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Preliminary Quality Evaluation of New Generic Brands of Ciprofloxacin Tablets

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ABSTRACT

Routine quality assessment is essential to ensure safety, efficacy, and compliance with pharmacopeial standards. This study evaluated six newly marketed generic brands of ciprofloxacin 500 mg tablets using in-vitro quality control tests. In-vitro quality control tests including weight uniformity, thickness, hardness, friability, and disintegration were performed in accordance with the British Pharmacopoeia standards. The ciprofloxacin content was determined using ultraviolet (UV) spectrophotometry (USP Monograph). All brands exhibited uniform white color, consistent shape, and intact markings with no evidence of breakage. Weight uniformity testing confirmed compliance with United States Pharmacopeia (USP) limits, although mean weight differences across brands were statistically significant ($p = 0.0001$). Tablet thickness showed minimal deviation (SD = 0.03–0.26) but significant inter-brand variation ($p = 0.001$). Hardness values fell within the 40–100 N range for all except Brand D; ANOVA revealed significant differences between brands ($p = 0.001$). Friability was below the USP threshold of 1% for all brands, with Brands E and F recording 0.00%. All brands completely disintegrated within 30 minutes, indicating acceptable in-vitro performance. Drug content assay showed that Brands B (103.6%), D (102.1%), E (99.9%), and F (101%) complied with USP specifications (90–110%), while Brands A (77.4%) and C (89.3%) failed.

In conclusion, most evaluated generics demonstrated satisfactory pharmaceutical quality; however, the failure of two brands in drug content assay underscores the need for routine post-market surveillance to safeguard therapeutic equivalence of ciprofloxacin tablets.

Keywords: Ciprofloxacin, generics,, quality assessment, tablets

1.0 INTRODUCTION

The menace of counterfeit and fake medicines with its negative impact on the health of the people remains a public health concern particularly in low- and middle-income countries (LMICs), including Nigeria (WHO, 2021). According to 2024 WHO report, approximately one out of every 10 medicines marketed in LMICs are either substandard or falsified, with highest cases recorded in the Sub-Saharan African regions (WHO, 2024). Though offering improved accessibility to cost effective medications by patients, the rising influx of generic brands of drugs into the drug market largely contribute for the circulation of counterfeit drugs in LMICs (Haider, 2019; Salami *et al*., 2023)

Literature reports established the presence of substandard drugs in the Nigerian drug market (Kasim *et al*., 2018; Abdullahi *et al*., 2021; Gabel *et al*., 2024; Kasim *et al*., 2025). The circulation of substandard or counterfeit drugs has consequences including poor drug therapy outcomes such as therapeutic failure, prolonged illness, adverse reactions as well as emergency of antimicrobial resistance, a growing public health concern that undermine future treatment options (Lima & Yonamine, 2023). In addition, circulation of substandard medicines can potentially erode trust in generic medicines, increase disease burden in patients, extend hospital visits and hospitalization and impact access to cost-effective medicines (Cavany *et al*., 2023; Raj *et al*., 2025).

Ciprofloxacin is one of the most common antibiotics used in the treatment of bacterial infection. The drug exhibits its antimicrobial action by interfering with microbial DNA synthesis (Collins *et al* 2024). It is specifically reserved for the management of antibiotic-resistant infections owing to its high potency, broad spectrum of activity and safety profile (Aiesh *et al*., 2024; Rubiñan *et al*., 2024). The drug is a fluoroquinolone with a cyclopropyl, and carboxylic acid group on positions 1 and 3 respectively. The IUPAC nomenclature of the drug is1-cyclopropyl-6-fluoro-4-oxo-7-piperazin-1-ylquinoline-3-carboxylic acid (Fig 1), with molecular mass of 331.346 g/mol. Several generics brands of ciprofloxacin are marketed and sold in Nigeria and newer ones are

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emerging. Although quality evaluation of existing brands is well represented in the literature, there is a lesser focus on newly introduced generic brands. The present study aims to evaluate the quality of six new generic brands of ciprofloxacin tablets obtained from retail pharmacy outlets in Ilorin, North Central, Nigeria using in-vitro methods.

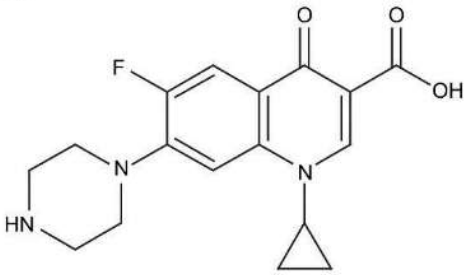

Figure 1:- Chemical structure of ciprofloxacin

2.0 MATERIAL AND METHODS

2.1 Instrumentation

A double beam spectrophotometer (Serial No: UQC1212006 by General Scientific Hong Kong Limited) was used for the quantitative determination of ciprofloxacin. The spectrophotometer was equipped with a 1 cm matched quartz cells for sample and reference solutions. It has a spectral bandwidth of 0.1 nm and a wavelength accuracy of ±0.5 nm. A calibrated analytical balance (Balance PA214) by Ohaus, USA was used for weighing, Hardness tester, thickness tester ((S.No.TDH-311, Pharma test, German)), friability test Apparatus (Serial No: ED001 Model: VFT-I, Erweka)

2.2 Chemicals and Reagents

Pure ciprofloxacin analytical reference standard was obtained from Toronto Research Chemicals Inc, Toronto, Canada. Double-distilled water, prepared in the laboratory using the Water Pure-Hit Still (BASIC/PH4 model), was used throughout the experiments.

2.3 Sample Collection

Seven new brands of ciprofloxacin 500mg tablets were purchased from various community pharmacy outlets using a convenience sampling technique and coded brand A-G to conceal the brand names. The samples were inspected visually for their physical features, packaging and labelling for evidence of counterfeiting in compliance with WHO guideline (WHO, 2015). All the samples were registered with NAFDAC and well within expiration date.

2.4 Weight Uniformity Test

Twenty tablets from each brand were randomly selected. Using an analytical balance, each tablet was weighed individually and average weight obtained and expressed as mean ± S.D. The percentage weight variations of the tablets were calculated. A brand is considered to have passed the weight uniformity test if not more than two tablets deviate from the average weight by more than 5%. and if none of the tablets differ by more than 10%.

2.5 Thickness and Diameter

Ten tablets randomly selected were used to assess the tablet thickness and diameter. The test was performed by placing each tablet in between the teeth of Vernier calliper and was gently screwed together until the tablet was held firmly ensuring not to screw to hard to avoid breakage. The result was computed in mean±SD and compared with standard specification (Ghimire *et al*., 2020).

2.6 Tablet Hardness

Ten tablets were randomly selected and each placed in between the anvils of the hardness tester instrument. One anvil was then moved towards the other (in a screwing manner) until the tablet broke. The force required to break each tablet was recorded (Rahman *et al*., 2014).

2.7 Friability Test

Six tablets were randomly selected from each brand, weighed, carefully dusted, and placed in the drum of a friabilator. The friabilator was operated at 25rpm for 4 minutes after which the tablets were dusted and re-weighed. The percentage loss in weight was computed using the equation below and compared with USP standard limits of percentage loss not exceeding 1% (USP, 2017).

$$\%\ Weight\ Loss = \frac{Initial\ Weight - Final\ Weight}{Initial\ Weight} \times 100$$

2.8 Disintegration Test

Ten randomly selected tablets per brand were used for this test. One tablet was placed in each of the six tubes (containing 800ml of double distilled water maintained at 37±2˚C. The time required for each of the 10 tablets to completely disintegrate was recorded .

2.9 Quantitative Determination of Ciprofloxacin

2.9.1 Determination of Ciprofloxacin Maximum Wavelength

A dilute concentration of pure solution of ciprofloxacin (10µg/ml) was manually scanned over an absorption wavelength between 190-400 nm. The wavelength that gave the highest UV absorption was chosen as the maximum wavelength of absorption of the drug.

2.9.2 Preparation of Standard, Working and Calibration Solutions

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A 1000µg/ml of reference ciprofloxacin solution was prepared by dissolving 100 mg of pure ciprofloxacin with double distilled water in a 40 mL volumetric flask and made up to volume with the same solvent. The solution was left to stand for 15 minutes, sonicated, and a working standard solution of 100 µg/ml was prepared by pipetting 10 mL of the reference solution into a 100 mL volumetric flask and made up to with the solvent. From the 100 µg/ml solution, five calibration solutions (10, 20, 30, 40 and 50µg/ml) were prepared by transferring suitable sample volumes/aliquots (5, 10, 15, 20, and 25 mL) into a 50 mL volumetric flask and made up to volume with distilled water. The absorbances of the solutions were measured on a UV spectrophotometer at a wavelength of 276 nm. A calibration curve of absorbance against concentration was plotted(Joda et al., 2018).

2.9.3 Preparation of Sample Solutions

Twenty tablets from each brand were randomly selected for the preparation of the sample solution. Then, the samples were weighed and then ground into a fine powder An accurately weighed portion of a powder, equivalent to 100 mg of ciprofloxacin was transferred to a 100 ml volumetric flask, 50 mL of distilled water was added, shaken and made up to make with double distilled water to prepare 1000µg/ml sample solution. The solution was left to stand for 15 minutes, sonicated, and a sample solution of 100 µg/ml was prepared by pipetting 10 mL of the reference solution into a 100 mL volumetric flask and made up to with the solvent. From the 100 µg/ml sample solution, a 20µg/ml of the sample solution was thereafter prepared by diluting 25 ml of the solution to 100 ml with distilled water. This procedure was performed for all the different brands of ciprofloxacin studied. The absorbances of the solutions were measured on a UV spectrophotometer at a wavelength of 276 nm and ciprofloxacin concentration was determined from standard calibration curve. The assay was carried out in triplicate and result presented as mean±SD (Joda et al., 2018).

2.10 Statistical Analysis

Data obtained from the experiments were processed in Microsoft Excel 2016. All results were presented in mean±SD. The result of weight and content uniformity, hardness, disintegration and thickness tests were analyzed by one way analysis of variance (ANOVA) on GraphPad prism 5. Statistically significant differences were considered when $P<0.05$.

3.0 RESULTS

A total of six in-vitro quality assessment tests including physical appearance, uniformity of weight, thickness, hardness, friability , disintegration and assay of drug contents, were performed on six different new generic brands of 500 mg ciprofloxacin tablets. Our results showed that all the tablets across the six brands had consistent shape, colour (white) and markings without any visible evidence of breakage or cracking. This indicates that the brands assessed in this study passed the physical appearance test (Table 1).

Table 1- Weight uniformity tests

Brands	Mean±SD	Number of tablets deviated by > 5%	Number of tablets deviated by > 10%	% deviation (Lower, Upper)	Comment
A	0.81±0.02	1	0	-2.98, 5.30	Pass
B	0.69±0.01	1	0	-2.28, 6.25	Pass
C	0.79±0.02	1	0	-8.12, 2.20	Pass
D	0.64±0.01	0	0	-2.78, 2.44	Pass
E	0.78±0.01	0	0	-1.45, 1.98	Pass
F	0.75±0.01	0	0	-3.35, 4.43	Pass

The average weight of twenty tablets of ciprofloxacin exceeds 324 mg for all the six brands. According to the USP specification, not more than 2 out of 20 tablets should deviate by more than 5% and none should deviate by more than 20% for a drug with an average strength greater than 324 mg. In this study, all the six brands passed the uniformity of weight test. ANOVA results at 95% confidence interval indicate a statistically significant difference ($P=0.0001$) in the mean weight of all brands of ciprofloxacin evaluated in this study. The result of the thickness test revealed that the individual tablet thickness for all the brands evaluated deviates minimally from the mean thickness, with standard deviation from the mean ranging between 0.03 – 0.26 (Table 2).

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Table 2: Thickness, Hardness and Friability test of Ciprofloxacin Tablets

Brand	Thickness (mm)		Hardness (N)		Friability Test			
		Comment		Comment	Before Friabilation	After Friabilation	% Friability	Comment
A	4.55±0.12	Pass	73.00±13.4	Pass	5.6415	5.5950	0.82	Pass
B	2.29±0.05	Pass	88.8±26.9	Pass	6.9060	6.8860	0.15	Pass
C	5.28±0.14	Pass	72.0±18.0	Pass	6.3180	6.2720	0.56	Pass
D	2.08±0.07	Pass	162±3.2	Fail	6.3525	6.3520	0.01	Pass
E	2.27±0.03	Pass	85.80±10.7	Pass	7.7970	7.7970	0.00	Pass
F	2.66±0.26	Pass	71.80±22.5	Pass	7.9260	7.9260	0.00	Pass

This finding indicates that all the brands have uniform tablet size and shape. However, statistical analysis of the tablet thickness revealed a significant difference ($p = 0.001$) between the mean thickness across all brands of ciprofloxacin evaluated. Most pharmaceutical conventional oral tablets require a hardness range of 40-100N to ensure tablets are hard enough for handling, packaging and shipping. With the exception of brand D, the mean hardness of the ciprofloxacin brands studied were within the standard range and thus, passed the hardness test. In contrary, the one-way ANOVA (95%) statistical analysis showed that between brand tablet hardness was significant ($p=0.001$).The United States Pharmacopoeia (2007) states that, the friability value of tablets should be less than 1%. From the result of friability presented in Table 2, all the brands assessed complied with USP friability specification, with percentage friability ranging from 0.00-0.82. Our results indicates that all the six brands of ciprofloxacin evaluated in this study completely disintegrated within USP specified 30 minutes for oral tablets (Table 3), and are likely to all have good absorption profile.

Table 3: Disintegration test results

Brands	Disintegration time(min) n=6	Comment
A	7.30±0.19	Pass
B	12.3±0.09	Pass
C	8.15±0.22	Pass
D	9.15±0.04	Pass
E	13.0±0.31	Pass
F	12.5±0.11	Pass

Standard curve of pure ciprofloxacin solution generated by plotting absorbance (measured at ciprofloxacin λ_{max} of 276nm against concentration. Linearity was observed over a concentration range of 10 – 50 μg/mL, correlation coefficient value of 0.995 (Fig 2)

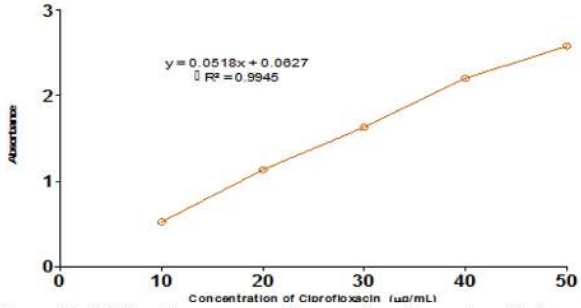

Figure 2: Calibration curve of pure ciprofloxacin solution

The regression equation generated from the standard curve, $y = 0.0518x + 0.0627$, was used to calculate ciprofloxacin concentrations. The percentage contents of brands B (103.58%), D (102.08%), E (99.88%) and F (100.95%) fell within the range of 92-104% specified by the USP and are of good quality concerning identity and active ciprofloxacin content of the formulations. Brand A (77.41%) and brand C (89.32%) do not met the USP specification concerning the active ciprofloxacin in the formulation (Table 4)

Table 4 Assay of Ciprofloxacin Tablets

Brands	% Content (Mean±SD)	Comment
A	77.41±0.16	Fail
B	103.58±0.39	Pass
C	89.32±0.89	Fail
D	102.08± 0.11	Pass
E	99.88± 0.78	Pass
F	100.95±1.24	Pass

4.0 DISCUSSION

The primary aim of the present study was to assess the quality of six new generic brands of ciprofloxacin 500 mg tablets using compendial tests including uniformity of weight, thickness, hardness, friability, disintegration, and assay by UV spectrophotometry. These in-vitro tests are essential in establishing drug quality and provide valuable

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insight on quality assessment of bioavailability, safety, and patient acceptability before in-vivo studies.

Three of the six generic brands (B, E and F) passed all the in-vitro tests and satisfied standard compendial requirements, thus indicating compliance with WHO good manufacturing practice (WHO, 2021) by the manufacturers of these formulations. The availability of high-quality generic brands of ciprofloxacin provides cost effective options to interchange the more expensive innovator brand thus improving patient access to the drug, particularly in a low- and middle-income countries like Nigeria.

One of the samples (Brand D) failed the hardness test despite meeting USP standard specification for drug disintegration and content uniformity. Although tablet hardness is not a direct pharmacopeial criteria for drug release, it serves as an important indicator of how well a tablet withstand abrasion, during handling, packaging and transportation. Poor hardness could compromise delivery as well as affect time and extent of dissolution, even when disintegration remains within limits (Anizor *et al*., 2023). Thus, Brand D cannot be considered pharmaceutically acceptable despite passing other tests.

Brands A and C failed the assay test, with ciprofloxacin contents falling below the United States Pharmacopeia (USP) lower limit of 90% (USP, 2017). Sub-Optimal drug level may have clinical consequences including poor drug therapy outcomes. It can also contribute to antimicrobial resistance (AMR), which is a growing global public health crisis (WHO, 2021; Osei-Tutu *et al*., 2023). Our findings align with previous reports of circulation of poor-quality ciprofloxacin tablets in Nigeria (Joda *et al*., 2018; Muhammad *et al*., 2020; John et al., 2023), raising concerns about regulatory oversight and supply chain integrity. The observed content uniformity failure of brands A and C may be due to non-compliance to good manufacturing practices and poor-quality control measures put in place by the manufacturers.
Our findings demonstrate significant variability in the quality of ciprofloxacin generics commercially marketed in Nigeria. While half of the brands studied demonstrated satisfactory compliance, the failures observed in hardness and assay testing call attention to the urgent need for routine post-market quality surveillance and stricter regulatory enforcement. Continuous monitoring remains critical, given the central role of ciprofloxacin as a broad-spectrum antibiotic in both hospital and community practice.

Though UV spectrophotometry remains a reliable and cost-effective technique for drug assay, its accuracy may be slightly affected by excipients and degradation products (Talath & Hani, 2024). Though less specific compared to HPLC method, UV spectrophotometry remains a reliable method for drug analysis, particularly in resource limited settings. Also, this was a preliminary in-vitro assessment and did not include dissolution profiling or bioequivalence studies, which are more directly predictive of in-vivo performance.

5.0 CONCLUSION

This study demonstrates the presence of poor-quality ciprofloxacin tablets in the Nigerian drug market. There is need for regulatory agencies to continually strengthen regulation and quality control activities to reduce the prevalence of substandard and falsified products in the country.

Authors' contributions

EOI conceptualized and supervised the research, FFM conducted the research. STA, BOD, AMO and GHB contributed to the supervision of the research. All authors approved the final version of the manuscript for submission

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