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Quality assessment of different brands of Ciprofloxacin 500 mg tablets from a drug outlet in Onitsha

Chigozie Celestina Ezeagha [1], Chiziterem Divine Okafor [1], Onumsinachukwu Consolata Orji [1] *, Amarachi Nwanyioma Anozie [2], Philip Chibuikem Onwukwe [1], Victor Otitochukwu Ejike [1] and Emmanuel Chuks Oranu [1]

[1] *Department of Pharmaceutical and Medicinal Chemistry, Faculty of Pharmaceutical Sciences, Chukwuemeka Odumegwu Ojukwu University Igbariam, Anambra State, Nigeria.*
[2] *National Agency for Food and Drugs, Administration and Control, Awka-Ekwulobia Road Agulu, Anambra State, Nigeria.*

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Abstract

Ciprofloxacin is a synthetic flouroquinolone antibiotic derivative with broad-spectrum antibacterial action. Ten brands of ciprofloxacin (500mg) tablets were purchased from the selected drug outlets in Anambra state for the study. The tablets were assessed for compliance with pharmacopeia specification. Analysis of the data generated indicated that all the brands except brand C6 complied with the compendia specification of weight variation, only three brands (C5, C8 and C10) were within the specified limits of content assay, all the brands complied with the official specification for disintegration time, five brands (C1, C3, C7, C8 and C10) complied with the official specification for rate of dissolution, only brands C2 and C9 were within the acceptable limit for hardness test and brands C1, C3, C5, C6, C9 and C10 complied with the specification for friability test. Among all the tablets that passed, brands C1, C3, C5, C8 and C10 have the highest quality because they complied with the compendia standards on weight uniformity, friability, disintegration time, content of active ingredients and drug release.

The study concluded that not all the brands tested are of sufficient good quality with up to five brands (C2, C4, C6, C7 and C9) failing most of the important tests. This may be due to deliberate counterfeiting, failure of not strictly following the current Good Manufacturing Practices (cGMP) or poor handling by wholesalers and retailers. Therefore, adequate product testing should be done to determine the quality and strict laws should be placed to prevent intentional counterfeiting of drugs.

Keywords: Ciprofloxacin; Quality assessment; Pharmaceutical analysis; Antibiotic efficacy; Pharmaceutical standards; Drug quality Control

1. Introduction

According to the WHO's 2018 definition, a counterfeit drug is one that has been purposefully and fraudulently mislabeled in terms of its identification and source. Also in that same 2018, WHO replaced the collective term "counterfeit medications" with the phrases "substandard", "falsified medical products and unregistered unlicensed" broadening the focus of efforts being made worldwide to stop these products from reaching consumers (WHO, 2018). The World Health Organization's (WHO) list of essential medicines includes Ciprofloxacin as one of the most crucial drugs required in the fundamental healthcare system. Uniformity of weight, assay, disintegration and dissolution are compendia standards to assess the quality of tablets while hardness and friability are referred to as non-compendia standards although friability is now included in the United State Pharmacopeia (USP).

* Corresponding author: Onumsinachukwu Consolata Orji

Ciprofloxacin is frequently used for the treatment of gonorrhea, skin and soft tissue infections, bone and joint infections, lower respiratory tract infections, bacterial diarrhea, and surgical prophylaxis. This medication was the first oral broad-spectrum antibiotic to be approved by the Food and Drug Administration (FDA) for use in the United States in 1987. [1] The quality assessment of Ciprofloxacin brands in Onitsha reflects the need for the consistent pharmaceutical standards, a concern echoed in research works on medical plants where nutritional value, provides a broader perspective on strengthening healthcare delivery. [2, 3, 4, 5]

Globally, there is an increase in product counterfeiting of all kinds, including money, plastic, software and most importantly, food and drugs. According to a study made by the WHO between 1999 and 2002, Antibiotics are the most counterfeit drugs and account for 28% of drug counterfeiting. [6] Out of the 163 fake antibiotics that were discovered worldwide up until 2009, 50% were beta-lactams, 12% were quinolones, 11% were macrolides, lincosamides, and synergistines, 7% were cyclins, and 20% were other antibiotics. [7]

In order to guarantee the identification and purity of a certain medication, a number of processes are used collectively under the name "quality control ". These processes could be as straightforward as carrying out simple chemical studies to identify and check for the presence of specific medicinal chemicals (such as thin layer chromatography, infrared spectroscopy, and so on) or as complex as following Pharmacopoeia monograph requirements. These process help to ascertain the quality and efficacy of pharmaceutical products, thereby, preventing treatment failure and antimicrobial resistance. Previous research works on antibiotics formulations has established methodologies that informed the design of this research. [8,9,10]

Nigeria, the most populous nation in Africa, has suffered greatly from the problem of drug trafficking and counterfeiting. As a result, fake medications, unlicensed drug dealers, quack physicians, and illegal drug stores have spread like wildfire throughout the nation. [11]

Due to their potentially harmful ingredients or absence of active ingredients, counterfeit medications represent a risk to the public's health. Their use might lead to treatment failure and increased resistance. [12] It denies the Nigerian people access to high-quality, safe medicines. [13]

In less developed nations, counterfeit or substandard antimicrobials, particularly antibiotics such as ciprofloxacin, are most frequently reported. In contrast to the limited information in the scientific literature, journalism serves as the primary information source when it comes to the counterfeiting of antimicrobials. There have not been many published systemic reviews of the research relating to substandard Ciprofloxacin. [14] Also, due to the lack of resources, expertise, and/or medication regulation, there is little information available on the negative impacts of using fake and substandard pharmaceuticals in Africa. Therefore, except from instances of major injuries or mass fatalities involving numerous people, the effects of counterfeit drugs consumption are generally indictable. [11] This study therefore will provide information about the quality and safety of ten brands of Ciprofloxacin tablets marketed to the public within Onitsha, Anambra, Nigeria using a well-defined analytical method.

The aim of this study is to evaluate the quality and safety of ten brands of Ciprofloxacin tablets marketed within Onitsha Pharmaceutical market using a well-defined quality assessment test.

The results of the quality evaluation study will be used to assess if the final Ciprofloxacin products reaching the end consumers are consistent, safe, effective, predictable and of high quality. Also, the information gathered from this post-market study may be utilized to hasten the creation of new products and regulation.

2. Materials and methods

2.1. Equipment

UV-vis spectrophotometry (752N UV-visible spectrometer), weighing balance (Ohaus pioneer analytical balance), glass funnel, measuring cylinder (2000ml, 100ml, 50ml, 10ml), pipette (0.1ml, 1ml, 10ml), hardness tester (BIOBASE), mortar and pestle, beaker (1000ml, 500ml, 250ml, 50ml), spatula, filter paper (Whatman), masking tape, test tubes (Pyrex), test tube rack, dissolution test apparatus (BIOBASE dissolution tester), disintegration test apparatus (BIOBASE disintegration tester), syringe

2.2. Chemicals and Reagents

Sodium hydroxide (NaOH), distilled water, concentrated Hydrogen chloride (HCl), pure Ciprofloxacin powder.

2.3. Sample collection

Ten (10) different brands of Ciprofloxacin 500mg were randomly purchased from different private and retail pharmacy Anambra state. They were labelled from C1 to C10. The Ciprofloxacin standard powder was obtained from Pauco Pharmaceutical Industry Limited, Awka, Anambra State.

2.4. Preparation and Assay of Standard Solution

To prepare the solution, 0.4g of NaOH was added to 100ml of distilled water to make 0.01M of NaOH.

2.5. Spectrophotometric Assay of Standard Solution

100mg of pure Ciprofloxacin powder was dissolved in 100ml of 0.01M NaOH to obtain a stock solution of 1mg/ml or 1000µg/ml. From this stock solution, 5ug/ml, 10ug/ml, 20ug/ml, 30ug/ml, 40ug/ml and 50ug/ml working concentrations were prepared. Utilizing a UV spectrophotometer, the absorbance values for these concentrations were determined at 270 nm. Following this, a standard graph was created by plotting the absorbance values on the Y-axis and the concentration values on the X-axis.

2.6. Preparation and Assay of Ciprofloxacin Sample Solution

The estimation of drug content for ciprofloxacin tablets was performed by crushing twenty tablets and quantity equivalent to 100mg was taken using 100ml of 0.01M NaOH to give stock solutions of 1mg/ml. From each stock, aliquots of 10ug/ml of each brand were prepared and their absorbance were determined using UV spectrophotometer at about 270 nm,

2.7. Disintegration test method

Six tablets from each brand were selected at random, and each was placed in a basket rack tablet disintegration tester (BIOBASE disintegration tester) with 900ml of distilled water serving as the disintegration medium at 37ºC. The time taken for each brand to disintegrate completely was recorded.

2.8. Dissolution test method

2.8.1. Preparation of dissolution medium

To prepare the dissolution medium, the concentration of 0.01N of HCl was calculated and 0.34g of HCl was dissolved in distilled water and made up to 1000ml.

2.9. Method

For this test, USP dissolution apparatus (USP II) was used. One tablet per brand was inserted in each of the six vessels, which contained 900 ml of 0.01N hydrochloric acid (HCl) as the dissolution medium and were kept at a constant temperature of 37 0.5 °C. The rotational speed of the apparatus was held constant at 50 rpm. At predetermined intervals (5, 10, 15, 20, 25, 30 minutes), a 5 ml sample was taken out and promptly replaced with the equal volume of new dissolution medium. The sample was filtered, and 1 ml of the filtrate was taken and diluted to make 50 ml with distilled water. The solution was thereby 50 times diluted. Using 0.01N HCl as a blank, the absorbance of the diluted filtrate was measured spectrophotometrically at a wavelength of 276 nm. Using standard ciprofloxacin, the percentage of medication released at Check this as well.

2.10. Determination of Weight Uniformity

Twenty (20) tablets from each of the brands were weighed individually using an analytical weighing balance. The average weight for each brand as well as percentage deviations were calculated.

2.11. Hardness test

Five tablets from each brands were individually placed vertically on the Monsanto Hardness tester. The load was then applied along the radial axis of the tablet. The weight or load required for breaking the tablet was noted down

2.12. Friability test

The friabilator was filled with ten tablets from each of the ten brands, weighed, and then run for four minutes at a speed of 25 rpm. After dedusting, the tablets were reweighed. The difference in the two weights were used to calculate friability

3. Results

Table 1 Result of Weight variation, Hardness test, Disintegration test and Friability test

Brand code	Weight variation (mg) Mean ± SD	Hardness (kgf) Mean ± SD	Disintegration time (mins)	Friability (%)
C1	740.5 ± 2.92	3.12 ± 1.00	2.11 ± 3.94	0.01
C2	525.5 ± 3.76	4.03 ± 0.47	11.0 ± 2.44	4.00
C3	1052.3 ± 3.21	2.61 ± 1.01	1.08 ±2.98	0.30
C4	787.9 ± 4.20	3.85 ± 1.32	1.75 ± 3.59	1.10
C5	848.15 ± 4.25	3.92 ± 1.00	11.93 ± 3.65	0.05
C6	814.7 ± 6.50	7.53 ± 0.24	13.91 ± 4.17	0.40
C7	911.8 ± 2.64	1.19 ± 0.50	2.00 ± 3.82	2.30
C8	801.4 ± 2.01	2.40 ± 0.32	2.61 ± 2.03	6.70
C9	804.1 ± 3.35	6.70 ± 0.38	7.08 ± 3.63	0.02
C10	672.1 ± 1.66	2.05 ± 0.34	4.55 ± 2.23	0.10

- According to the USP 2020, Weight variation acceptance limit for film coated tablets is < ±5% deviation.
- The accepted range of hardness for tablets is 4 to 10kgf (kilogram force).
- According to USP 2020, disintegration time limit: ≤15min (uncoated tablets), ≤60min (film coated tablets).
- Limit: Friability (%) = Not More Than 1.0 %

Table 2 Result of Ciprofloxacin content in the ten brands

Brand code	Labelled drug content (mg)	Actual drug content (mg)	Percentage drug Content (%)
C1	500mg	316.5	63.3
C2	500mg	316.5	63.3
C3	500mg	316.5	63.3
C4	500mg	316.5	63.3
C5	500mg	483.0	96.6
C6	500mg	150	30.0
C7	500mg	316.5	63.3
C8	500mg	483.0	96.6
C9	500mg	316.5	63.3
C10	500mg	483.0	96.6

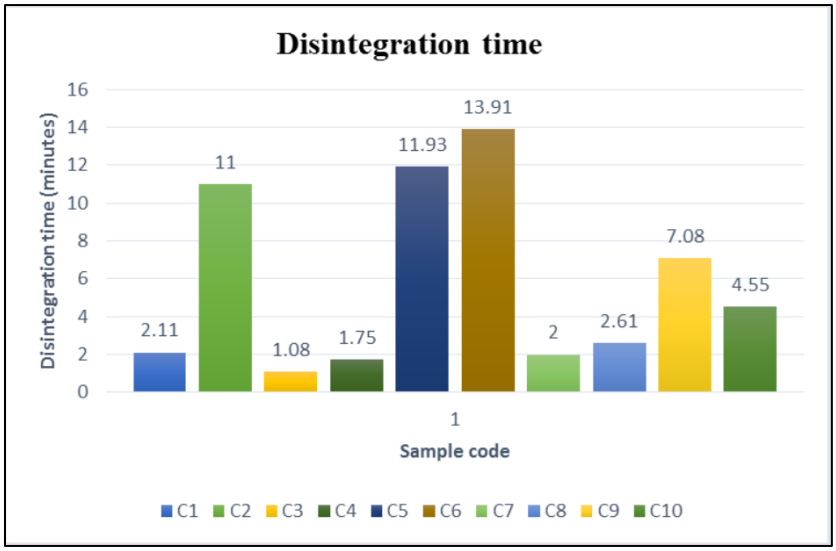

Figure 1 Disintegration time of ten brands of Ciprofloxacin tablets

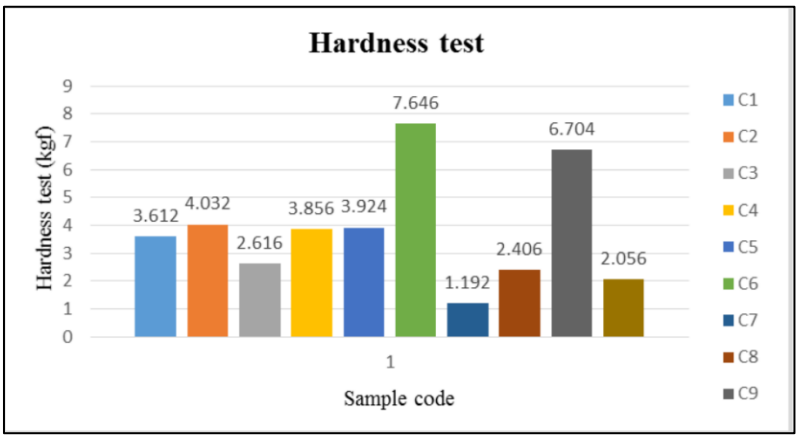

Figure 2 Hardness test of ten brands of Ciprofloxacin tablets

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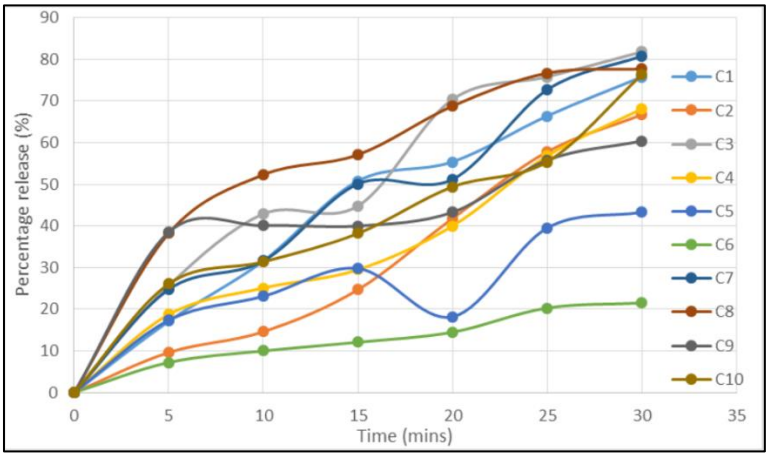

Figure 3 Percentage release of the ten brands of Ciprofloxacin

4. Discussion

According to the result in Table 1, all brands complied with the compendia specification of weight variation. The weight variations of all the brands were achieved by calculating the percentage deviation of the twenty tablets used from the mean weight. The USP 2020 weight variation specification for both coated and uncoated tablets (over 345mg) specifies that not more than two of the individual tablets weight deviates by 5%.

Analysis of the assay of the drug is very important to determine the presence, absence, or quantity of one or more components in the dosage form. In this study, Ciprofloxacin were assayed by using UV Spectroscopic Technique. [14] The USP Specification for assay is 100±10% while British Pharmacopeia (BP) Specification for assay is 100±5% [15]. According to the result obtained in Table 2, only three (3) brands (C5, C6 and C10) were within the specified limits. The rest were out of specification. This means that the drug content was not up to the labelled claim.

The BP Specification for uncoated tablet is not more than 15 minutes and 30 minutes for coated tablets while USP Specification for uncoated and film coated tablet is not more than 30 minutes. [17] According to the result, all the brands complied with the specification. This can be as a result of the binders, disintegrants used and the tablet hardness. The ability of the brands to disintegrate within the specified time limit is a good indication that the tablets will disintegrate in the gastrointestinal tracts and release their content into the system.

Drugs with poor dissolution profile will not be available in the body to elicit therapeutic effect. [18,19,20] The general dissolution requirement of the USP is that 75% of the drug content must be dissolved within 45 minutes. [16] From the dissolution profile only C1, C3, C7, C8 and C10 complied. The rest showed a poor dissolution rate and may exhibit poor bioavailability in vivo as well as poor clinical performance

Crushing strength (hardness) test assesses the ability of tablets to withstand handling without fracturing or chipping. It can also influence friability, disintegration and dissolution. The harder a tablet., the less friable and the more time it takes to disintegrate. [15] The acceptable range for tablet hardness is 4-10kgf (kilogram of force). From the result, only brands C2 and C9 were within the acceptable limit which showed that the tablets possess good mechanical strength.

Friability test is used to evaluate the tablets resistance to abrasion. The USP and BP specified that the batch should not be more than 1% friable. [17] From the result, brands C1, C3, C5, C6, C9 and C10 were within the specification. This shows that the tablets possess good mechanical strength and can withstand abrasion without loss of tablet integrity.

5. Conclusion

It is evident from the study that there are some substandard drug products still circulating the market. The circulation and use of these substandard Ciprofloxacin tablets also contribute to the risk of treatment failure and microbial resistance in the population. To ensure that patients do not lose confidence in the value of pharmaceuticals and stop following their treatment regimens, it is crucial to find a solution to the substandard drug issue.

Among all the tablets that passed, brands C1, C3, C5, C8 and C10 have the highest quality because they conformed to compendia standards on weight uniformity, friability, disintegration time, content of active ingredient and drug release. Although, C1 and C3 did not pass the assay test and C5 did not pass the dissolution test. The rest of the brands did not fully meet up to the Pharmacopoeia specifications. This may be due to deliberate counterfeiting, failure of not strictly following the current Good Manufacturing Practices (cGMP) or poor handling by wholesalers and retailers. Therefore, the government in collaboration with the WHO, NAFDAC and NDLEA should provide comprehensive guidelines for testing of the product for quality, efficacy and safety. There should also be drug quality assurance and strict laws and regulations for manufacturing, importation, distribution, and sale of ciprofloxacin. This is necessary to combat the risk of using substandard medications, such as antimicrobial resistance and therapy failure.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors confirm that there are no known conflicts of interest.

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