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Research Article

In-vitro quality assessment of commercially available ciprofloxacin tablets marketed in Arba Minch City, Ethiopia

Teshale Etiso Wado[1], Yesuf Nuri[1], Kefita Kashala[2]

[1]Pharmacy Directorate, College of Medicine and Health Sciences, Arba Minch University, Arba Minch, Ethiopia
[2]Department of Biomedical Science, College of Medicine and Health Sciences, Arba Minch University, Arba Minch, Ethiopia

Abstract

This investigation focused on examining the quality of various ciprofloxacin tablets sold in drug outlets in Arba Minch, applying criteria from Pharmacopoeia as well as non-official measures. Samples were obtained through convenience sampling from local pharmacies in Arba Minch, Southern Ethiopia. Quality testing was performed at the Jimma University drug quality control laboratory. Each sample underwent assessments for identity, weight uniformity, solubility, friability, and assay, following the guidelines of the United States and British Pharmacopoeias. Among the tested brands, C1 showed the highest friability value (0.199). None of the brands deviated more than 5% from the average tablet weight, which is within acceptable limits. All brands released over 80% of the active ingredient within 30 minutes during dissolution testing. ANOVA analysis revealed no significant differences in dissolution profiles across brands, and the Korsmeyer–Peppas kinetic model provided the finest fitting description of dissolution behavior. Identification tests confirmed consistency with the reference standard, as retention times differed by less than 0.1 minutes. All seven brands met the assay requirements. Overall, all ciprofloxacin tablet brands examined complied with pharmacopeial in vitro quality standards.

Keywords: Assay test; Dissolution; Friability; Quality assessment; Weight uniformity

* Corresponding author: teshale.etiso@amu.edu.et

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1. Introduction

Ciprofloxacin is a synthetic fluoroquinolone antibiotic that was first developed by Bayer in Germany in 1981 and later endorsed by the U.S. Food and Drug Administration in 1987. (Uddin et al., 2017; Van Thuan et al., 2022). It is widely recognized for its strong antibacterial activity, particularly against Gram-negative bacilli (Al-Wahaibi et al., 2021; Gai et al., 2019). Extensive global research has confirmed its effectiveness and safety, with studies indicating that its use in children is as safe as in adults (Fass, 1987; Gutiérrez-Castrellón et al., 2015; Kljucar et al., 1989; Marciniec et al., 2020; Masoumi et al., 2019). Ciprofloxacin is internationally acknowledged as an

essential medicine, included in the Model List of Essential Medicines published by the World Health Organization, and is distributed worldwide in affordable generic forms under numerous brand names Seitzer et al., 2021; WHO, 2019).

For generic medicines to be considered equally effective as their branded counterparts, they must establish bioequivalence with the original product (M. S. Uddin et al., 2017). The International Organization for Standardization (ISO) defines quality as the complete set of product attributes that guarantee compliance with intended requirements (Mok et al., 2020). In the case of tablet formulations, several quality checks are required before they can be marketed. These include official pharmacopeial tests such as dissolution, weight uniformity, and assay, as well as non-official evaluations like friability, thickness, and hardness (Abebe et al., 2020). Any failure to comply with these standards signals potential risks during patient use (Tabernero et al., 2019).

The pharmaceutical industry is currently challenged by the widespread circulation of poor-quality medicines, which are generally classified as either substandard or counterfeit. Evidence from a systematic review conducted across 25 countries with limited and moderate-income levels revealed that falsified medications have a median prevalence of 28.5% (Sweileh, 2021). The impact of such products is profound: the World Health Organization estimates that counterfeit treatments for malaria and pneumonia are responsible for approximately 116,000 and 72,430 additional deaths annually (White, 2021). In the case of ciprofloxacin, the problem is particularly concerning, as studies have shown that substandard and falsified versions are far more common among informal drug vendors (26.7%) compared to licensed pharmacies (2.6%) (Tchounga et al., 2023). The use of these inferior antibiotics often results in underdosing, which accelerates the development of antimicrobial resistance (AMR) (Murray et al., 2022). The rise and spread of resistant strains worsen clinical outcomes, increase mortality rates, and force reliance on more costly and less effective therapies. This growing resistance crisis highlights the urgent need for ongoing monitoring and strict enforcement of drug quality standards (Morris & Cerceo, 2020; WHO, 2018).

While earlier investigations have identified quality issues in certain ciprofloxacin brands obtained from different regions of Ethiopia, no thorough assessment has yet been conducted in Arba Minch city (Desta, 2020; Kahsay et al., 2007; Kahsay & Egziabher, 1871). To address this gap, the present study aimed to carry out in-lab testing of ciprofloxacin tablets sourced from local pharmacies. The analysis focused on several parameters, including drug identification, friability, assay, weight variation, and dissolution time.

2. Materials and Methods

2.1 Area of study and sample size

This research was conducted using ciprofloxacin tablet samples obtained from Arba Minch City, located in Southern Ethiopia. At the time of collection, the city had 22 registered drug retail outlets, and all of them were included in the study to ensure comprehensive coverage.

2.2 Study design and period

An exploratory laboratory-based study employing physicochemical analysis was carried out. Ciprofloxacin tablet samples were obtained from drug retail outlets in Arba Minch city during the period from January 3 to February 20, 2022. The subsequent quality assessments were performed at the Drug Quality Laboratory (JuLaDQ), located within Jimma University.

2.3 Sampling techniques

A convenience sampling approach was employed to obtain different ciprofloxacin tablet brands currently sold in the market. Since the availability of brands varied, some retail outlets were visited more than once. To minimize bias, collectors used standard prescriptions and did not disclose the purpose of sampling to dispensers. At each site, ten individuals were assigned to collect the drug samples. After collection, the tablets were placed in dry, waterproof packaging and stored on shelves under cool, dry conditions. Immediately upon removal from the retail outlets, key product details—including brand name, batch number, manufacturer, production date, and expiry date—were recorded. The quality of the collected samples was then routinely monitored.

2.4 Eligibility criteria

The study focused on ciprofloxacin dosage form with a potency of 500 mg per tablet, all attained in properly labeled packaging. Any product showing discoloration, physical damage, or supplied in a dosage form other than tablets was excluded from the quality evaluation.

2.5 Ciprofloxacin working standards

The ciprofloxacin working (reference) standard was supplied by the Ethiopian Food and Drug Administration (EFDA). This standard was employed in testing the quality and quantity of the active therapeutic ingredient present in the tablet samples.

2.6 Laboratory analysis

Each brand was analyzed independently. From the 100 tablets collected per brand, subsets were randomly chosen for specific tests: twenty pills for assay analysis and identification, six for dissolution studies, and twenty for variation of weight and friability assessment. The remaining

tablets were kept as reserves. The subsequent evaluations were carried out using a combination of official methods outlined in the British Pharmacopoeia (BP) and United States Pharmacopoeia (USP), along with selected non-official procedures (British Pharmacopoeia, 2013; Hirschfelder, 1930; Soni et al., 2018; WHO, 2012).

2.7 Friability testing

Tablet friability was evaluated using a friability tester, which operates at 25 rpm and consists of a two-part plastic chamber. For each sample, twenty tablets were initially weighed, placed in the tumbling chamber, and subjected to 100 rotations over four minutes. During each revolution, the tablets were dropped from a set height to simulate mechanical stress (WHO, 2012).

After tumbling, the tablets were dedusted and reweighed to determine mass reduction. The percentage loss was calculated using the formula (Eq. 1):

$$\text{Friability (\%)} = \frac{W1-W2}{W1} \text{x } 100\% \quad (1)$$

Where W1 represents the original mass of the twenty pills and W2 the ending mass after testing at twenty-five revolution per minute, for four minutes (Abebe et al., 2020). The test was generally performed once per batch. A weight loss not exceeding 1.0% is considered acceptable for most products (Kassahun et al., 2019).

2.8 Weight variation testing

An electronic balance was used to randomly select and weigh twenty tablets from each brand. The average tablet weight was calculated using the combined mass of ten tablets and dividing accordingly. From this, the average tablet weight, percentage fluctuation, and percentage deviation were established. According to the British Pharmacopoeia specification, a batch sample is considered acceptable provided that not more than two units deviate from the mean mass by over 5%, and no unit shows a variation exceeding two times the specified limit (Soni et al., 2018). Percentage variation was derived through the use of the following formula (Eq. 2):

$$\text{Weight Variation (\%)} = \frac{Wx-Wav.}{Wav.} \text{x } 100\% \quad (2)$$

Where Wav represents the mean tablet weight, and Wx denotes the individual tablet weight (Uddin et al., 2020).

2.9 Ciprofloxacin dissolution testing

Dissolution testing was conducted to verify the solubility and obtainability of the drug substance from the tablets. Following the British Pharmacopoeia (BP) guidelines, a Paddle apparatus (type II) was run at a speed of 50 rpm. The test employed 900 mL of deionized water as the

dissolution medium, kept at 37 °C ± 0.5 °C. After filling the vessels and stabilizing the temperature, the apparatus was set to the required speed, and one tablet was introduced into each jar.

Drug release was monitored by withdrawing 10 mL samples at predetermined intervals (0, 5, 15, 30, 45, and 60 minutes). To maintain the amount consistency, an equivalent quantity of newly prepared medium was added immediately after each withdrawal. The concentration of ciprofloxacin released was assessed with the aid of UV/Visible spectrophotometry, measured at 276 nanometers. For calculations, it was noted that 1 mg of ciprofloxacin hydrochloride corresponds to 0.9010 mg of ciprofloxacin base ($C_{17}H_{18}FN_3O_3$). Dilution corrections were applied, and drug content was quantified by comparison with the reference standard. According to BP specifications, at least 80% of the labeled ciprofloxacin content must dissolve within 30 minutes (British Pharmacopeia, 2013).

2.10 Model-based approaches to drug release kinetics in dissolution study

The outcomes of the dissolution experiments were analyzed using several kinetic models, as outlined in Table 1, to evaluate the release behavior of ciprofloxacin from the tablets. The most appropriate model was identified as the one yielding the highest regression coefficient (R^2), which indicates the best fit to the experimental data (Uddin et al., 2017).

Table 1. The release kinetics equations

Model Name	**Formula**	**Key Concept**
Zero-order kinetics	$Q_t=Q_0+K_0t$	Drug liberation proceeds at a uniform pace, regardless of the remaining concentration.
First-order kinetics	$\log Q_t=\log Q_0+K_1t/2.303$	Drug liberation occurs in proportion to the quantity still present in the dosage unit.
Higuchi kinetics	$Q_t=K_ht^{½}$	Drug liberation follows a diffusion-controlled mechanism, with release progressing as the square root of time.
Korsmeyer–Peppas kinetics	$Q_t/Q_0=Kt^n$	Describes complex release mechanisms; exponent nn indicates the type of transport.
Hixson–Crowell model	$Q_0^{1/3}-Q_t^{1/3}=K_st$	Considers variations in surface area and tablet size as the dosage form dissolves.

K_o → Zero-order release constant (rate of drug release independent of concentration), K_1 → First-order liberation constant (rate depends on the residual drug concentration), K_s → Hixson–Crowell release constant (accounts for changes in surface area/geometry of tablets), K_h → Higuchi release constant (represents diffusion-controlled release), Q_t / Q_o → Proportion of drug liberated at time t relative to the starting quantity, K → General rate constant used in the Korsmeyer–Peppas model, n → Release exponent in the Korsmeyer–Peppas model, which indicates the process governing drug liberation: n = 0.5 → Fickian diffusion (drug liberation governed primarily by diffusion processes). 0.5 < n < 1.0 → Anomalous (non-Fickian) transport (interplay of diffusion and erosion). n = 1.0 → Case-II transport (release controlled by polymer relaxation/erosion).

2.11 Identification and assay of ciprofloxacin tablets

Following the guidelines of the USP, the identification procedure was performed through comparison of the retention time for the principal peaks in the sample solutions with that of the reference solution (British Pharmacopoeia, 2013).

Quantitative analysis of ciprofloxacin tablets was conducted by High-Performance Liquid Chromatography (HPLC) fitted with a Diode-Array ultraviolet detector. The chromatographic system employed a C18 chromatographic column made of stainless steel, measuring 25 cm in length and 4.6 mm in diameter, operated at a wavelength of 278 nm and maintained at 30 ± 1 °C. The mobile phase was introduced into the system at 1.5 mL per minute. System suitability was confirmed with the following criteria: column efficiency exhibiting a minimum efficiency of 2500 theoretical plates, a tailing factor of 2.0 or below for the retention peak of ciprofloxacin, and replicate injections having a relative standard deviation within 1.5%. For analytical purposes, 10 µL of the standard solution and the assay preparation were injected individually. The ciprofloxacin content (mg) was calculated by comparing the peak areas of the standard solutions and the samples (British Pharmacopeia, 2013). The amount of ciprofloxacin present in each tablet was determined by applying the equation below (Eq. 3):

$$\text{Ciprofloxacin content (mg)} = \left(\frac{331.34}{367.81}\right)\left(\frac{\text{CL}}{\text{D}}\right)\left(\frac{\text{ru}}{\text{rs}}\right) \quad (3)$$

In which 331.34 = ciprofloxacin base molecular weight, 367.81 = anhydrous ciprofloxacin hydrochloride molecular weight, C = concentration (mg/mL) of ciprofloxacin HCl working standard, L = ciprofloxacin labeled quantity (mg) per tablet, D = ciprofloxacin concentration (mg/mL) in the assay preparation, as per labeled content and dilution factor, r_u = peak area of ciprofloxacin derived from the assay sample, r_s = ciprofloxacin peak area determined from the standard preparation injection

The diluent solution was prepared by combining 0.025 M phosphoric acid (pH adjusted to 2.0 ± 0.1 with triethylamine) and acetonitrile in an 87:13 ratio, followed by filtration and degassing. Solution A: is 0.025M phosphoric acid prepared by dissolving 1.7 mL H_3PO_4 in distilled water to 1000 mL, adjusted to pH 2.0 ± 0.1 with triethylamine.

Solution B: is an acetonitrile mixture with Solution A (13:87).

Solution C: is 0.025M a phosphoric acid adjusted with triethylamine to pH 3.0 ± 0.1.

Mobile phase: Filtered and degassed mixture of Solution C and acetonitrile (87:13).

Ciprofloxacin working standard (0.5 g) was dissolved in diluent (Solution B) and diluted to 100 mL. An aliquot of 4 mL was taken and diluted to a volume of 100 mL to yield a solution containing 0.2 mg/mL ciprofloxacin. From each brand, five tablets were pulverized and introduced into a 500 mL volumetric flask. After adding 400 mL of diluent, the mixture was sonicated for 20 minutes to ensure

dissolution, then diluted to volume. A 4 mL aliquot was passed through a 0.45 µm filter membrane and diluted to 100 mL, producing a solution of 0.2 mg/mL ciprofloxacin. As per USP guidelines, ciprofloxacin tablets should contain between 90.0% and 110.0% of the stated label claim (British Pharmacopeia, 2013).

2.12 Quality assurance and data management

To maintain accuracy and dependability across all experimental processes, Standard Operating Procedures (SOPs) were established and strictly followed, with all analyses conducted using calibrated equipment. A nylon membrane filter was employed to purify water and assay solutions, thereby eliminating heavy metals and preventing column blockage during dissolution and chromatographic processes. Clean, dry glassware was consistently used to avoid contamination during sample preparation.

For traceability and safety, outcomes of the laboratory analysis were documented in a logbook, while chromatograms generated from HPLC analyses were printed and archived. In addition, electronic copies of the information were securely kept in multiple locations (In excess of three) to safeguard against data loss.

2.13 Data entry and statistical analysis

Microsoft Excel 2010 served as the tool for data recording and analysis. Each experiment was repeated three times, and the results are expressed as averages. The physicochemical properties of the different tablet brands were summarized using descriptive statistics. A standard calibration curve was constructed and graphically presented to support quantification.

To evaluate whether the dissolution profiles among the various brands were comparable or significantly different, statistical analysis was performed using ANOVA. The concentration of the active API in the dissolution medium was determined using the calibration curve derived from the sample measurements.

3. Results

There were seven brands of ciprofloxacin tablets collected from drug outlets, and their information was recorded in Table 2.

The friability values of the seven ciprofloxacin tablet brands were observed in the following order: C4(0.003)<C7(0.006)<C6(0.013)<C5(0.027)<C2(0.033)<C3(0.110)<C1(0.199)<C4(0.003)< C7 (0.006) < C6 (0.013) < C5 (0.027) < C2 (0.033) < C3 (0.110) < C1 (0.199).

As illustrated in Figure 1, Brand C1 (0.199) exhibited the highest friability, indicating a greater likelihood of particle loss during handling. In contrast, Brand C4 (0.003) showed the lowest friability, suggesting superior mechanical resistance and minimal risk of particle loss.

Table 2. Product sample collected for the ciprofloxacin tablet from drug retail outlets in Arba Minch city

Code	Brand name	country of origin	Batch No.	Date		Price (Birr/tablet)
				Manufacturing	Expiry	
C1	Cipro-Denk	Germany	24909	Oct-20	Oct-23	25.00
C2	Floxine	South Korea	THB001	Aug-20	Aug-23	7.00
C3	Ciprobid	India	T9333	Nov-19	Oct-22	2.25
C4	Ciproquin	India	K11421003	Jan-21	Dec-23	2.25
C5	Akcipro	India	ATB073	Mar-21	Feb-24	2.50
C6	Zindolin	Cyprus	90714	Oct-20	Oct-25	7.00
C7	Cipro-SSP	Ethiopia	00321040030	Aug-21	Mar-23	2.25

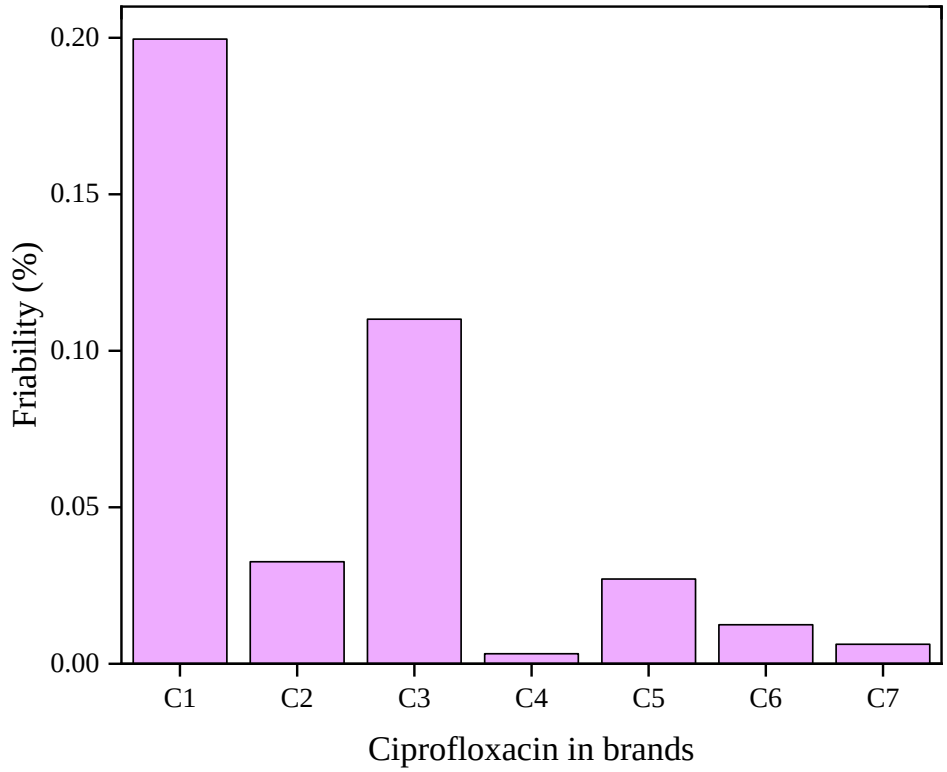

Figure 1. Percentage friability of ciprofloxacin tablets

The minimum and maximum percentage weight variation (Table 3) for each brand of ciprofloxacin tablet were -3.242 and 4.160 C1, -1.26 and 0.86 C2, -3 and 3.36 C3, -1.51 and 2 C4, -3.35 and 2.5 C5, -1.19 and 1.22 C6, -1.29 and 1.21 C7, respectively. The highest percentage weight deviation was found in brand C1 (4.160), and the smallest was obtained in brand C5 (-3.35).

Table 3. The measured weight of each ciprofloxacin tablet and the calculated percentage

Individual tablet weight (IW) (mg)							**% Deviation =(IW-M)/M ×100**						
C1	C2	C3	C4	C5	C6	C7	C1	C2	C3	C4	C5	C6	C7
734.3	734.7	712.4	624.1	699.3	808.0	798.4	0.28	-0.15	-2.53	-0.86	0.23	1.22	-0.02
733.8	736.5	723.8	631.3	699.0	792.4	804.4	0.21	0.09	-0.97	0.29	0.19	-0.74	0.73
732.4	726.6	732.4	631.2	687.5	799.3	790.9	0.02	-1.26	0.20	0.27	-1.46	0.13	-0.96
742.7	739.7	724.7	634.9	701.4	803.9	804.4	1.43	0.52	-0.85	0.86	0.53	0.71	0.73
724.2	729.8	737.8	631.2	694.9	801.4	789.0	-1.10	-0.82	0.94	0.27	-0.40	0.39	-1.20
729.5	733.9	751.5	620.0	701.1	795.7	805.4	-0.37	-0.26	2.81	-1.51	0.49	-0.32	0.86
740.9	733.8	712.7	625.0	715.1	794.8	804.5	1.18	-0.28	-2.49	-0.71	2.50	-0.43	0.74
719.6	740.3	738.5	630.0	693.6	799.6	788.3	-1.73	0.61	1.04	0.08	-0.59	0.17	-1.29
736.3	731.0	724.1	632.2	674.3	796.8	799.6	0.55	-0.66	-0.93	0.43	-3.35	-0.18	0.13
708.5	736.4	732.2	624.9	682.5	793.9	795.2	-3.24	0.08	0.17	-0.73	-2.18	-0.55	-0.42
729.3	733.2	716.1	638.8	701.8	802.8	801.4	-0.40	-0.36	-2.03	1.48	0.59	0.57	0.35
724.0	741.7	741.7	642.1	709.9	795.8	800.6	-1.13	0.80	1.47	2.00	1.75	-0.31	0.25
731.6	734.1	755.5	628.0	712.7	793.7	795.2	-0.09	-0.24	3.36	-0.24	2.15	-0.57	-0.42
732.4	730.6	722.4	633.3	703.9	798.3	790.7	0.02	-0.71	-1.17	0.60	0.89	0.00	-0.99
759.5	734.4	709.0	628.9	709.1	795.6	795.8	3.72	-0.20	-3.00	-0.10	1.64	-0.33	-0.35
714.9	740.5	741.2	627.6	689.2	804.4	803.4	-2.37	0.63	1.41	-0.30	-1.22	0.77	0.60
730.4	740.3	725.1	622.5	692.1	794.0	799	-0.25	0.61	-0.80	-1.11	-0.80	-0.53	0.05
762.7	742.2	743.8	625.5	693.1	805.6	808.2	4.16	0.86	1.76	-0.64	-0.66	0.92	1.21
730.7	741.2	735.4	633.8	697.4	788.8	799.8	-0.21	0.73	0.61	0.68	-0.04	-1.19	0.15
727.1	735.9	738.2	624.7	695.8	800.6	797.2	-0.70	0.01	1.00	-0.76	-0.27	0.29	-0.17
732.24 +12.7	**735.84 +4.4**	**730.93 +13.0**	**629.50 +5.5**	**697.69 +10.1**	**798.27 +5.0**	**798.6 +5.76**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**

SD=Standard deviation, M=Mean weight of 20 tablets, C1=Cipro-Denk, C2=Floxine, C3=Ciprobid, C4=Ciproquin, C5=Akcipro, C6=Zindolin, C7=Cipro-SSP, NA=Not applicable

The calibration curve of standard ciprofloxacin, which was constructed for the dissolution test, is given in Figure 2 ($y = 1.7429x + 0.6705$, $R^2 = 0.999$). The percentage of drug released after 30 minutes for each ciprofloxacin brand was as follows: C1 (97.37%), C2 (89.99%), C3 (82.95%), C4 (94.70%), C5 (88.15%), C6 (96.70%), and C7 (100.25%) as depicted in Table 4. The minimum acceptance limit for the ciprofloxacin dissolution test after 30 minutes is not less than 80 % released. All brands exceeded the limit, with C3 (82.95%) having the smallest percentage and C7 (100.25%) having the highest.

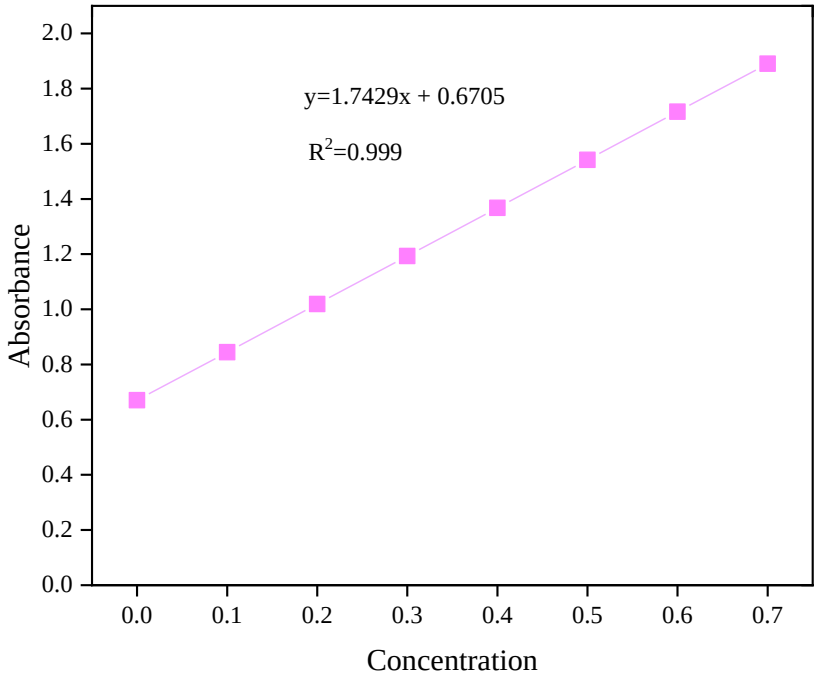

Figure 2. Ciprofloxacin 500 mg tablets dissolution test calibration curve

Table 4. Ciprofloxacin percentage dissolution at sampling time points

	Brands						
Sampling time (min)	C1	C2	C3	C4	C5	C6	C7
0	0	0	0	0	0	0	0
15	93.93	83.15	58.51	81.09	76.34	95.60	89.04
30	97.37	89.99	82.95	94.70	88.15	96.70	100.25
45	100.45	91.18	91.24	98.44	97.39	101.57	101.69
60	102.71	95.20	94.45	100.83	98.25	102.48	101.86

C1=Cipro-Denk, C2=Floxine, C3=Ciprobid, C4=Ciproquin, C5=Akcipro, C6=Zindolin, C7=Cipro-SSP

The seven brands of ciprofloxacin had a similar graph of the dissolution profile as revealed in Figure 3. At each dissolution time-point, the amount of API was similar.

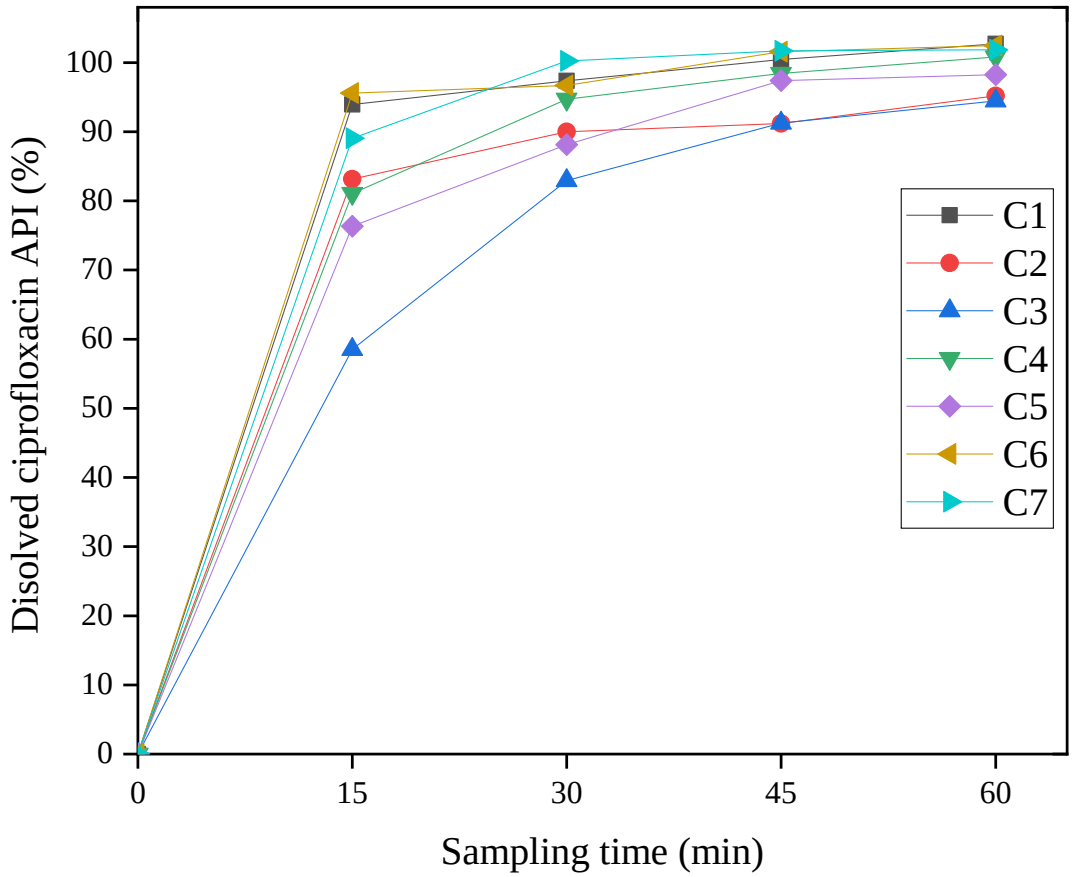

Figure 3. Drug release profiles of ciprofloxacin tablets across different manufacturers

The dissolution profiles of the seven ciprofloxacin tablet brands (C1–C7) were studied with multiple kinetic models, including zero-order, first-order, Higuchi, Hixson–Crowell, and Korsmeyer–Peppas, as outlined in Table 5. Among these, the Korsmeyer–Peppas model consistently produced the highest regression coefficient (R^2) values across all seven brands.

Table 5. Assessment of dissolution of brands of ciprofloxacin pills by the model-dependent method

Model name	R^2-value of different brands						
	C1	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**
Kor's-Peppas	0.9403	0.954	0.9934	0.9819	0.9873	0.945	0.9631
Zero-order	0.5741	0.6022	0.7995	0.6745	0.6963	0.5898	0.6199
Huguchi	0.832	0.8535	0.9683	0.9044	0.9178	0.8421	0.8677
Fist-order	0.9122	0.8433	0.984	0.9801	0.9723	0.924	0.9488
Hixson	0.8652	0.7486	0.9384	0.9454	0.9083	0.892	0.9137

C1=Cipro-Denk, C2=Floxine, C3=Ciprobid, C4=Ciproquin, C5=Akcipro, C6=Zindolin, C7=Cipro-SSP

The dissolution data for the seven ciprofloxacin tablet brands were subjected to statistical analysis using single-factor analysis of variance. As presented in Table 6, the evaluation revealed no statistically significant variation among the brands (P = 0.097117).

Table 6. Single-factor ANOVA of ciprofloxacin tablets dissolution assessment of seven brands

Source of variation	SS	Df	MS	F	P-value	F-c
Between groups	962.3954	6	160.3992	2.095836	0.097117	2.572712
Within Groups	1607.1790	21	76.5324			
Total	2569.5750	27				

Df=Degrees of freedom, F-c=F-critical, MS=Mean square, SS=Sum of squares

As presented in Table 7, the system suitability parameters for ciprofloxacin met the acceptance criteria. The percentage standard deviation (%RSD) calculated from six repeated injections of the ciprofloxacin reference was 0.55%, which is well below the maximum limit of 1.5%. The mean tailing factor obtained from six injections was 0.94, satisfying the requirement of not more than 2.0. Additionally, the mean theoretical plate count was 3476.92, exceeding the minimum threshold of 2500.

Table 7. Summary of system suitability assessment outcomes for the ciprofloxacin tablets test

Injections	Peak area (mAU*s)	Tailing factor	Theoretical plates
1	6657.50	0.95	3464.20
2	6710.81	0.96	3458.52
3	6747.57	0.92	3430.60
4	6761.69	0.96	3504.00
5	6731.83	0.94	3540.00
6	6706.99	0.92	3464.20
Mean	**6719.40**	**0.94**	**3476.92**
%RSD	**0.55%**	**1.95%**	**1.12%**

%RSD=Percentage relative standard deviation

In this study, ciprofloxacin tablets exhibited retention times between 6.114 minutes (C1) and 6.253 minutes (C5), while the retention time of the ciprofloxacin reference was 6.16 minutes, as presented in Table 8.

Table 8. Retention time data for the ciprofloxacin tablet peaks

Samples	Peak retention time (min)	Identity test
CRS	6.162	Pass
C1	6.1145	Pass
C2	6.238	Pass
C3	6.2425	Pass
C4	6.2365	Pass
C5	6.253	Pass
C6	6.211	Pass
C7	6.24	Pass

CRS=Ciprofloxacin reference standard, C1=Cipro-Denk, C2=Floxine, C3=Ciprobid, C4=Ciproquin, C5=Akcipro, C6=Zindolin, C7=Cipro-SSP

According to the updated SANTE/SANCO guideline (European Commission, 2021), all ciprofloxacin samples successfully met the identification criteria, as the difference between the retention times of the sample and the reference didn't exceed 0.1 minutes.

As shown in Table 9, the assay results for ciprofloxacin tablets demonstrated that the active API content across the seven brands ranged from 91.4% (C3) to 109.6% (C1). According to the USP specification, ciprofloxacin pills must contain between 90.0% and 110.0% of the labeled quantity.

Table 9. The assay test result of ciprofloxacin pills

Injection	C1		C2		C3		C4		C5		C6		C7	
	Mg	%	Mg	%	Mg	%	Mg	%	Mg	%	Mg	%	Mg	%
I1	549.0	109.8	461.1	92.2	456.7	91.3	511.6	102.3	471.2	94.2	511.4	102.3	544.9	109.0
I2	546.6	109.3	463.3	92.7	457.4	91.5	511.0	102.2	471.0	94.2	511.9	102.4	543.4	108.7
M±SD	547.8	109.6+	462.2	92.4	457.1	91.4	511.3	102.3	471.1	94.2	511.7	102.3	544.1	108.8
	+1.6	0.3	+1.5	+0.3	+0.5	+0.1	+0.4	+0.1	+0.2	+0.0	+0.3	+0.1	+1.1	+0.2

I1=Initial injection, I2=Subsequent injection, M±SD=Mean quantity ± Standard deviation of API, Mg=quantity of API in milligram, %=Percentage of API, C1=Cipro-Denk, C2=Floxine, C3=Ciprobid, C4=Ciproquin, C5=Akcipro, C6=Zindolin, C7=Cipro-SSP

4. Discussion

Drug quality must remain uncompromised, as it directly impacts the overall health and wellness of consumers. In developing nations such as Ethiopia, the circulation of substandard medicines poses a serious risk to already fragile primary health-care systems (WHO, 2018). Rigorous quality check of medicinal products is therefore essential to ensure that only safe and effective medicines reach patients. Pharmacopoeias play a central role in this process by establishing internationally recognized quality standards for pharmaceutical products. These standards apply uniformly to medicines manufactured with the same active API, thereby safeguarding consistency, efficacy, and patient safety across different brands and regions (British Pharmacopeia, 2013; Hirschfelder, 1930).

As per USP guidelines, the friability of compressed tablets is required to remain under 1%. Tablets with friability values above this threshold are more susceptible to mechanical erosion during handling, packaging, and transportation. Such erosion can lead to the loss of tablet fragments and, consequently, a reduction in the amount of active API delivered to the patient. This deterioration ultimately compromises the medication's effectiveness and therapeutic reliability (Seitz & Flessland, 1965). The alteration in tablet appearance also has a detrimental impact on the customer's liking for that particular brand, which is highly friable. Since less than 1% of the ciprofloxacin tablets in this study are friable, all brands meet the criteria. This outcome is

consistent with research on ciprofloxacin pills from the pharmaceutical markets in Bangladesh and Nigeria (Arefin et al., 2021; Joda et al., 2018).

The tablet weight reflects the quantity of particles required to deliver the medicinal ingredient in the amount specified on the label. Any significant variation in tablet weight compromises uniformity of content, making it difficult to guarantee that a separate unit comprises the precise dose of the active API (Abebe et al., 2020). Tablets may be underweight or overweight for several reasons (Uddin et al., 2017). Excessive tablet weight can lead to toxicity, while insufficient weight results in under-dosing and reduced therapeutic effectiveness Morshed & Sharmin, 2015). According to pharmacopeial standards, a batch of tablets passes the test if only two or fewer tablets show a deviation greater than 5% from the calculated mean weight. All seven ciprofloxacin products tested fall within the acceptable pharmacopeial limits, confirming uniformity of weight and compliance with USP requirements. A study conducted to assess the ciprofloxacin quality collected from pharmacies and drug stores in Addis Ababa depicted that one brand had failed the weight uniformity test, as three tablets out of twenty significantly varied from the mean weight (Kahsay et al., 2007). Another study conducted in northern Ethiopia had a similar result to this study, in which all tested brands fulfilled USP standards for the weight uniformity test (Desta, 2020).

In tablet formulations, the active API is absorbed through the gastrointestinal tract. Prior to absorption, the drug must first dissolve into solution. The proportion of the API that becomes available in systemic circulation is directly influenced by both the rate and level of dissolution. Consequently, dissolution is a critical determinant of bioavailability and serves as a key factor in guaranteeing the therapeutic efficacy of a medicine (Cohen, 2008). The BP dissolution requirement for ciprofloxacin states that not less than 80% of the API dissolves within 30 minutes of dissolution time. All ciprofloxacin tablet brands examined in this study met the established acceptance criteria. Analysis confirmed statistical equivalence of the dissolution profiles for the seven brands ($p > 0.05$), reflecting similar in-vitro outcomes. When the dissolution data were analyzed using a model-dependent approach, the Korsmeyer–Peppas model consistently produced the highest determination coefficient (R^2) across all brands. This finding suggests that the release kinetics of ciprofloxacin tablets are best explained by the Korsmeyer–Peppas equation, a model originally developed to define drug release out of a polymeric matrix. Its applicability here highlights the role of diffusion and matrix-related mechanisms in governing ciprofloxacin release (Marcos, 2015). A related investigation conducted on six marketed formulations of ciprofloxacin tablets

obtained from the Tigray region of Ethiopia reported that one brand did not meet the pharmacopeial dissolution acceptance criteria, releasing only 77.60 ± 2.84% of the labeled amount (Kahsay & Egziabher, 2010). Another investigation conducted on four brands of ciprofloxacin tablets from Ibadan, Nigeria, revealed that the formulations did not meet pharmacopeial dissolution requirements. Specifically, all four brands failed to release more than 70% of the API within 45 minutes (Adegbolagun et al., 2007). For ciprofloxacin brands evaluated in Nigeria, the best linearity for the dissolution data plot was obtained in the first-order model and the Korsmeyer-Peppas model (Olayemi, 2023).

Ciprofloxacin tablets were identified by comparing the retention time of each brand with that of the reference. It ranged from 6.11 minutes (C1) to 6.25 minutes (C5), while the reference standard exhibited a retention time of 6.16 minutes. All brands successfully passed the identification test, as their peak retention times did not deviate by more than 0.1 minutes from the standard. This approves the authenticity of ciprofloxacin as the API in all analyzed preparations (European Comission, 2021).

As outlined in the USP, the HPLC system qualifies for the ciprofloxacin assay provided certain requirements are fulfilled. These include a theoretical plate exceeding 2500, with a tailing factor ≤ 2.0 and a relative standard deviation (RSD) ≤ 1.5%, which is computed based on the peak area recorded through multiple injections of the reference standard (Hirschfelder, 1930). In this study, the system suitability test satisfied all of these USP requirements, thereby confirming that the HPLC method employed was reliable, precise, and appropriate for the quantitative assay of ciprofloxacin tablets.

The assay test is a vital component of pharmaceutical quality control, as it determines whether the amount of active API in a formulation is close to the specified quantity. Any deviation from the acceptable range indicates poor product quality. A lower assay value suggests insufficient API content, which can cause underdosing and reduce therapeutic effectiveness, while a higher value implies excess API, increasing the risk of overdosing, adverse reactions, and potential toxicity. In this study, the assay results confirmed that the concentration of the drug substance in all ciprofloxacin tablet samples complied with USP-defined acceptable limits of 90%–110%, thereby ensuring compliance with pharmacopeial standards and supporting both safety and efficacy (Hirschfelder, 1930). A study that was conducted in Nigeria has revealed that three brands of ciprofloxacin tablets failed the BP assay specifications test out of ten study brands collected from the Uyo metropolis (Igboasoiyi et al., 2018). Another similar investigation, which was done

in Bangladesh on ten brands of ciprofloxacin tablets, had revealed that all brands fulfilled the assay test criterion (Uddin et al., 2017).

5. Conclusion

Based on both pharmacopeial and non-pharmacopeial evaluation criteria, the seven ciprofloxacin tablet brands assessed in this study through in-vitro quality tests demonstrated acceptable quality standards. These findings indicate that the formulations are consistent with established requirements for safety and efficacy.

Consent for Publication

All authors affirm their readiness to submit copies of the signed consent forms to the journal's editorial office upon request.

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Authors' Contributions

TEW conceived the study and determined the research design. KK contributed to the evaluation of the study results, while YN was responsible for interpreting the results. The final manuscript was read and approved by all authors.

Conflict of Interest

The authors declare the absence of any competing interests related to this work.

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