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ASSESSMENT OF QUALITY OF AMOXICILLIN BEING USED IN LUSAKA, ZAMBIA

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Background: Antibiotics remain the cornerstone of modern medicine, preventing deaths from bacterial infections that would otherwise have been fatal. However, the widespread circulation of counterfeit and substandard medicines, especially in developing countries, has emerged as a critical challenge for public health. Amoxicillin, a broad-spectrum beta-lactam antibiotic, is among the most prescribed drugs in Zambia, yet little evidence exists on the quality of brands circulating in the local market. This study assessed the quality standards of amoxicillin capsules sold in Lusaka, Zambia, with a focus on active pharmaceutical ingredient (API) content, stability, labelling, and compliance with international standards.
Methods: A descriptive cross-sectional study was conducted between August and September 2023 in the Lusaka district. Twelve brands of amoxicillin capsules were randomly collected from pharmacies, hospitals, and informal retail outlets, yielding 384 capsule samples. Analytical testing was performed using High-Performance Liquid Chromatography (HPLC) according to United States Pharmacopoeia (USP) standards. Data on labelling and packaging were also collected. Results were analysed using SPSS version 21.0.
Results: Out of the twelve brands tested, only three (25%) complied with USP specifications for API content (90–120% of the labelled claim). Nine brands (75%) contained insufficient API, ranging from 52% to 88%. Stability tests over 14 days revealed a significant decline in API content, raising concerns about degradation during storage. Labelling analysis showed that 25% of brands lacked manufacturer license numbers and 50% failed to indicate the date of manufacture. All samples contained amoxicillin as indicated, but varied greatly in concentration.
Conclusion: The study demonstrates a high prevalence of substandard amoxicillin capsules in Zambia, with major implications for antimicrobial resistance (AMR), treatment failure, and public health. Strengthening local manufacturing, enforcing Good Manufacturing Practices (GMP), and enhancing pharmacovigilance systems are crucial steps forward. This study provides baseline data for policymakers, regulators, and healthcare practitioners.

Keywords: Amoxicillin, substandard drugs, antibiotic resistance, Zambia, pharmaceutical quality, HPLC, USP compliance.

1.0 Introduction

The discovery and widespread use of antibiotics in the early 20th century marked a turning point in modern medicine, significantly reducing morbidity and mortality associated with infectious diseases (Currie et al., 2014). Among these agents, amoxicillin a semisynthetic penicillin belonging to the beta-lactam class remains one of the most extensively prescribed antibiotics for the management of respiratory, urinary, and gastrointestinal infections (Hubschwerlen, 2007). Its broad-spectrum activity, favourable oral bioavailability, and affordability have made it a cornerstone of treatment in both primary and tertiary healthcare settings. Indeed, beta-lactam antibiotics account for more than 65% of global antibiotic prescriptions (Thakuria and Lahon, 2013).

Notwithstanding their clinical importance, the effectiveness of antibiotics is increasingly compromised by the proliferation

of counterfeit and substandard medicines. Counterfeit medicines are deliberately mislabelled with respect to identity or source, whereas substandard medicines fail to meet established quality specifications due to deficiencies in manufacturing, storage, or distribution (Johnston and Holt, 2014). Both categories pose serious public health risks, including therapeutic failure, toxicity, and the acceleration of antimicrobial resistance (Newton et al., 2010). The World Health Organisation (WHO, 2017) estimates that between 10% and 30% of medicines in parts of Sub-Saharan Africa, Southeast Asia, and Latin America may be counterfeit or of poor quality. Antibiotics, antimalarials, and antiretrovirals are particularly vulnerable due to their high demand and widespread use (Cockburn et al., 2005).

Empirical studies across different regions highlight the magnitude and variability of this problem. In the Middle East, Kyriacos et al. (2008) reported that 56% of tested amoxicillin capsule samples in Lebanon, Jordan, Egypt, and Saudi Arabia failed to meet United States Pharmacopoeia (USP) standards. Similarly, Hobeika et al. (2020) identified inconsistencies in potency and labelling of amoxicillin–clavulanic acid formulations in Lebanon. Evidence from Africa presents mixed findings. Koech et al. (2020) found that nearly 40% of samples in Kenya failed USP requirements, while Fadeyi et al. (2015) demonstrated significant variability in amoxicillin quality across Ghana, Nigeria, and the United Kingdom, reflecting differences in regulatory effectiveness and supply chain integrity. Ensuring access to safe, effective, and high-quality essential medicines is a fundamental component of resilient healthcare systems (World Health Organisation [WHO], 2017; Wirtz et al., 2017; Zulu, 2017). In Zambia, this objective is central to national health policy; however, challenges persist in maintaining the quality of imported pharmaceuticals. Amoxicillin is among the most frequently prescribed antibiotics in the country, yet anecdotal reports from healthcare professionals and patients suggest variability in therapeutic effectiveness. Despite these concerns, there is a notable scarcity of published data evaluating the quality of amoxicillin formulations available on the Zambian market. This study, therefore, aims to address this evidence gap by systematically assessing the quality of amoxicillin capsule brands available in Lusaka, Zambia. Specifically, it evaluates their active pharmaceutical ingredient (API) content, stability, and compliance with labelling and packaging requirements in accordance with standards set by the Regulatory Authority. The findings are expected to provide critical evidence to support regulatory decision-making, enhance pharmaceutical quality assurance, and contribute to efforts aimed at mitigating antimicrobial resistance.

2.0 Methodology

This descriptive cross-sectional experimental-based study utilised both systematic and random sampling techniques to collect amoxicillin capsules from pharmacies, health facilities, and informal vendors in Lusaka between August and September 2023. A total of twelve brands were included, with 32 capsules sampled per brand, resulting in an overall sample size of 384 capsules. Purposive sampling was subsequently applied to select capsules for laboratory analysis.

Of the sampled products, the majority originated from India (n = 192, 50%), followed by the United Kingdom (n = 64, 16.7%) and Kenya (n = 64, 16.7%). Smaller proportions were sourced from South Africa (n = 32, 8.3%) and Dubai (n = 32, 8.3%). Sample quality was evaluated using five parameters: (i) physical appearance, (ii) labelling compliance, (iii) packaging material, (iv) presence of active ingredient, and (v) percentage content of active ingredient, as outlined in the United States Pharmacopoeia convention (Convention 2017). High-Performance Liquid Chromatography (HPLC) was employed for quantitative analysis. HPLC remains the gold standard for assessing drug potency and purity due to its high sensitivity and reproducibility (Moldoveanu & David, 2013). Table 1 below shows the supplementary HPLC parameters for amoxycillin analysis.

Table 1: Supplementary Table S1: HPLC System Parameters for Amoxicillin Analysis

Parameter	Specification	Justification
HPLC System	UV–Vis HPLC system (e.g., Agilent 1260 Infinity or equivalent)	Widely validated analytical platform
Column Type	Reverse-phase C18 column	Suitable for moderately polar compounds like amoxicillin
Column Dimensions	250 mm × 4.6 mm, 5 µm particle size	Standard for pharmaceutical analysis
Mobile Phase Composition	Phosphate buffer (pH 4.5): Acetonitrile (95:5 v/v)	Ensures optimal peak resolution and stability
Flow Rate	1.0 mL/min	Balances resolution and run time
Injection Volume	20 µL	Ensures adequate sensitivity and reproducibility
Detection Wavelength	230 nm	Corresponds to the maximum absorbance of amoxicillin
Column Temperature	Ambient (25°C) or controlled at 30°C	Maintains consistency in retention time
Run Time	10 minutes	Allows complete elution of the analyte
Retention Time	~4–6 minutes (amoxicillin peak)	Confirms analyte identification
System Suitability Criteria	%RSD < 2%, tailing factor < 2	Ensures system performance
Diluent	Mobile phase	Prevents peak distortion
Filtration	0.45 µm membrane filter	Removes particulates

The assay was carried out using an MRC HPLC System consisting of an Ultra-Violet visible Detector L-2420, Column oven L-2300, an auto sampler/injector L-2200, and a pump L-2130. The MRC Computer data system software generated the visual view of the monographs/calibration curves of each compound. Data were analysed using SPSS version 21.0. Ethical approval was obtained from Levy Mwanawasa Medical University Research Ethics Committee. No human participants were involved. The stability study parameters were done according to the conditions outlined in Table 2 below;

Table 2: Supplementary Table S2: Stability Testing Conditions

Parameter	Condition	Rationale
Temperature	25 ± 2°C	Represents ambient storage conditions in Lusaka
Relative Humidity	60 ± 5% RH	Standard condition for stability studies (ICH guidelines)
Light Exposure (Protected Group)	Stored in original packaging, away from light	Simulates proper storage conditions
Light Exposure (Exposed Group)	Exposed to fluorescent laboratory light (~500–1000 lux)	Assesses photodegradation risk
Sunlight Exposure	None	Avoids uncontrolled variability
Storage Environment	Well-ventilated laboratory	Prevents moisture accumulation
Monitoring Equipment	Digital thermometer and hygrometer	Ensures accuracy of conditions
Study Duration	14 days	Short-term stability assessment
Sampling Time Points	Day 0 and Day 14	Enables comparison over time

3.0 Results

A total of 384 amoxicillin capsule samples, representing 12 different brands, were evaluated in this study. The samples were obtained from a variety of sources across Lusaka, including registered pharmacies, health facilities, and informal vendors, to ensure a broad representation of products available to the public.
Table 3 presents the detailed general characteristics of the sampled amoxicillin capsules, including information on brand origin, source of purchase, and distribution across the different sampling sites. This overview provides important context for understanding the diversity and potential variability in the quality of amoxicillin products circulating within the local market

Table 3: Detailed information on amoxicillin capsules included in the study

SN	Date Purchased	Place	Condition of the Dosage Form	Name of drug	API, as indicated by the manufacturer	Date of manufacture	Date of expiry	License No.
1	26.09.23	Kamwala South	Good/Intact	AMX 1001	Amoxicillin trihydrate capsules BP 250mg	Apr-22	Mar-24	
2	20.09.23	Inter City Bus Terminus	Good/Intact	AMY 1002	Amoxicillin trihydrate capsules BP 250mg	Jan-23	Dec-24	285/014
3	20.09.23	Chawama Township	Good/Intact	AMX 1003	Amoxicillin trihydrate capsules BP 250mg	Sep-22	Aug-25	200/004
4	11.09.23	Great East Park Mall	Good/Intact	AMX 1004	Amoxicillin trihydrate BP 500mg		Oct-25	PL 43461/0002
5	12.09.23	Arcades Shopping Mall	Good/Intact	AMX 1005	Amoxicillin trihydrate BP 250mg		Oct-24	0001/O/21-BC/001/I
6	14.09.23	Great East Park Mall	Good/Intact	AMX 1006	Amoxicillin trihydrate BP EQ. Amoxicillin 500mg capsules		Jul-25	X/20.1.2/197

Continuation of Table 3

7	06.09.23	Lumumba Bus Station.	Good/Intact	AMX 1007	Amoxicillin trihydrate BP EQ. amoxicillin 250mg	May-22	Apr-25	075/096
8	26.08.23	Zanimuone – Great North Road	Good/Intact	AMX 1008	Amoxicillin trihydrate BP EQ. Amoxicillin 250mg		Sep-25	
9	25.08.23	Meanwood/ Mutumbi	Good/Intact	AMX 1009	Amoxicillin trihydrate BP EQ. amoxicillin 250mg		Jul-25	BD/25
10	24.08.23	Mutendere East	Good/Intact	AMX 1010	Amoxicillin trihydrate BP EQ. Amoxicillin 250 mg capsules		Sep-25	
11	22.08.23	Matero-Chingwere	Good/Intact	AMX 1011	Amoxicillin trihydrate BP EQ. Amoxicillin 250mg capsules	May-22	Apr-24	G1174
12	21.08.23	Matero Township	Good/Intact	AMX 1012	Amoxicillin trihydrate BP EQ Amoxicillin 250mg capsules	Jul-22	Jun-25	KTK/28A/67 1/2007

Analysis revealed that 75% (as shown in Table 4 below) of the brands tested contained less than 90% of the labelled API, rendering them non-compliant with USP standards. Only three brands (25%) met the required pharmacopeial limits.

Table 4: Proportions of Active Pharmaceutical Ingredient (API) in the sampled brands of amoxicillin

BRAND NAME	PRESENCE OF API	PEAK AREA	% CONCENTRATION
AMX 1001	Present	35948.2	66%*
AMY 1002	Present	56285.8	99%
AMX 1003	Present	50526.6	90%
AMX 1004	Present	43562	78%*
AMX 1005	Present	42886.3	77%*
AMX 1006	Present	32224.5	60%*
AMX 1007	Present	47278.9	84%*
AMX 1008	Present	51189.3	91%
AMX 1009	Present	48888.2	87%*
AMX 1010	Present	49697.8	88%*
AMX 1011	Present	27486	52%*
AMX 1012	Present	38139.4	69%*

Products with a star '*' indicate that the API content is below the USP specification.

Stability tests indicated (as shown in Table 5 below) that API content declined significantly over 14 days of storage at ambient conditions. Labelling analysis showed 25% lacked manufacturer license numbers, while 50% omitted the date of manufacture

Table 5: Active pharmaceutical ingredient and dissolution test results for the stability of amoxicillin capsules

Sample code	Country of origin	Labelled active ingredients (mg/5 ml)	Chemical content as % label claim (RSD) Day 0	Day 14
AMX 1001	United Kingdom	250	93.56 (0.26)	90.12(0.63)
AMY 1002	DUBAI	250	98.56 (1.36)	96.13 (0.2)
AMX 1003	INDIA	250	99.56 (0.25)	95.48 0.67)
AMX 1004	INDIA	250	101.18 (0.96)	96.70(0.19)
AMX 1005	INDIA	250	98.56 (0.68)	96.24(0.52)
AMX 1006	INDIA	250	95.60 (1.12)	90.11(0.64)
AMX 1007	INDIA	250	104.21 (0.97)	100.08(1.21)
AMX 1008	INDIA	250	102.97 (0.77)	95.32 (0.26)
AMX 1009	KENYA	250	101.58 (0.33)	95.71 (0.36)
AMX 1010	SOUTH AFRICA	500	100.22 (0.21)	97.03 (1.35)
AMX 1011	UNITED KINGDOM	250	103.91 (1.05)	96.79 (0.33)
AMX 1012	UNITED KINGDOM	250	93.56 (0.26)	90.12(0.63)

Figure 1 and Table 6 represent the linear regression analysis of the calibration curve, where it represents the slope of the equation with the value of 611.94, the intercept -4275.98 and correlation coefficient R^2 =0.9684. With the standard error of 1.37. The data obtained are statistically significant with a p-value of 0.0024.

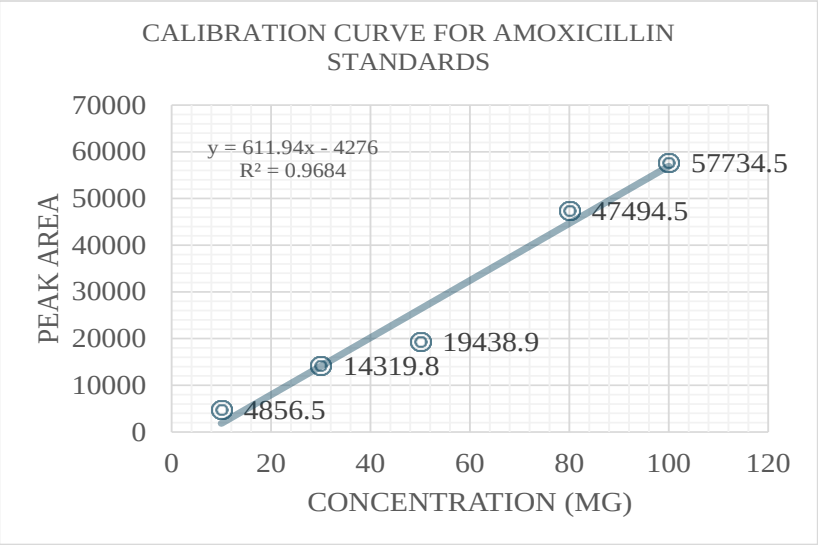

Figure 1: Showing the correlation between concentration and peak area.

Table 6: Showing the regression analysis, with correlation coefficient, slope and intercept obtained from linear regression

SUMMARY OUTPUT								
Regression Statistics								
Multiple R	0.984053165							
R Square	0.968360633							
Adjusted R-Square	0.957814177							
Standard Error	4658.007875							
Observations	5							
ANOVA								
	df	SS	MS	F	Significance F			
Regression	1	1992191231	1992191231	91.81858325	0.002411593			
Residual	3	65091112.08	21697037.4					
Total	4	2057282343						
	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-4275.984962	4028.8949	-1.0613295	0.366412027	-17097.72665	8545.756726	-17097.72665	8545.756726
X Variable 1	611.941203	63.86227745	9.58220138	0.002411593	408.7029341	815.1794719	408.7029341	815.1794719

Figure 2 illustrates representative monographs obtained for both the amoxicillin reference standard and the test sample. The first profile corresponds to the amoxicillin reference standard and serves as the benchmark for identification and comparison. The second profile represents a typical monograph of an amoxicillin capsule sample analysed in this study.

Comparing these profiles allows for assessment of similarity in key analytical characteristics, thereby supporting confirmation of the presence and integrity of the active pharmaceutical ingredient in the sampled products.

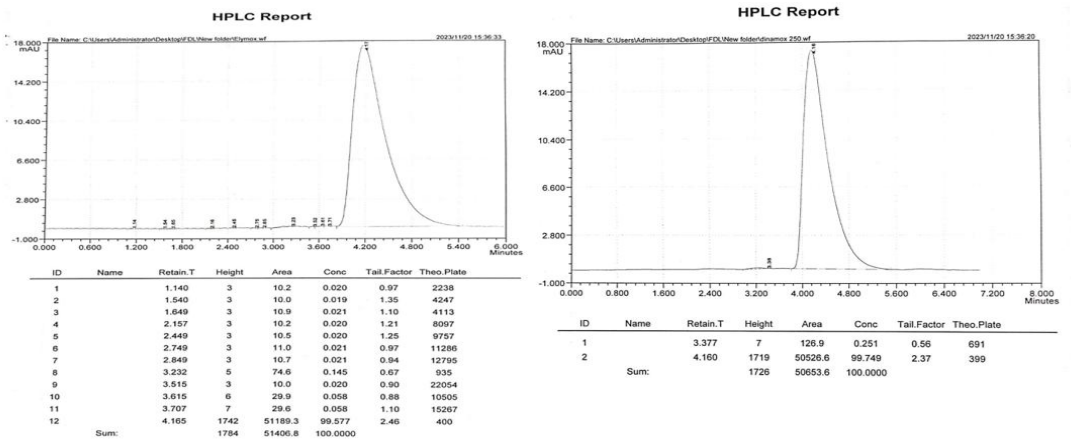

Figure 2: Typical monographs: First figure showing amoxicillin reference standard monograph, while the second one shows amoxicillin sample monograph

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4.0 Discussion

This study demonstrates an alarmingly high prevalence of substandard amoxicillin capsules in Zambia, with three-quarters of the tested brands failing USP standards. These findings align with results from Kenya (Koech et al., 2020) and the Middle East (Kyriacos et al., 2008 suggesting regional differences in regulatory enforcement and supply chains.

The implications of substandard antibiotics are far-reaching. They contribute to treatment failure, prolong illnesses, increase healthcare costs, and accelerate the spread of antimicrobial resistance (Newton et al., 2010). In Zambia, where antibiotics are frequently used empirically, the presence of ineffective formulations could undermine national efforts to curb infectious diseases such as pneumonia, tuberculosis, and diarrheal infections. The observed decline in API stability after 14 days also raises concerns about poor storage conditions and inadequate packaging. This finding is consistent with global evidence that high humidity and temperature contribute to drug degradation in tropical countries (Delepierre et al., 2012).

According to the USP (2018), Amoxicillin Capsules should contain the equivalent of Not Less Than 90.0% and Not More Than 120.0% of the labelled amount of amoxicillin. Table 4 presents the proportion of sampled amoxicillin capsule formulations whose active ingredients are either within or outside the Pharmacopoeia limit as specified in the official monographs of the United States Pharmacopoeia (USP). In all, 3 out of the 12 brands (25%) of the samples studied contained active ingredients within the appropriate limits. In contrast, 9 out of 12 (75%) had active ingredients outside the set pharmacopoeia limit and were therefore non-compliant with the USP (2018) specifications for percentage content. In general, most of the amoxicillin capsules sampled ($n = 192$, 50%) were from India, while the rest originated from the UK ($n = 64$, 16.7%), Kenya ($n = 64$, 16.7%), South Africa ($n = 32$, 8.3%), and Dubai ($n = 32$, 8.3%).

The failure of certain amoxicillin brands to meet pharmacopeial standards in this study can be attributed to multiple interrelated factors, particularly linked to manufacturing quality, supply chain integrity, and storage conditions.

4.1 Inadequate Active Pharmaceutical Ingredient (API) Content)

The primary reason for failure was insufficient API levels. In your study, 75% of brands contained only 52%–88% of the labelled amount, below the acceptable 90–120% range. This suggests poor formulation practices, inaccurate dosing during manufacturing and possible intentional substandard production. Substandard API levels are widely reported in low- and middle-income countries due to weak regulatory enforcement (Newton et al., 2010).

4.2 Poor Manufacturing Standards (GMP Non-compliance)

Many failing brands are likely produced under inadequate Good Manufacturing Practices (GMP). The study shows that 50% of samples originated from India, and several of these fell below acceptable limits. This aligns with global findings that variability in regulatory oversight across countries contributes to inconsistent drug quality (Fadeyi et al., 2015).

4.3 Weak Regulatory Oversight in Exporting and Importing Countries

Countries with less stringent pharmaceutical regulation or enforcement tend to export more substandard products. In this study, failing brands were largely from India (the majority of samples and failures) and Kenya and Dubai (some non-compliant samples). In contrast, some products from the United Kingdom and South Africa showed relatively better compliance, reflecting stronger regulatory systems.

4.4 Degradation Due to Poor Storage Conditions

The study demonstrated a significant decline in API content over 14 days, indicating instability. This suggests exposure to heat and humidity (common in tropical climates like Zambia) and inadequate packaging or transport conditions. Drug degradation under such conditions is well documented (Delepierre et al., 2012).

4.5 Poor Labelling and Traceability

A significant proportion of failing brands lacked Manufacturer license numbers (25%) and Manufacturing dates (50%). This indicates weak quality assurance systems and possible entry of unregulated or falsified medicines into the supply chain (Cockburn et al., 2005).

5.0 Limitations of the Study

Sampling from a single city (Lusaka)
The cross-sectional design
The short stability observation window of 14 days, and
The absence of patient outcome data.

6.0 Conclusion and Recommendations

This study provides the first empirical evidence of substandard amoxicillin formulations in Zambia. With only 25% of brands meeting pharmacopeial standards, urgent action is needed to protect patients and public health. Recommendations include: (i) strengthening local manufacturing under strict GMP guidelines; (ii) intensifying pharmacovigilance and market surveillance by the regulatory agencies; (iii) enforcing stringent labelling and packaging standards; and (iv) fostering collaboration with international regulatory agencies. Sustained efforts are necessary to ensure that Zambians have access to safe, effective, and high-quality medicines.

Disclaimer

The findings of this study are based on samples obtained from specific batches and may not be representative of all batches produced by the manufacturers.

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