

Quality Attributes and Antimicrobial Activity of Brands of Ciprofloxacin Hydrochloride Caplets from Kaduna Metropolis, Nigeria

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ABSTRACT

Quality assurance and evaluation of medicines are paramount for monitoring the distribution of substandard and fake medicines in the drug supply chains and ensuring the desired therapeutic efficacy and safety to the patients. This study was undertaken to evaluate some quality parameters of seven brands of ciprofloxacin hydrochloride (HCl) 500 mg caplets marketed in Kaduna metropolis. Identity, weight variation, disintegration, friability, thickness, diameter, and antimicrobial study were the conducted tests to assess the quality attributes and antimicrobial activity of the brands. The tests were performed according to official specifications. Ciprofloxacin HCl caplet samples were randomly purchased from pharmacy outlets and patent medicine stores. All the brands of ciprofloxacin HCl caplets complied with the official specifications for weight variation, disintegration, friability, thickness, and diameter tests. All the brands had shown disintegration time within 1 to 11 min, and friability value below 0.7%. For the antimicrobial study, the inhibition zone diameter (mm) produced by 5µg/mL concentration of each sample showed that all the samples satisfied the standard specifications. All seven brands of ciprofloxacin HCl caplets being marketed in Kaduna metropolis have demonstrated satisfactory physical quality attributes and antimicrobial activity, hence, the brands can be used interchangeably. The statistical analysis indicated significant differences in the assessed parameters between the brands ($p > 0.05$).

KEYWORDS: Quality control assessment, Ciprofloxacin caplets, Kaduna, Substandard drugs, Antimicrobial

INTRODUCTION

Quality control evaluation of drug products is considered an essential integral part of the processes of the modern pharmaceutical industry (Elhamili *et al.*, 2014). It is crucial to monitor the performance of drug products to ensure that they are fit for their intended use, their safety and efficacy, and their compliance with the requirements of the compendiums (Reis *et al.*, 2015). The current globalisation trend has necessitated tough regulation for the entry as well as quality assurance of pharmaceutical products into the nations' markets (Desta and Teklehaimanot, 2020; Okonkwo *et al.*, 2006). Therefore, it is paramount to ensure the quality of every drug product. This will enable the detection of substandard, adulterated, or fake drug products that may be flooding the market, especially in third-world countries such as Nigeria (Aminu *et al.*, 2017; Aminu and Gwarzo, 2017).

A drug product is said to be substandard or fake if its contents contradict what was purported on its label (Aminu *et al.*, 2020). The proliferation and circulation of substandard and fake medicines is one of the major reasons behind many health hazard incidences in developing countries (Aminu *et al.*, 2020, 2017; Aminu and Gwarzo, 2017). This is the case because the focus of health advocates in many of these nations is to get drug products into their supply chain at cheap prices while mostly ignoring the quality (Kahsay *et al.*, 2007). In addition to the health hazards, substandard and fake medicines can cause enormous economic burdens to patients, pharmaceutical firms, and governments (Aminu and Gwarzo, 2017). For these reasons, the practice of manufacture, distribution, and sale of drug products have to be properly controlled.

Ciprofloxacin (Figure 1) is a synthetic fluoroquinolone derivative antibiotic with a broad-spectrum antibacterial activity. It is used to treat various bacterial infections of Gram-negative and Gram-positive origin (Kahsay *et al.*, 2007; Mumuni *et al.*, 2020). There are several brands of ciprofloxacin hydrochloride (HCl) in the form of tablets or caplets being marketed worldwide, Nigeria inclusive.

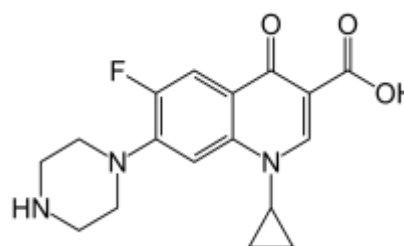


Figure 1: Chemical structure of ciprofloxacin

There is a need to continue to assess the quality of different brands of ciprofloxacin HCl caplets available in the country due to the increasing level of its usage as a result of its therapeutic versatility (Adegbolagun *et al.*, 2007). Assessment of the quality of the caplets may involve physicochemical and antimicrobial analyses. For evaluating the safety and effectiveness of antimicrobial products, it is recommended to conduct antimicrobial susceptibility (sensitivity) tests (Nazir Mughal *et al.*, 2009). Antimicrobial susceptibility tests demonstrate the ability of antimicrobial agents to inhibit bacterial growth *in vitro* under specified conditions. Various researchers have employed these methods for the evaluation of ciprofloxacin tablets/caplets. For example, pharmaceutical evaluation of marketed ciprofloxacin tablets/caplets were investigated in many countries like

Ethiopia (Desta and Teklehaimanot, 2020; Kahsay *et al.*, 2007), Pakistani (Agha *et al.*, 2017), United Arab Emirates (Fahmy and Abu-Gharbieh, 2014), Yemen (Alyahawi and Alsaifi, 2018), Bangladesh (Rahman *et al.*, 2019), and Sudan (Masaad *et al.*, 2016), and also locally in Nigeria in Ibadan, Oyo state (Adegbolagun *et al.*, 2007), Uyo, Akwa Ibom state (Akpabio *et al.*, 2011; Igboasoiji *et al.*, 2018), Awka, Anambra state (Osonwa and Abali, 2016), Onitsha, Anambra state (Okonkwo *et al.*, 2006), Kano, Kano state (Shaibu and Audu, 2018), Owerri, Imo state (Ejele *et al.*, 2015), Jos, Plateau state (Ngwuluka *et al.*, 2009), and Lagos (Joda *et al.*, 2018). However, there are no reported studies for quality evaluations of brands of ciprofloxacin HCl caplets being marketed in Kaduna state, Nigeria, despite the widespread of the drug products in the state. It is important to assess the quality of brands of ciprofloxacin HCl caplets being marketed in Kaduna state as the drug comes from a variety of origins.

This study is, therefore, undertaken to evaluate the physical parameters and antimicrobial activities of seven brands of ciprofloxacin HCl 500 mg caplets being marketed in different retail outlets in Kaduna state, Nigeria, to ascertain whether the brands are of acceptable quality. Assuring the quality of the brands of ciprofloxacin available in the Kaduna metropolis may give confidence to the local healthcare practitioners to use these brands interchangeably and may increase the awareness of the National Agency for Food and Drug Administration and Control (NAFDAC) to ensure the production of quality medicines by pharmaceutical companies. This stresses the need for continuous post-marketing surveillance of the drug products to ensure that patients get the right drug products, in the right quality, from the right source, and in the right form.

MATERIALS AND METHODS

Materials

Nutrient agar was purchased from HiMedia Laboratories Pvt. Ltd., Mumbai, India. Normal saline was purchased from a registered pharmacy in Kaduna, Nigeria. Distilled water was produced in-house by QuickFit water still (QWS4), UK, and freshly prepared distilled water was used throughout the study. All other reagents used were of analytical grade. The bacterial strains used in this study comprise Gram positive, namely, *Bacillus subtilis*

ATCC® (American Type Culture Collection) 6633 and *Staphylococcus aureus* ATCC® 29213; and Gram negative, namely, *Escherichia coli* ATCC® 25922, *Salmonella Typhi* ATCC® 19214, and *Pseudomonas aeruginosa* ATCC® 27853. The bacterial concentrates were appropriately incubated and diluted to match the 0.5 McFarland turbidity standard (Aminu *et al.*, 2019).

Seven brands of ciprofloxacin HCl 500mg caplets were randomly obtained from different pharmacy outlets and patent medicine stores from areas of Kaduna city, Nigeria such as Tudun Wada, Anguwan Rimi, Anguwan Sarki, Kawo, Malali, Barnawa, and Rigasa. All the brands were labelled to contain 500 mg of ciprofloxacin HCl per caplet. The brands were coded as samples A, B, C, D, E, F, and G (Table 1). The study was performed before the product's expiration dates, and it was carried out and interpreted as per official specifications.

Methods

Visual Inspection

The samples were properly checked for their physical appearance (size, shape, and colour), the name of the manufacturer, batch number, date manufactured, expiry date, and NAFDAC registration number.

Weight Variation

The weight variation study was conducted using the pharmacopeial procedure described in the USP 32 NF 27, 2009 (United States Pharmacopeial Convention, 2009). Twenty caplets from each sample were randomly selected and weighed individually using an electronic weighing balance (Mettler Analytical Balance, Phillip Harris Ltd, England). The caplets' mean weight for each brand and the percentage deviation from the mean value were calculated using equation 1.

$$\text{Standard deviation} = \sqrt{\frac{\sum (X - \bar{X})^2}{n - 1}} \quad (1)$$

Where X is the weight of each tablet, $\bar{X}$ is the average weight of the tablets, and n is the total number of the tablets.

Table 1: Details of the brands of ciprofloxacin HCl caplets evaluated

SAMPLE CODE	BATCH NUMBER	NAFDAC NUMBER	MANUFACTURING DATE	EXPIRY DATE	COUNTRY OF ORIGIN	SOURCE OF MEDICINE
A	UG1614	04-0723	11/2016	10/2019	India	Pharmacy store
B	MTFT-1601	A4-9436	06/2016	05/2019	India	Pharmacy store
C	1563-A	04-3002	09/2016	08/2019	India	Patent medicine store
D	17031103	A4-6601	03/2017	02/2021	Nigeria	Pharmacy store
E	UTGSSXB602	04-3458	11/2016	10/2019	India	Pharmacy store
F	CY37009	B4-6310	07/2017	06/2020	India	Pharmacy store
G	170301	B4-5263	03/2017	03/2020	China	Pharmacy store

NAFDAC, National Agency for Food and Drug Administration and Control

Disintegration Test

Disintegration test was carried out according to the pharmacopeial procedures (British Pharmacopoeia Commission, 2009; Kassahun *et al.*, 2018; United States Pharmacopeial Convention, 2009). Five caplets from each brand were randomly selected and used for the disintegration test using the Erweka Disintegration Apparatus (Type WF 31012, Germany). The apparatus was set at 50 rpm and temperature of $37 \pm 0.5^\circ\text{C}$, and each vessel was filled with 900 mL of distilled water. The time taken for each caplet to completely disintegrate was recorded and the average disintegration time for each brand was calculated. The caplets are considered completely disintegrated when all their particles pass through the wire mesh.

Friability

The friability study was performed according to BP, 2009 procedure (British Pharmacopoeia Commission, 2009). Twenty caplets were randomly selected from each batch for the friability test. The caplets were dusted with the aid of a sieve and weighed using an electronic balance. Then, the caplets were subjected to abrasion shock in the drum of the tablet Friabilator (Type TA3R, Erweka, Germany) which was operated at 25 revolutions per minute (rpm) for 4 min. The caplets were reweighed after dusting. The percentage loss in weight was determined for each sample according to equation 2.

$$\text{Friability (\%)} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100 \quad (2)$$

Thickness Test

Fisher Scientific electronic calliper (New Hampshire, United States) was used in the measurement of the thickness according to the method reported by Aminu *et al.* (2020). The caplets were placed between the jaws of the device and the device was adjusted to obtain the

thickness of each caplet, making sure that the caplet did not get chipped or break. The values were recorded in millimetres (mm). This process was carried out on ten caplets from each brand selected randomly and the mean was calculated.

Diameter Test

The method reported by Aminu *et al.* (2020) was adapted for the diameter test. The diameters of ten randomly selected caplets from each brand were measured using an electronic calliper (Fisher Scientific, England). The caplets were placed between the jaws of the calliper and the micrometre was adjusted to obtain the diameter of the individual caplet. The values obtained were recorded in millimetres (mm) and the mean was calculated.

Determination of Minimum Inhibitory Concentration

The minimum inhibitory concentration (MIC) of ciprofloxacin for the selected bacterial strains was determined using a standard agar diffusion method reported by Kronvall (2000). The MIC limits for interpretation of susceptibility were $S \leq 1.0 \text{ mg/L}$. Species-related MIC limits for ciprofloxacin are $S \leq 0.06 \text{ mg/L}$ for *Staphylococcus* species, $S \leq 0.12 \text{ mg/L}$ for both members of the Enterobacteriaceae and *Enterococcus* species, and $S \leq 1.0 \text{ mg/L}$ for *Pseudomonas* species (Kronvall, 2000). Accordingly, various concentrations (0.1 to 10 $\mu\text{g/ml}$) of each brand were prepared in sterilized distilled water. The bacterial strains (0.5 McFarland turbidity) were inoculated onto agar plates. Antibiotic disks were placed on the surface, and this was followed by pre-diffusion at room temperature for 30 min and then by overnight incubation at 37°C . Inhibition zone diameter values were read by a calliper in millimetres and the minimum concentration that inhibited the growth of each organism was taken as the MIC (Kronvall, 2000; Idowu and Shonubi, 2020).

Antimicrobial Study

The antimicrobial study was conducted according to a reported method (Aminu *et al.*, 2019; Nazir Mughal *et al.*, 2009). About 20 mL of molten nutrient agar media was poured into sterilized petri plates that were previously labelled according to the names of the organisms and brand samples. When the temperature reached around 40 °C, about 0.2 mL of an overnight suspension of culture strains (0.5 McFarland turbidity) was added onto nutrient agar plates. The culture was evenly distributed in the medium and then allowed to fully solidify. Three wells (cavities) equidistant from the centre of the plate and each other were made in the solidified medium using a well-borer, which was previously sterilized by the flame. Bottom of the wells was sealed with a drop of sterilized molten agar to prevent irregular creep of the fluid from the wells. In each Petri plate, 1 ml of sample solution equivalent to 5 µg/mL of ciprofloxacin HCl was introduced into the first well. The second well was filled with 1ml of sterilized distilled water as control 1, while the third well was left empty as control 2. The test solution and distilled water were allowed to diffuse for 2 hr at room temperature. The petri plates were inverted and then incubated in an incubator at 37 °C for 24 hr. The diameter of the growth inhibition zone surrounding each agar well was measured with calliper in millimetres (mm).

Statistical Analysis

Statistical significance of the data sets was assessed by one-way analysis of variance (ANOVA) followed by Tukey's Multiple Comparison Test using version 7.0 Graphpad Prism® statistical software. A 95% confidence interval was considered as statistically significant.

RESULTS AND DISCUSSION

Visual Inspection

All samples of the seven tested brands of ciprofloxacin HCl caplets used in this study were within their shelf life. Results of the visual inspection which comprises aesthetic assessment showed that all the samples have a good physical appearance. Except for sample E which appeared pink, all the samples were white in colour, oblong in shape, and bitter in taste (Table 2).

Weight Variation

The weight variation test for all the tested brands of ciprofloxacin HCl caplets gave values that comply with the specification of official books for weight variation, as none of the brands deviated by more than 5% from the mean value (Table 3). The pharmacopeial specification for weight variation for uncoated tablets/caplets weighing more than 324 mg required that no more than 2 of the tablets/caplets under test should differ from the average weight by more than 5%, and no tablet/caplet should

differ in weight by more than double of that percentage (United States Pharmacopeial Convention, 2009). Statistical analysis by ANOVA for weight variation data indicates with a 95% confidence interval that, there is a significant difference ($p < 0.05$) in the weight between some brands (Figure 2). However, inter-brand differences have nothing to do with their quality as each brand used a different amount of excipients. Thus, from the results obtained, all the samples have passed the test for weight variation.

Weight variation test of tablets/caplets is an important parameter of tablets/caplets evaluation because high weight variation indicates variation in the amount of active ingredients and/or excipients. Variations of active ingredients may lead to toxicity, ineffectiveness or unpredictability of actions of the product and ultimately alter the bioavailability of the drug (Cockburn *et al.*, 2005; Fernandez *et al.*, 2015). Example of factors that affects weight variation include inconsistency of granule size and uneven filling of dies during the compression of the tablets/caplets (Ciancio, 2007).

Disintegration test

Disintegration test is usually performed to estimate the time required for a dosage form to breakdown into granules of specified size under carefully specified conditions (Tella *et al.*, 2019). This test is used as a quality assurance measure to determine the time at which a tablet/caplet disintegrates when placed in a liquid medium under prescribed conditions of temperature and pH. Disintegration is a crucial step in drug release from the dosage form. Therefore, tablet/caplet disintegration is a prerequisite to its dissolution and subsequent absorption of the drug into the body system (Kassahun *et al.*, 2018).

As shown in Table 3, all the samples of the present study disintegrated within the range of 0.51 ± 0.07 to 10.10 ± 0.84 min. Sample E had the least disintegration time while sample B had the highest (Table 3). British Pharmacopoeia (BP) specification for disintegration test states that uncoated tablets/caplets should disintegrate within 15 min (British Pharmacopoeia Commission, 2009). Therefore, all the samples passed the disintegration time test. The rapid disintegration time exhibited by all the tested brands of ciprofloxacin HCl caplets may be attributed to the nature and amount of disintegrating agents used in the production of the caplets. The rate of disintegration is influenced by the rate of influx of water into the caplets which is also dependent on the porosity of the caplets (Olusola *et al.*, 2012).

Table 2: Organoleptic properties of ciprofloxacin HCl 500 mg caplets used for the present study

SAMPLES	COLOUR	SHAPE	TASTE
A	White	Oblong	Bitter
B	White	Oblong	Bitter
C	White	Oblong	Bitter
D	White	Oblong	Bitter
E	Pink	Oblong	Bitter
F	White	Oblong	Bitter
G	White	Oblong	Bitter

Friability

Friability is a measure of the strength or weakness of tablets/caplets. The test was performed to measure the resistance of the caplets to abrasion during packaging and other handling operations. From the friability result presented in Table 4, all the tested brands of ciprofloxacin HCl caplets satisfied the compendial requirement of less than 1%. BP states that the friability value of tablets/caplets should be under 1% (British Pharmacopoeia Commission, 2009). Most of the samples did not yield any friability value, and the highest value obtained was 0.60 ± 0.10 by sample D (Table 4). This indicated that all the samples could withstand mechanical stress during packaging and transportation without losing their significant parts.

Thickness Test

Regulation of the physical dimensions of tablets/caplets such as thickness and size are important for the acceptability of consumer and uniformity of the tablets/caplets (Aminu *et al.*, 2020). The thickness of tablets/caplets is evaluated to assess the consistency in size and shape within a particular batch and brand of tablets/caplets. The result of the thickness test is shown in Table 4. The average thickness values of the tested brands fall within the range of 4.91 ± 0.91 to 6.05 ± 0.34 mm. Deviation from the mean value was 0.05 to 0.91. All seven brands of ciprofloxacin HCl caplets were within the acceptable range of thickness of less than 5% deviation from the mean value (Joda *et al.*, 2018).

Diameter Test

The diameter test result is presented in Table 4. From the result, it can be observed that the average diameters and standard deviations are in the range of 7.63 to 9.09 mm and 0.16 to 0.90, respectively. The average diameters of all the tested brands varied within 5% of the mean values, which is in accordance with the official requirement (Joda *et al.*, 2018).

Determination of Minimum Inhibitory Concentration

For the MIC, all the brands exhibited activity against all the tested organisms at the MIC concentration range of

0.01 to 1 $\mu\text{g/mL}$. As can be seen from Table 5, the MIC for *B. subtilis*, *E. coli* and *S. typhi* is $\leq 0.12 \mu\text{g/mL}$ which indicates their susceptibility to the tested brands of ciprofloxacin caplets. Similarly, the MIC for *S. Aureus* and *P. aeruginosa* was found to be $\leq 0.06 \mu\text{g/mL}$ and 0.1 $\mu\text{g/mL}$, respectively, confirming the susceptibility of these organisms. These findings are consistent with the study reported by Kronvall (2000). This demonstrates that ciprofloxacin has a good antibacterial broad spectrum and high potency at lower concentrations.

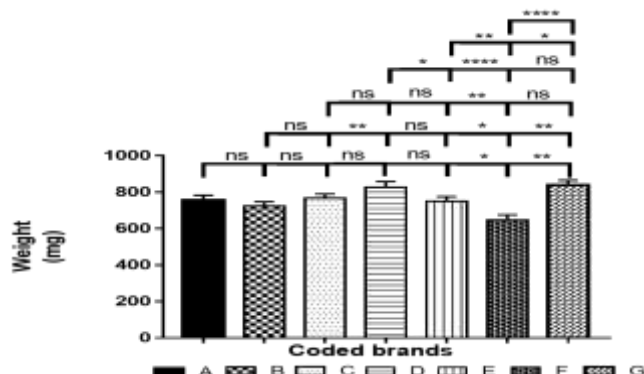
Antimicrobial Study

The antimicrobial study was conducted to compare the antibacterial activity of the seven different brands of ciprofloxacin HCl caplets of the same 500 mg strength. The concentration of the test solution for all samples was 5 $\mu\text{g/mL}$. The results of the antimicrobial study in terms of inhibition zone diameters produced by all the brands are given in Table 5. The found inhibition zone diameters (mm) for each bacterial strain were compared with the control limits set by the United States National Committee for Clinical Laboratory Standards (NCCLS) for monitoring inhibitory zone diameters (Idowu and Shonubi, 2020; National Committee for Clinical Laboratory Standards, 1994; Nazir Mughal *et al.*, 2009). The results for all the brands fall within the acceptance ranges (footnote of Table 6) set by NCCLS. From Table 5 it can be observed that all the seven brands showed similar activity as that of the reference standard. These bacterial inhibition activities of ciprofloxacin promise a high degree of efficacy in the treatment of bacterial infectious diseases. Therefore, in this study, it was determined that all seven tested brands of ciprofloxacin HCl 500 mg caplets showed good sensitivity against the 5 tested microorganisms. In practice, if the observed zone of inhibition is greater or equal to the size of the standard zone, the microorganism is considered to be susceptible to that antimicrobial agent being tested. Conversely, if the observed zone of inhibition is smaller than the standard size, the microorganism is considered to be resistant to the antimicrobial agent (Idowu and Shonubi, 2020; National Committee for Clinical Laboratory Standards, 1994; Nazir Mughal *et al.*, 2009).

Table 3: Quality control tests results for weight variation and disintegration time of the various samples of ciprofloxacin HCl 500 mg caplets

SAMPLES	MEAN CAPLETS WEIGHT (mg) $\pm$ SD	MEAN DISINTEGRATION TIME (MIN) $\pm$ SD
A	787 $\pm$ 27.24	5.98 $\pm$ 1.62
B	714 $\pm$ 8.24	10.10 $\pm$ 0.84
C	776 $\pm$ 4.25	5.99 $\pm$ 2.02
D	822 $\pm$ 25.30	5.86 $\pm$ 1.91
E	757 $\pm$ 10.95	0.51 $\pm$ 0.07
F	624 $\pm$ 10.31	7.08 $\pm$ 1.70
G	865 $\pm$ 29.25	6.25 $\pm$ 1.53

SD, Standard Deviation

**Figure 2:** Weight variation of different brands of ciprofloxacin HCl caplets (A-G) indicating significant and insignificant differences between the brands (inter-brands). The data are expressed as means $\pm$ SD for three (n = 3) determinations. ns, no significant difference ($p > 0.05$); * $p < 0.05$; ** $p < 0.01$; **** $p < 0.0001$ when compared to the other brands.**Table 4:** Quality control tests results for friability, thickness, and diameter of the various samples of ciprofloxacin HCl 500 mg caplets

SAMPLES	MEAN CAPLETS FRIABILITY (%) $\pm$ SD	MEAN CAPLETS THICKNESS (mm) $\pm$ SD	MEAN CAPLETS DIAMETER (mm) $\pm$ SD
A	0.00 $\pm$ 0.00	5.94 $\pm$ 0.05	7.63 $\pm$ 0.66
B	0.00 $\pm$ 0.00	5.30 $\pm$ 0.82	8.44 $\pm$ 0.43
C	0.27 $\pm$ 0.02	6.05 $\pm$ 0.34	8.07 $\pm$ 0.90
D	0.60 $\pm$ 0.10	4.91 $\pm$ 0.91	9.04 $\pm$ 0.65
E	0.00 $\pm$ 0.00	5.01 $\pm$ 0.48	8.15 $\pm$ 0.82
F	0.00 $\pm$ 0.00	4.99 $\pm$ 0.30	8.23 $\pm$ 0.79
G	0.00 $\pm$ 0.00	5.23 $\pm$ 0.07	9.09 $\pm$ 0.16

Table 5: MIC of evaluated brands of ciprofloxacin HCl caplets on selected test organisms

SAMPLES	<i>B. subtilis</i> (μ g/mL)	<i>S. aureus</i> (μ g/mL)	<i>E. coli</i> (μ g/mL)	<i>S. typhi</i> (μ g/mL)	<i>P. aeruginosa</i> (μ g/mL)
A	0.10	0.06	0.12	0.10	0.8
B	0.12	0.05	0.12	0.12	1.0
C	0.12	0.06	0.12	0.10	1.0
D	0.10	0.06	0.12	0.12	0.8
E	0.10	0.06	0.12	0.12	0.8
F	0.10	0.06	0.12	0.10	0.8
G	0.12	0.05	0.10	0.10	1.0

Zone of inhibition testing is a fast-qualitative means to measure the ability of an antimicrobial agent to inhibit the growth of microorganisms (Aminu *et al.*, 2019). The

degree to which microorganisms are inhibited by a chemical substance is vital in the selection of an effective antimicrobial agent. There are additional factors that can

be considered in choosing an appropriate antimicrobial agent for a given situation. For example, are the chemical properties of the antimicrobial agent (e.g., pH and solubility) appropriate for the situation? This is to know whether the chemical substance is compatible with the body system, i.e., non-toxic to cells, tissues, and friendly

microorganisms (Idowu and Shonubi, 2020). Susceptibility and Minimum Bactericidal Concentration (MBC) tests were not reported herein, and this is a limitation of this study. Future research in this perspective may wish to consider performing these tests.

Table 6: Results of antimicrobial study showing zone of inhibitions caused by the different samples of ciprofloxacin HCl 500 mg caplets

SAMPLES	<i>B. subtilis</i> (mm)	<i>S. aureus</i> (mm)	<i>E. coli</i> (mm)	<i>S. typhi</i> (mm)	<i>P. aeruginosa</i> (mm)
A	28	40	41	40	39
B	27	39	40	41	40
C	26	38	39	39	38
D	28	40	40	40	40
E	30	43	44	44	44
F	29	41	42	42	43
G	25	37	40	39	39

Reference inhibition range for 5µg/mL of ciprofloxacin: *Bacillus Subtilis* = 23 – 30 mm; *Staphylococcus Aureus* = 22 – 30 mm; *Escherichia Coli* = 30 – 40 mm; *Salmonella Typhi* = 35 – 40 mm; *Pseudomonas aeruginosa* = 25 – 33 mm (National Committee for Clinical Laboratory Standards, 1994; Nazir Mughal *et al.*, 2009).

CONCLUSION

It is concluded that all the tested brands of ciprofloxacin HCl caplets demonstrated physical integrity and acceptable antimicrobial activity and, hence, the brands can be prescribed interchangeably by physicians. However, further tests such as assay of active content, hardness, bioequivalence assessment, and dissolution are warranted to ascertain the complete quality of these brands that are circulating in the Kaduna metropolis. It is recommended that NAFDAC should ensure that all drug products imported or manufactured in Nigeria undergo quality control analyses and meet the stated specifications before they are approved for marketing. Post-marketing surveillance should also be regularly carried out by both drug regulatory agencies (such as NAFDAC) and research institutions so that the quality of drug products in circulation is monitored.

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