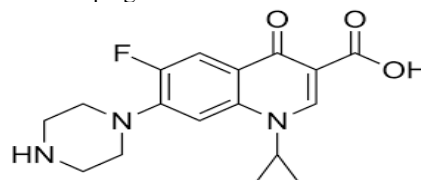


Figure (1). Structure of ciprofloxacin

The substandard and counterfeit drugs don't met pharmacopeia specifications and therefore not effective and not safe for use in patients due to they don't contain active ingredients, contain low active ingredient strength than therapeutic concentration, may be wrong packaging and incorrect ingredients [6]. The risk effect caused by counterfeit drugs is more serious than effect produced from substandard drugs, however both are unsafe, ineffective, major cause of morbidity and mortality that lead to low confident in population in these products [7], [8].

According to WHO and FDA reports, 10% of the universal pharmaceutical products markets includes counterfeit drugs, it is percentage rises to 25% in poor and developing countries, and may reach to 50% in some countries [9] specially China and India that are responsible for most production of these types of products in the world [10],[11]. The substandard and counterfeit products are also appeared, produced and marketed in developed countries in which life-threatening drugs as anticancer were found without active ingredients [12],[13]. The major conditions to accept the drug product quality include safety, stability, efficacy, potency, regulatory compliance, patient acceptability, no

variation from batch to another [14],[15]. To be sure in drug quality, the drug producers must inspect their preparations through and post production at different periods of product shelf-life [16]. The bioequivalence studies must be done to compare the bioavailability values between generic and original products [17]. The products are called bioequivalent when they are corresponding in concentration, purity, content uniformity, disintegration and dissolution values [18].

Many reasons have been justified this study as the high distribution of substandard and counterfeit products in medical markets specially in war conditions countries (as Yemen), the availability of large number of ciprofloxacin brands including Indian companies, inability of health agencies in Yemen to evaluate the imported products due to war conditions, increase in number of counterfeit drugs especially these days of war, misuse of ciprofloxacin brand products and big difference in prices of different brands. Antibiotics in Yemen are dispensed as OTC without prescription, Ciprofloxacin is one of these antibiotics. So the main aim of this study was to evaluate the quality characters of various selected brands of Ciprofloxacin 500mg tablet commercially available in the Yemeni market (Taiz city) to ensure that the tablets meet the standards set by the USP and BP Pharmacopeias. Quality parameters of tablets such as content uniformity, drug potency, thickness, diameter, friability, disintegration time and dissolution rate that must be equal for pharmaceuticals equivalents [19],[20]. Also in this study it was aimed to evaluate if there a relationship between quality and price of this brands in the pharmaceutical market of Taiz city.

2. Study site

Due to the most common misuse of ciprofloxacin in Yemen specially in Taiz city, this study carried out in this area.

3. Methods

3.1. Materials

3.1.1. Selection Criteria and Sampling Method for Commercial Classes of CF

There are a lot of products of Ciprofloxacin tablets 500mg existing in Yemeni market. 10 commercially presented leading brands of Ciprofloxacin 500mg were selected according to most common dispensed and continuous availability in the market. Samples used during this study were collected as gifts from different local stores of medical companies in Taiz city, Yemen which were coded blindly as F1, F2, F3, F4, F5, F6, F7, F8, F9 and F10. These products were checked for their, manufacturing company, manufacturing date, expiry date, manufacturing license number, batch number at the time of collections as shown in Table (1). The standard ciprofloxacin powder was obtained from Global pharma, Sanaa, Yemen. Unless otherwise specified, all other chemicals were of analytical grade.

Table (1). Leading brands of Ciprofloxacin 500mg used in this study

Code No.	Brand Name	Manufacturer	Country	Man. Date	Exp. Date
F1	Ciprodenk	Denk pharma	Germany	03/2023	03/2026
F2	Ciprofin	Modren Pharma	Yemen	08/2022	08/2025
F3	Cinox	Schizoid Pharma Lab.	Pakistan	10/2022	10/2025
F4	Ciprofast	Global Pharma	Yemen	12/2022	12/2025
F5	Ciplox	Cipla-medica Pharma	India	10/2021	10/2024
F6	Hicipro	Yephco	Yemen	08/2023	08/2026
F7	Jocipro	JOSWE	Jordan	05/2021	05/2024
F8	Ciprosan	Shiba Pharma	Yemen	09/2021	09/2024
F9	Ceprozo	El-saad Pharma	Syria	07/2022	07/2025
F10	Ceflox	Laborate Pharma	India	02/2023	02/2026

3.2. Instruments

UV- visible Spectrophotometer (Labtech ,India), Friabilator (Shanghai, China), Disintegrator (VEEGO, Japan), USP Dissolu-

tion tester (Minhua, China), Electronic balance (Ohaus, China), Digital Hardness tester (Minhua, China), UV-Visible spectrophotometer (Shanghai, China), Digital Caliber (Shanghai, China). Mortar and Pestle are available in laboratory.

3.3. The study design

The study employed a laboratory-based experimental design to assess the quality control of ten brands of Ciprofloxacin 500mg tablets available in Taiz market, Yemen. The study design focused on in-vitro assessments to determine the physicochemical properties and quality parameters of the Ciprofloxacin tablets. All quality tests, including weight variation, drug content, hardness, friability, disintegration time, dissolution profile, thickness and diameter tests, were conducted in the laboratory setting. The tablets from each brands were subjected to the same set of quality tests to ensure a standardized evaluation process. Data from the quality tests were collected, recorded, and analyzed to compare the performance of the different tablet varieties in meeting established quality standards according to United States Pharmacopeia [21].

3.3.1. General appearance

They are evaluated by visual examination the different physical appearance properties as shape, color and texture of various brands of tablets.

3.4. Quality control tests

The quality control tests of tablets includes the following tests:

3.4.1. Weight variation test

As per the guidelines outlined in the United States Pharmacopeia, a weight variation test was conducted by individually weighing 20 tablets from each of the ten brands using a precise electronic digital balance. The average weight for each brand was then calculated, and the weight of each tablet was compared to this average. The variation in weights was determined using the following formula:

$$\text{Weight variation} = (Iw - Aw)/Aw \times 100\% \quad (1)$$

where, Iw = Individual weight of the tablet and Aw = Average weight of the tablet. The tablet complies with the test if not more than two of the individual weights deviate from the average weight by more than the 5% [22].

3.4.2. Thickness test

The thickness of the tablets was measured using a Vernier caliper. The scale was first set to zero, and each tablet was positioned laterally between the caliper's jaws. Care was taken to ensure the jaws lightly contacted the tablet's surface without applying pressure. The reading displayed on the scale was then recorded. After each measurement, the tablet was removed, the jaws were cleaned, and the caliper was reset. Three tablets from each brand were selected randomly for measurement, and the standard deviation of thickness was calculated and expressed in millimeters. The thickness of most tablets typically falls within the range of 2 mm to 6 mm. If the standard deviation large that means the die of machine need to maintained accurately [23],[24].

3.4.3. Hardness test

This test evaluates the pressure needed to fracture tablets placed diametrically by applying force through a coiled spring. Tablet hardness was measured using a Monsanto hardness tester. Three tablets were randomly selected from each of the ten brands for testing. Each tablet was placed on the lower plunger, and the initial reading on the Monsanto tester scale was set to zero. The tester, with a range of "0 to 20 kg," was adjusted by moving the screw knob forward until the tablet fractured, and the required force was recorded. The acceptable limit for this test is 6 ± 2 kg/cm². The average hardness value, calculated from three randomly selected tablets for each brand batch, was expressed in kg/cm² [24].

3.4.4. Friability test

Friability is an indicator of tablet strength and the binding of granules. The friability test was conducted using a friabilator according to the following procedure. Twenty tablets from each of the ten brands were initially weighed and placed in the friabilator, which was operated at 25 rpm for a duration of 4 minutes. Afterward, the tablets were dedusted and reweighed. The percentage of friability was calculated using the following formula:

$$\text{Friability (\%)} = [(Iw - Fw) / Iw] \times 100\%$$

Where:

Iw = Total initial weight of the tablets

Fw = Total final weight of the tablets

According to the United States Pharmacopeia (USP), conventional compressed tablets with a weight loss of less than 0.5%–1.0% are generally considered acceptable [25].

3.4.5. Disintegration test

The disintegration test was carried out using the USP disintegration apparatus. One tablet from each brand was placed in the respective tube of the basket rack, which was submerged in a 1000 mL vessel containing 900 mL of water maintained at a temperature of $37 \pm 2^\circ\text{C}$. The tablets were positioned to remain 2.5 cm below the surface of the liquid during upward movement and no closer than 2.5 cm from the vessel's bottom during descent. A motor-driven mechanism was used to move the basket assembly up and down over a distance of 5–6 cm at a frequency of 28–32 cycles per minute. Perforated plastic discs were employed to prevent the tablets from floating. The apparatus was operated for 30 minutes, during which the tablets were required to disintegrate completely, with all particles passing through a 10-mesh screen. Any remaining residue was examined to ensure it consisted only of a soft mass with no firm core. Six tablets from each brand were tested in distilled water at 37°C using an Electrolab disintegration tester, and the disintegration time was recorded as the time required for complete dissolution with no visible particles remaining [26].

3.4.6. Calibration curve preparation of standard ciprofloxacin solution

To prepare the calibration curve, a specific amount of ciprofloxacin hydrochloride dust was accurately weighed and melted in 10 mL of DW, followed by dilution to 100 mL to attain a stock solution of 1000 $\mu\text{g/mL}$. From this stock, 10 mL was further diluted to 100 mL to prepare a solution with a concentration of 100 $\mu\text{g/mL}$. Serial dilutions were then made to obtain concentrations of 5, 10, 15, 20, 25, 30, and 35 $\mu\text{g/mL}$. The absorbance of these solutions was measured at 278 nm using a UV spectrophotometer, and a standard curve was plotted with absorbance values on the Y-axis and concentration on the X-axis [27].

3.4.7. Drug content test

To determine the drug content, tablets from each brand were powdered, and an amount equivalent to 100 mg of ciprofloxacin was dissolved in 100 mL of 0.1 M hydrochloric acid. Further dilutions were made to prepare a solution with a concentration of 100 $\mu\text{g/mL}$. A 4 mL aliquot from each brand was diluted to 100 mL with 0.1 M hydrochloric acid, filtered, and the absorbance was measured at 278 nm against a blank. The experiment was performed in triplicate, and the average values were calculated. According to USP standards, ciprofloxacin content should be between 90% and 110%, while BP specifies a range of 95% to 105%. Due to the unavailability of advanced instrumentation in Taiz city, a UV spectroscopic method was used, which has been supported by several studies as a reliable alternative to high-performance liquid chromatography (HPLC) for ciprofloxacin analysis [28].

3.4.8. In-vitro drug release study

The in-vitro dissolution study was performed using the USP Dissolution Apparatus II. A single tablet from each 500 mg ciprofloxacin brand was placed in a vessel containing 900 mL of 0.1 M hydrochloric acid (pH 1.2) maintained at $37 \pm 0.5^\circ\text{C}$. The apparatus

was operated at a constant rotational speed of 50 rpm. Samples of 5 mL were withdrawn at specific time intervals (5, 15, 30, 45, and 60 minutes), with the withdrawn volume replaced by an equal amount of fresh dissolution medium. The samples were filtered, and 1 mL of filtrate was diluted to 50 mL with distilled water. Absorbance was measured at 278 nm using 0.1 M hydrochloric acid as the blank. The percentage of drug release was calculated using a standard ciprofloxacin solution. According to USP, tablets pass this test if at least 75% of the drug is released within 45 minutes, while BP requires a minimum release of 80% within the same time frame [29].

3.4.9. In-vitro drug release kinetics

To study the drug release kinetics, the in-vitro release data were analyzed using various kinetic models, including zero-order, first-order, Higuchi, and Korsmeyer–Peppas equations. These models are expressed as:

$$\text{Zero-order kinetics: } Q_t = Q_0 + K_0t \quad (3)$$

$$\text{First-order kinetics: } \log Q_t = \log Q_0 + K_1t/2.303 \quad (4)$$

$$\text{Higuchi kinetics: } Q_t = K_h t^{1/2} \quad (5)$$

$$\text{Korsmeyer - Peppas kinetics: } Q_t/Q_0 = Kt^n \quad (6)$$

where, K_0 , K_1 and K_h indicates zero-order, first-order and Higuchi rate constants respectively, Q_t/Q_0 means fraction of drug released at time t , K means rate constant and n means release exponent. The kinetics that gives high regression coefficient (R^2) value is considered as the best fit model [30],[31].

3.4.10. Statistical analysis

All results were reported as mean $\pm$ standard deviation (SD). The data from the dissolution tests were analyzed using one-way analysis of variance (ANOVA) to determine statistical significance. Microsoft Excel 2010 (Roselle, IL, USA) was utilized for both statistical analysis and graphical representations. A probability value of $P < 0.05$ was considered statistically significant.

4. Results and Discussion

4.1. General appearance

Table (2) represent the different physical appearance characters of various brands that shows that all brand products have the same shape and texture (biconvex shape and smooth texture) but different in the color in which each product has specified color.

Table (2). General characters of different leading brands of ciprofloxacin 500mg tablets.

Code no.	Shape	Color	Texture
F1	Biconvex	White	Smooth
F2	Biconvex	White	Smooth
F3	Biconvex	Pink	Smooth
F4	Biconvex	Yellow	Smooth
F5	Biconvex	Yellow	Smooth
F6	Biconvex	White	Smooth
F7	Biconvex	White	Smooth
F8	Biconvex	White	Smooth
F9	Biconvex	Sunset	Smooth
F10	Biconvex	White	Smooth

4.2. Weight variation test

The weight variation test is conducted to ensure the uniform distribution of ingredients throughout the batch. Several factors can contribute to significant weight variation, such as poor granule flow, inconsistency in granule size due to improper sieving, the presence of excessively fine granules, and improper machine adjustments. Significant weight variation can affect content uniformity, potentially leading to tablets that are either excessively overweight or underweight. This can result in patients receiving either an overdose or underdose, causing unpredictable therapeutic responses. A tablet is considered compliant with this test if no more than two individual tablet weights deviate from the average weight by more than 5% (USP, 22). The mean weight variation results for the ten brands were as follows, listed in descending order: F8 (4.25%) > F2 (3.95%) > F7 (3.51%) > F5 (3.36%) > F10 (3.07%) > F3=F4 (2.41%) > F1 (2.28%) > F9 (2.29%) > F6

(1.43%), respectively given in Figure (3). Among all tablets, the highest weight variation was found in F8, (4.25%) and the lowest was found in F6, (1.43%). This means that all the brands complied with the compendial specifications [22]. The results were approximately corresponding to the in vitro bioequivalence studies on ten brands of ciprofloxacin 500mg tablets sold in Dhaka, Bangladesh also reported similar results [3].

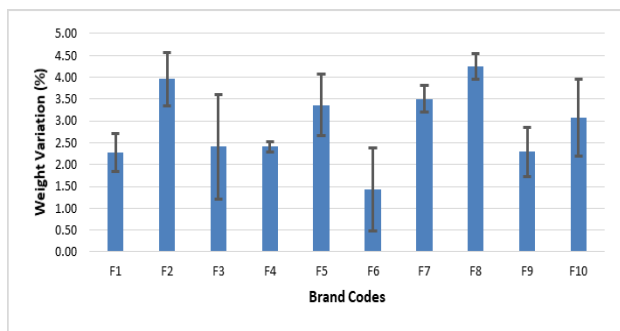


Figure (3). Weight variation values of different brands of ciprofloxacin 500mg tablets (mean ± SD, n = 20/brand)

4.3. Thickness test

The thickness of a tablet is inversely related to its hardness, meaning that as the thickness increases, the hardness decreases, and vice versa. A tablet that is too thick can impact the packaging, whether it's blister or plastic container. It was noted as shown in Figure (4) that the standard deviations of different values of tablet thickness were as the following descending order: F7 (2.09) > F3 (1.87) > F10 (1.54) > F6 (1.50) > F9 (1.12) > F1 (0.98) > F8 (0.87) > F2 (0.76) and F4 (0.34). All brand thickness's values are within the permissible limit, it shows that F4 with less standard deviation (0.34) while F7 higher values (2.09). It was noted also the error rate was small indicated that the accuracy of the values and their closeness to each other. Brand F7 that had a slightly large different error value than the others, while the F4 was the least value of deviation that means high accuracy.

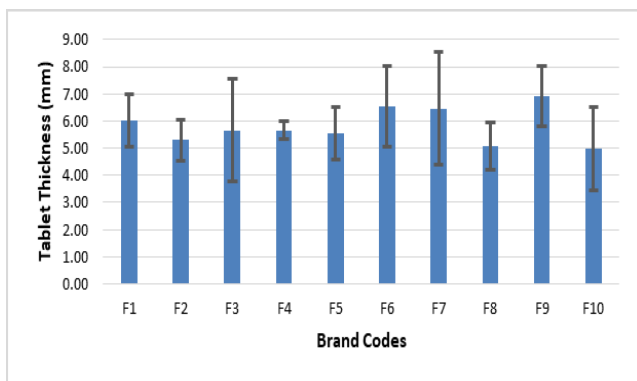


Figure (4). Thickness test results of ten leading brands of ciprofloxacin 500mg tablets (mean ± SD, n = 3/brand)

4.4. Hardness test

Tablets must possess a certain level of hardness to endure the automatic stresses encountered during manufacturing, packaging, and distribution. Additionally, they should be able to withstand reasonable handling by consumers. Adequate tablet hardness and resistance to powdering are essential for purchaser receiving. Of late, the connection between tablet hardness, disintegration, and, more importantly, the drug dissolution rate, has become increasingly evident. The hardness of tablets can be attributed to the varying properties of the excipients used in the formulation of different brands. However, no correlation was found between tablet hardness and friability values [33]. Increase in hardness values means tablets not disintegrate easily and vice versa low value of hardness means tablets not resist the handling process, so the harness must be in accepted range according to USP. The mean hardness results are shown in Figure (5) for ten brands

obtained were in the specified descending order: F10 (11.70 kg/cm²) > F9 (9.50 kg/cm²) > F1 = F8 (8.70 kg/cm²) > F5 (8.60 kg/cm²) > F4 = F6 (8.20 kg/cm²) > F7 (8.10 kg/cm²) > F2 (7.90 kg/cm²) > F3 (7.60 kg/cm²). It can be seen that Brand F10 (11.70 kg/cm²) had the highest hardness value while Brand F3, (7.60 kg/cm²) had the lowest value. All of the tablets met the in-house specifications for this test. In bioequivalence studies conducted on selected ciprofloxacin tablet brands in the Nigerian market, with Ciproflox® as the innovator brand, Ayodeji et al. demonstrated that all of the brands complied with the specifications for this test [20].

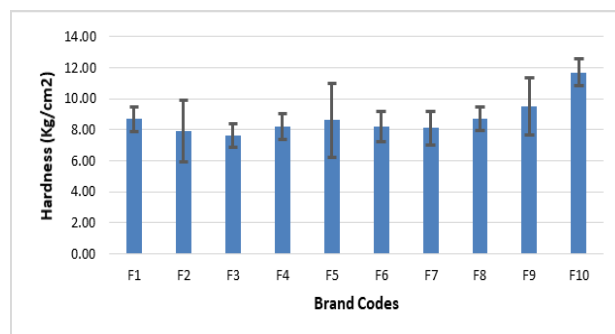


Figure (5). Hardness test values of ten leading brands of ciprofloxacin 500m tablets (mean ± SD, n = 3/brand)

4.5. Friability test

Friability refers to the ability of tablets to withstand shock and abrasion during packaging, handling, and shipping. Tablets that are friable lose their sharp edges, which can compromise pharmaceutical elegance and patient acceptance. Additionally, friability can result in weight loss, potentially affecting the therapeutic response. Figure 6 shows the mean friability results for ten brands of ciprofloxacin tablets in the following descending order: Brand F4 (0.33%) > Brand F2 (0.22%) > Brand F6 (0.19%) > Brand F9 (0.17%) > Brand 8 (0.14%) > Brand 3 (0.09%) > Brand F1 (0.08%) > F5 (0.04%) > Brand F10 (0.03%). Thus, Brand F4 was the most likely to lose particles during handling (0.33%), while Brand F10 was the least likely (0.03%). All brands showed friability values below 1%, meeting the compendial specifications. In a comparative in vitro evaluation of generic ciprofloxacin tablets, Salih and Hamam reported that all four different brands of ciprofloxacin tablets complied with USP requirements for this test [20].

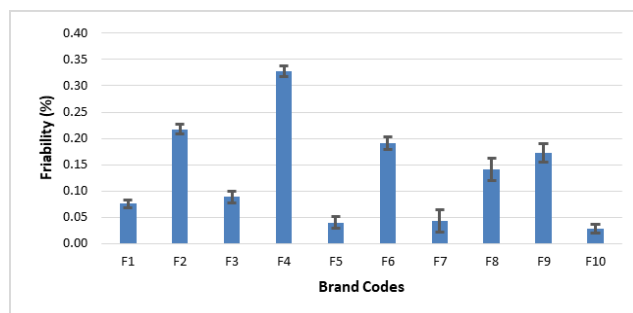


Figure (6). Friability test results of ten leading brands of ciprofloxacin 500mg tablets (mean ± SD, n = 20/brand)

4.6. Disintegration test

Before a drug can be absorbed by the body, it must first be in solution form. For most tablets, the initial and critical step toward achieving this solution is the breakdown of the tablet into smaller particles or granules, a process known as disintegration. Disintegration is directly related to dissolution and, consequently, the bioavailability of the drug [34]. The disintegration times for ten brands of 500 mg ciprofloxacin tablets are shown in Figure 7, listed in ascending order as follows: F1 = F7 (2.50 min) < F4 (3.30 min) < F2 (3.60 min) < F9 (3.65 min) < F10 (3.90 min) < F8 (4.50 min) < F5 (5.00 min) < F3 (7.00 min) < F6 (7.30 min).

The highest disintegration time was observed in Brand F6 (7.30 min), while the lowest disintegration time was recorded for Brands F1 and F7 (2.50 min). All brands complied with the compendial specifications for this test, with a disintegration time of less than 30 minutes for immediate-release tablets. Similar findings were reported by Kahsay and Egziabher [35].

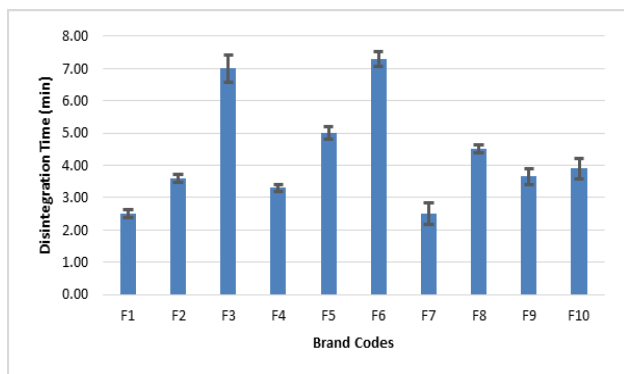


Figure (7). Disintegration times of ten leading brands of ciprofloxacin tablets (mean $\pm$ SD, $n = 6$ /brand)

4.7. Calibration curve preparation of standard ciprofloxacin solution

The calibration curve of standard ciprofloxacin is given in Figure (2) with equation:

$y = 0.0258x + 0.7077$ and correlation coefficient, $R^2 = 0.979$.

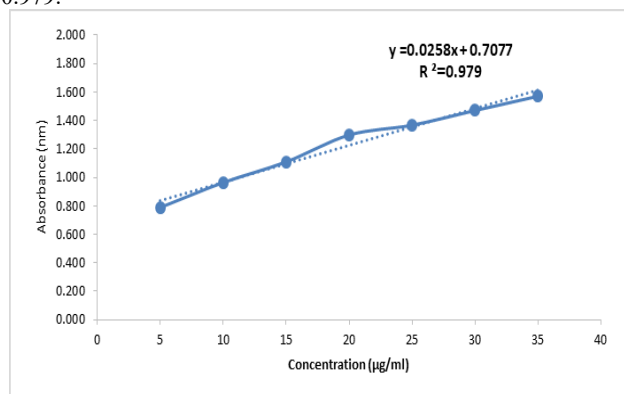


Figure (2). Standard calibration curve for ciprofloxacin

4.8. Drug content uniformity test

Drug content assay is conducted to ensure that each tablet contains the intended amount of active drug substance, with minimal variation between tablets within a batch. This assay is performed on the finished product to determine the amount or concentration of active ingredients present in the tablets. Additionally, the rate of dissolution is determined, which is directly related to the efficacy of the tablet and bioavailability differences between formulations [36]. The mean percentages of drug content for the ten brands of ciprofloxacin tablets are presented in the following descending order: F1 (101.30%) > F7 (98.07%) > F2 (97.87%) > F9 (95.87%) > F4 (94.87%) > F5 (93.78%) > F3 (92.98%) > F10 (90.76%) > F8 (90.34%). These results are shown in Figure 8. According to USP standards, the mean drug content percentages for all tested brands were above 90%, thus meeting the USP criteria for assay. However, three brands—F5, F3, F10, and F8—did not meet the BP specifications. In a study on in vitro quality assessment and bioequivalence of ten ciprofloxacin 500 mg tablet brands marketed in Dakka, Bangladesh, Md. Sahab Uddin et al. reported that four brands failed to meet the dissolution profile requirements [37]. The results demonstrated that all the brands exhibited drug assays within the acceptable range of 90–110% of the labeled amount, in line with USP standards. Brand F1 showed 101.30% of the labeled amount. The values for F7, F9, and F2 were closest to the standard, with minimal variation, indicating

high-quality formulations. Similarly, Usman et al., in their evaluation of dissolution testing for ciprofloxacin (500 mg) tablets in Ras Al Khaimah (UAE), found that all ciprofloxacin tablets complied with the content assay test [38].

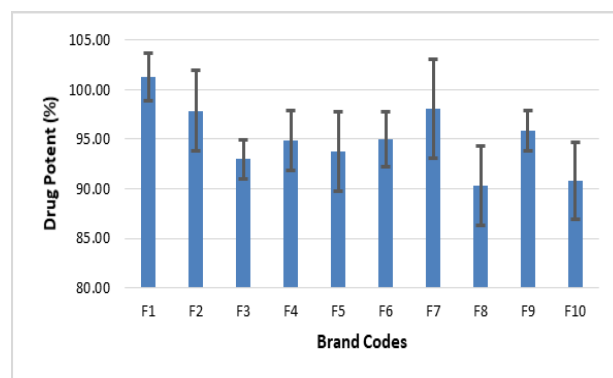


Figure (8). Percentage of drug content uniformity of ten leading brands of ciprofloxacin tablets (mean $\pm$ SD, $n = 20$ /brand)

4.9. In-vitro drug release study

Drug release test is performed to check the percentage release of active ingredient from the tablet at different times. The percentages of the drug content release of the ten brands of ciprofloxacin tablets after one hour were obtained in the following stated sequence: F1 (99.10%) > F9 (98.00%) > F6 (97.57%) > F2 (96.87%) > F7 (96.23%) > F4 (95.00%) > F3 (94.09%) > F8 (90.76%) > F10 (89.06%) and F5 (82.98%). The data showed that not all the brands met the BP and USP-NF specifications as shown in Figure (9) for drug release. The drug released percentages increase over time and have been measured at different intervals, ranging from 5 to 60 minutes. It was observed that all brands showed gradual increases within the first 30 minutes and then rapid increase within 30 – 45 minutes that followed by very slow release when the time is more than 45 minutes. At the 45-minute mark, brands (F1, F9, F2 and F6) had a release rate of over 80% whereas the other brands had a release rate lower than 80% that means not within the acceptance limits of USP specifications. In the same manner, at 45-minute mark, F4, F7, F8 and F3 had a release rate over 75% whereas F10 and F5 had failed to release 75% that made them out of limits of BP specifications.

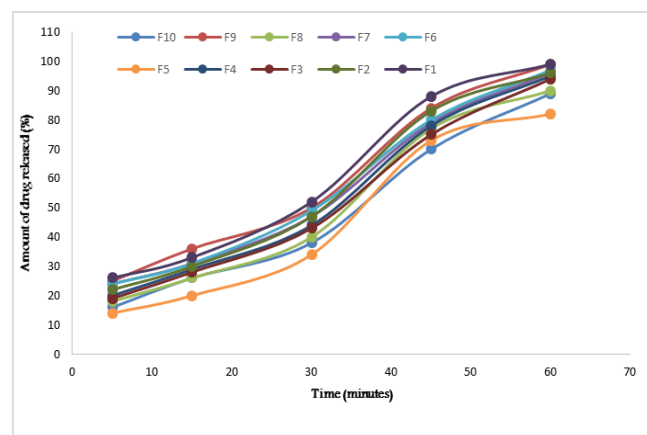


Figure (9). In-vitro release profile of ten leading brands of ciprofloxacin tablets (mean $\pm$ SD, $n = 6$ /brand)

4.10. In-vitro drug release kinetics

The drug release kinetics of the proposed brands were analyzed using different kinetic models, such as zero-order, first-order, Higuchi, and Korsmeyer–Peppas, as mentioned in Table (3). Analyzing the drug release kinetics is crucial for determining the most suitable release model for the dosage form. Table (3) presents the various kinetic models used to plot different parameters for determining R^2 . It shows that all the mentioned kinetics fit the first-order kinetic model, which was the best fit for all the tested brands.

Table (3). Kinetics of drug release from ten leading brands of ciprofloxacin tablets

Brands	Regression coefficient (R ²)			
	Zero order	First order	Higuchi	Korsmeyer–Peppas
F1	0.984	0.985	0.961	0.952
F2	0.985	0.987	0.960	0.959
F3	0.989	0.992	0.961	0.966
F4	0.988	0.990	0.960	0.963
F5	0.973	0.982	0.945	0.951
F6	0.990	0.992	0.963	0.952
F7	0.988	0.992	0.959	0.954
F8	0.981	0.987	0.954	0.966
F9	0.988	0.988	0.965	0.966
F10	0.987	0.989	0.957	0.957

4.11. Statistical analysis

The results presented in Table 3 indicate that there are no significant differences in the release patterns of the different brands, with a p-value of < 0.05.

5. Conclusion

The results of assay potency tests, dissolution, disintegration time, hardness, and the weight variation for all marketed ciprofloxacin products obey with pharmacopoeial limits, with a few exceptions. Most brands demonstrated quality that meets USP specifications, though some did not fully meet BP criteria. It can be concluded that both locally manufactured and imported 500 mg ciprofloxacin tablets are pharmaceutically equivalent and meet the quality standards according to USP specifications. Therefore, these tablets can be used safely to achieve the desired therapeutic effect. The study clearly demonstrated that all leading brands of 500 mg ciprofloxacin tablets met the criteria established in the official USP monographs for all quality control tests, except for the dissolution test, for 4 products (Brand F, Brand I, Brand H, and Brand J). Additionally, the locally manufactured Yemeni products met the USP quality standards, confirming their safety and efficacy for patient use. Although the study was conducted on a limited scale, the findings provide valuable insights that can assist the Drug Control Expert in assessing the quality status of marketed ciprofloxacin preparations in Taiz city.

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Conflicts of Interest

The authors declare that they have no competing interests.

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