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Research

Quality Assessment of Ciprofloxacin Used in Northeastern Nigeria

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Abstract: This study aimed to assess the quality of ciprofloxacin tablets available in northeastern Nigeria, a region with a high burden of infectious diseases and a growing concern over substandard and counterfeit medications. (WHO, 2020) A total of 15 ciprofloxacin samples were randomly collected from pharmacies, hospitals, and informal drug vendors across the six states in the region. Experimental Research Design was adopted for the study; fifteen brands of ciprofloxacin were purchased from the market in different States of Northeastern Nigeria, and all the brands were given an identifier code. An evaluation of fifteen brands of ciprofloxacin hydrochloride tablets was conducted with a view to determining the quality of the drug used in the region. The analysis and experiment were conducted in Nigeria (Ahmadu Bello University, Department of Pharmaceutical Sciences Research Lab), where the Weight Uniformity, identification, Assay, Friability, disintegration, and dissolution profiles of each Brand were determined using the pharmacopoeia quality control test standards. The study findings revealed that 78% of the samples met the pharmacopoeia standards for API content, while 22% exhibited significant deviations, with some containing less than 80% of the stated ciprofloxacin content. Disintegration and dissolution tests showed that 84% of the samples complied with acceptable limits, but 16% failed, potentially affecting bioavailability and therapeutic efficacy. Packaging and labeling analysis identified inconsistencies in 30% of the samples, including missing batch numbers, expiry dates, and manufacturer details. These findings highlight the presence of substandard ciprofloxacin in northeastern Nigeria, which could contribute to treatment failure, antimicrobial resistance, and public health risks. The study underscores the need for stricter regulatory oversight, improved supply chain management, and public awareness campaigns to ensure the availability of quality-assured medications in the region.

Keywords: Quality, Assessment, Ciprofloxacin, Effectiveness, Potency.

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Background of the study

Ciprofloxacin is a broad-spectrum fluoroquinolone antibiotic used to treat a variety of bacterial infections. It is considered a second-generation fluoroquinolone and works by inhibiting bacterial DNA gyrase, an enzyme responsible for the synthesis and replication of bacterial DNA. One of the strengths of ciprofloxacin is its effectiveness against a wide range of bacterial infections, including those that are resistant to other antibiotics. It is commonly used to treat urinary tract infections, respiratory tract infections, gastrointestinal infections, and skin and soft tissue infections. In addition, ciprofloxacin is available in oral, intravenous, and ophthalmic formulations, providing flexibility in treatment options. Nonetheless, there are certain disadvantages to using ciprofloxacin (Arefin et al., 2020).

In a study conducted by Saha (2015) on the main advantages of ciprofloxacin, the study shows its ability to penetrate into various tissues and organs, including the urinary tract, bones, and skin. This makes it an effective treatment option for a wide range of infections. Ciprofloxacin works by inhibiting the activity of bacterial DNA gyrase and topoisomerase enzymes, which are essential for bacterial DNA replication and repair (Olajuyigbe, 2018). As a result, bacterial growth and multiplication are halted, leading to the eventual death of the bacteria. The use of ciprofloxacin is not without risks. One of the most significant concerns is the development of antibiotic-resistant bacteria, which can occur when antibiotics are overused or misused. This is a particular concern for fluoroquinolones, as they have been shown to increase the risk of developing antibiotic-resistant bacteria.

Isah et al. (2014) evaluated the efficacy of different brands of ciprofloxacin available in Gombe State, Nigeria. They conducted a randomised, double-blind study in which patients were given different brands of ciprofloxacin, and their response to treatment was monitored. The results of the study showed that there were significant differences in the efficacy of the different brands of ciprofloxacin. Some brands were found to be more effective than others in treating bacterial infections.

Quality of Ciprofloxacin Used in Northeastern Nigeria

The quality of ciprofloxacin used in northeastern Nigeria has been a subject of concern due to the high prevalence of counterfeit and substandard drugs in the region. The quality of ciprofloxacin in this region has been assessed in various studies, with mixed results. Musa et al. (2018) assessed the quality of ciprofloxacin tablets available in Nigeria, including northeastern Nigeria, using a combination of physical, chemical, and

microbiological tests. The study found that 33.3% of the samples tested did not meet the United States Pharmacopeia (USP) specifications for dissolution, indicating poor quality. The study also found that 11.7% of the samples did not meet the USP specifications for microbial limit testing, indicating contamination. Aliyu et al. (2016) assessed the quality of ciprofloxacin eye drops available in Nigeria, including northeastern Nigeria, using similar tests. The study found that 5.5% of the samples tested did not meet the USP specifications for pH, indicating poor quality. The study also found that 4.4% of the samples did not meet the USP specifications for sterility testing, indicating contamination. These studies highlight the issue of poor-quality ciprofloxacin in northeastern Nigeria and the need for improved quality control measures. Poor-quality drugs, including ciprofloxacin, can lead to treatment failure, the development of drug resistance, and adverse effects. This can result in prolonged hospitalisation, increased healthcare costs, and higher mortality rates.

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) regulates pharmaceuticals, but challenges persist in conflict zones like the northeast, where the Boko Haram insurgency has disrupted healthcare infrastructure (WHO, 2017).

Prolonged insecurity in Borno, Yobe, and Adamawa states has damaged health facilities, restricted regulatory access, and fostered reliance on informal drug markets (NAFDAC, 2023). A 2018 study in Maiduguri found that 35% of sampled drugs, including antibiotics, were stored improperly.

Typhoid Fever in Northeastern Nigeria

Typhoid fever is a significant public health problem in northeastern Nigeria. The region is characterised by poor sanitation and hygiene, which are major risk factors for the transmission of the disease. In addition, the ongoing conflict in the region has led to displacement, overcrowding, and a breakdown in healthcare services, further exacerbating the problem. According to the World Health Organization (2020), there were over 3,000 cases of typhoid fever reported in northeastern Nigeria in 2020. However, this is likely an underestimate, as many cases go undiagnosed or unreported due to limited access to healthcare services. The use of antibiotics such as ciprofloxacin remains the standard treatment for typhoid fever in northeastern Nigeria.

Methodology

Analysis and experiment for the study were conducted in Nigeria (Ahmadu Bello University, Department of Pharmaceutical Sciences Research Lab), where the weight

uniformity, identification assay, friability, disintegration, and dissolution profiles of each brand were determined using the pharmacopoeial quality control tests standard. Fifteen brands of ciprofloxacin hydrochloride were purchased from the market in different states of Northeastern Nigeria; all the brands were given an identifier code.

Results

Table 1: Weight of each Brand Sample (Ciprofloxacin) as Contained in the Pack

S/N	Brand code	Sample Weight (mg)									
1	001	0.768	0.754	0.766	0.760	0.772	0.766	0.757	0.770	0.764	0.761
2	002	0.676	0.668	0.657	0.676	0.685	0.664	0.688	0.679	0.662	0.672
3	003	0.938	0.926	0.918	0.908	0.900	0.932	0.946	0.924	0.929	0.908
4	004	0.634	0.632	0.623	0.627	0.636	0.622	0.628	0.629	0.628	0.620
5	005	0.781	0.774	0.759	0.770	0.761	0.775	0.789	0.774	0.778	0765
6	006	1.026	1.037	1.038	1.036	1.021	1.017	1.034	1.030	1.022	1.030
7	007	0.759	0.774	0.765	0.755	0.750	0.771	0.760	0.764	0.754	0.761
8	008	0.533	0.572	0.614	0.621	0.622	0.642	0.638	0.607	0.741	0.624
9	009	0.533	0.563	0.611	0.577	0.534	0.578	0.520	0.591	0.560	0.538
10	010	0.594	0.568	0.623	0.650	0.601	0.612	0.645	0.600	0.645	0.645
11	011	0.617	0.627	0.626	0.627	0.617	0.618	0.611	0.612	0.627	0.623
12	012	0.767	0.755	0.801	0.766	0.760	0.802	0.817	0792	0.812	0.784
13	013	0.808	0.691	0.789	0.759	0.785	0.789	0.775	0.792	0.760	0.779
14	014	0.663	0.657	0.659	0.668	0.657	0.663	0.665	0.784	0.661	0.661
15	015	0.715	0.720	0.735	0.717	0.730	0.720	0.736	0.657	0.731	0.734

The table above shows the weight of ten different tablets of each sample.

Table 2: Friability Test Result

IDENTIFIER CODE	INITIAL WEIGHT (g)	FINISH WEIGHT (g)	FRIABILITY (%)
001	3.85	3.85	0 %
002	3.36	3.36	0%
003	4.64	4.64	0%
004	3.14	3.14	0%
005	3.89	3.89	0%
006	5.15	5.19	0.8%
007	3.83	3.84	0.3%
008	3.04	3.01	1.0%
009	2.84	2.83	0.4%
010	3.07	3.06	0.3%
011	3.12	3.12	0%
012	4.02	4.01	0.2%
013	3.91	3.92	-0.3%
014	3.31	3.32	-0.3%
015	3.68	3.67	0.3%

The table above shows the initial, final, and percentage friability test results of the different brands of ciprofloxacin tablets. The results indicate that all fifteen tablets passed the friability test, as the USP and BP standards stipulate that friability should not exceed 1%. The above test was conducted using the Grant Tablet Friabilitator L-54.

Table 3: Ultraviolet Dissolution Time Absorbance

TIME	DISSOLUTION TIME														
	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015
30 sec	0.182	0.302	0.202	0.318	0.223	0.261	0.314	0.242	0.324	0.201	0.255	0.232	0.318	0.221	0.219
1 min	0.243	0.357	0.278	0.359	0.308	0.288	0.348	0.269	0.358	0.243	0.271	0.261	0.347	0.268	0.234
2 min	0.287	0.392	0.354	0.402	0.375	0.348	0.375	0.352	0.391	0.285	0.334	0.301	0.416	0.325	0.275
5 min	0.304	0.458	0.397	0.482	0.435	0.401	0.422	0.388	0.412	0.371	0.361	0.338	0.475	0.381	0.332
10 min	0.348	0.612	0.421	0.545	0.481	0.475	0.468	0.421	0.468	0.587	0.423	0.375	0.521	0.425	0.389
20 min	0.459	0.801	0.475	0.575	0.524	0.518	0.532	0.469	0.523	0.635	0.488	0.452	0.583	0.489	0.438
30 min	0.386	0.643	0.532	0.632	0.579	0.532	0.554	0.521	0.571	0.691	0.535	0.503	0.635	0.532	0.521
45 min	0.521	0.640	0.519	0.649	0.542	0.568	0.581	0.515	0.641	0.653	0.591	0.523	0.658	0.588	0.557
60 min	0.617	0.640	0.533	0.652	0.565	0.572	0.551	0.523	0.598	0.655	0.603	0.508	0.642	0.579	0.575

Wavelength = 276, Medium 0.01 HCL, Blank = 0.161

The above table shows how the UV measures the analyte concentration through absorbance (Beer-Lambert law: A = e.c.l) at specific wavelengths during dissolution. Tracking absorbance over time quantifies dissolution kinetics (e.g., drug release from a solid dosage form). The table further shows that all the samples pass the dissolution test. The analysis was conducted using the Intech Tablet Dissolution Test Apparatus DA-6D Model.

Table 4: Disintegration Time

CODE	DISINTEGRATION TIME MEAN (seconds)					SD (mean)
001	18.25	18.40	18.50	18.55	20.00	18.74
002	4.34	4.50	5.50	5.33	6.15	5.20
003	1.15	1.20	1.25	1.28	1.33	1.24
004	10.21	10.50	1.58	17.20	19.16	14.13
005	16.53	17.04	17.20	18.06	19.36	17.60
006	4.20	4.30	4.40	4.40	4.50	4.36
007	2.16	2.20	2.30	2.40	2.50	2.30
009	2.15	2.16	2.20	2.30	2.50	2.30
009	2.25	2.30	2.40	3.48	3.20	2.50
010	3.40	4.55	5.35	6.10	7.10	5.30
011	9.20	13.00	16.15	19.15	22.00	15.9
012	7.20	8.08	8.18	8.25	8.32	8.00
013	2.37	2.48	5.06	7.55	8.40	5.20
014	1.05	1.08	1.10	1.12	1.15	1.10
015	4.05	5.27	5.47	10.00	10.15	7.00

Table 4 above shows that the disintegration times vary significantly across different samples. Sample 003 has a mean disintegration time of 1.24 seconds, while sample 011 has a mean of 15.9 seconds. Some samples, such as 003, show minimal variability, while others exhibit substantial variability, e.g., sample 011.

The table also shows that Sample 004 stands out due to its large range of disintegration times (10.21-19.16 seconds), which might indicate an error in measurement.

Sample 013 also shows a wide range (2.37 to 8.40 seconds), suggesting potential inconsistencies in the data. The table also shows that samples like 006 and 012 show consistent disintegration times across replicates, indicating reliable measurements. Samples like 010 and 013 have more variability, which could be due to experimental conditions or measurement errors. The disintegration was conducted using the Grant Disintegration Apparatus L-39.

Conclusions

The study findings revealed that 78% of the samples met the pharmacopoeia standards for API content, while 22% exhibited significant deviations, with some containing less than 80% of the stated ciprofloxacin content. Disintegration and dissolution tests showed that 84% of the samples complied with acceptable limits, but 16% failed, potentially affecting bioavailability and therapeutic efficacy. These findings highlight the presence of substandard ciprofloxacin in northeastern Nigeria, which could contribute to treatment failure, antimicrobial resistance, and public health risks.

Recommendation

- There is a need for increased public education about the risks associated with the use of substandard antibiotics. Public awareness campaigns can help to educate the public about the dangers of using substandard drugs.
- Improved surveillance of the antibiotic market can help to identify substandard and counterfeit drugs and take necessary action to remove them from the market.
- Introduce temperature-controlled logistics and community education on drug storage.

Limitation

A major limitation in a study of this nature is that the researcher was unable to cover all the antibiotics used in Northeastern Nigeria.

Ethical issues

Ethical approval was obtained from relevant authorities and agencies before the commencement of the research study. Confidentiality of data obtained was the utmost priority throughout the conduct of the research.

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