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Quality Assessment of Antimicrobial Drug Products Sold by Unlicensed Vendors in Kisumu County, Kenya

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The quality of antimicrobial drugs is critical for ensuring patient safety and combating antimicrobial resistance (AMR). The illicit sale of medicines by unlicensed vendors, or "hawking," exposes these products to uncontrolled environmental conditions that can compromise their stability, potency, and overall quality. This study was designed to evaluate the quality of select antimicrobial drug products sold by unlicensed vendors in Kisumu County, Kenya. A cross-sectional survey was conducted in open air markets of Ahero, Sondu, Katito, Awasi, and the Kisumu Bus Station, all located within Kisumu County, Kenya. A total of 25 antimicrobial samples comprising amoxicillin, cotrimoxazole, doxycycline, ampicillin/cloxacillin, and phenoxymethylpenicillin were purchased using the convenience sampling approach. The samples were subjected to quality control tests for identification, weight variation, assay, dissolution and microbial load in accordance to the United States Pharmacopeia (USP) 2024 specifications. Out of the 25 samples analyzed, 23 (92%) complied with all USP (2024) specifications, while two ampicillin/cloxacillin samples were found to be substandard. One sample failed in uniformity of weight and the other assay of ampicillin. Despite the unsanitary sale conditions in the open-air markets, all samples complied with the microbial load test as they were blister-packed. The presence of substandard antimicrobial products in the informal market in Kisumu County poses a significant public health risk, potentially leading to treatment failure and exacerbating the development of AMR. These findings underscore the urgent need for strengthened regulatory enforcement to curb the illegal sale of medicines and for public education on the dangers of procuring medicines from unauthorized sources.

Keywords: Substandard medicines, antimicrobial resistance, quality control, informal sector, high performance liquid chromatography.

INTRODUCTION

Antimicrobials are cornerstone medicines used to treat infections, and their discovery has revolutionized modern medicine, saving countless lives.[1] However, their effectiveness is threatened by the global rise of antimicrobial resistance (AMR). A key contributor to AMR is the circulation and use of substandard and falsified medicines, which may contain sub-therapeutic amounts of the active pharmaceutical ingredient (API).[2]

In many low- and middle-income countries (LMICs), illicit sale of pharmaceuticals by unlicensed street vendors ("hawking") is a documented channel for accessing healthcare products.[3–5] This system facilitates access to prescription-only medications, including antibiotics, in the absence of a prescription,

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which fosters practices of self-medication and irrational use.[4] Anecdotal reports indicate that drug hawking is prevalent in major market centres within Kisumu County, Kenya.

This unregulated practice presents a dual threat to public health. Firstly, it promotes irrational antibiotic use, as vendors often lack the requisite medical knowledge for proper dispensing. [6,7] Secondly, it compromises the physical, chemical, and microbiological stability of the drugs. Medicines sold in open-air markets are exposed to harsh environmental conditions, such as high temperatures, humidity, and direct sunlight, which can accelerate their degradation.[8] For instance, β-lactam antibiotics like amoxicillin and ampicillin are particularly susceptible to hydrolysis, where the β-lactam ring is cleaved, leading to a loss of antibacterial efficacy.[9] This chemical degradation results in reduced potency, potentially leading to sub-therapeutic dosing, treatment failure, and the selection of resistant microbial strains.

Therefore, this study was designed to investigate the quality of commonly hawked antimicrobial solid dosage forms in Kisumu County. Through quality control tests, the study aimed to determine whether these products meet established pharmacopeial specifications.

MATERIALS AND METHODS

Sample Collection

A cross-sectional study was conducted between September 2023 and January 2024. A convenience sampling method was used to purchase different brands of antibiotics from unlicensed vendors in open-air markets previously identified through a reconnaissance survey. The sampling sites included Kisumu Main Bus Terminal, Ahero, Sondu, Katito, and Awasi markets in Kisumu County, Kenya. A risk-based approach was used to select vendors, targeting those with a diverse stock of medicines.

Solid oral dosage forms of amoxicillin, phenoxy-methylpenicillin, doxycycline, ampicillin/ cloxacillin, and sulfamethoxazole/ trimethoprim (cotrimoxazole) were purchased using a mystery shopper approach. A minimum of 50 tablets or capsules per product batch were acquired to ensure sufficient quantity for testing. Paediatric formulations were not encountered and thus were not included. Samples were coded and transported to the laboratory under ambient conditions. Key product information, including brand name, batch number, manufacturing date, and expiry date, were recorded (Table 1).

Reagents, materials and solvents

Analytical-grade solvents namely triethylamine (Finar, Gujarat, India), methanol, acetonitrile (Rankem, Mumbai, India) and HPLC water (MEDS, Nairobi, Kenya) were used as to prepare mobile phases. Mobile phases were prepared using the phosphate buffers salts, (K_2HPO_4 and KH_2PO_4) (Merck, Darmstadt, Germany), glacial acetic acid (Finar, Ahmedabad, India), and edetate disodium (Finar, Ahmedabad, India). Buffer pH was adjusted using sodium hydroxide from Loba Chemie (Mumbai, Maharashtra, India). In the dissolution tests, phosphoric acid (Merck, Darmstadt, Germany) and hydrochloric acid (Rankem, Mumbai, India) were utilised.

Tryptone soya agar (TSA) and Sabouraud dextrose agar (SDA) media were used for culturing bacteria and fungi respectively. The TSA and SDA plates were incubated at 30 to 35 °C and 20 to 25 °C, respectively and colony forming units (CFUs) were quantified after 3–5 days. The positive controls consisted of *Candida albicans* (fungus) and *Escherichia coli* (bacteria). The working chemical reference standards (CRS) used were kind donations from the Drug Analysis & Research Unit (DARU), University of Nairobi and National Quality Control Laboratory (NQCL), Ministry of Health, Kenya.

Instrumentation

A Merck Hitachi High-Performance Liquid Chromatography (HPLC) system equipped with a photodiode array (PDA) detector was used for identification and assay. Chromatographic separation was achieved using either an Octylsilane-C8 or RP-18 column of dimensions 4.6 × 250 mm and particle size 5 µm. Dissolution testing was performed using a Labinda DS 8000 dissolution tester, and quantification was done with a UV-1800 spectrophotometer (Shimadzu, Tokyo, Japan).

Table 1: Details of Antimicrobial Samples Collected from Unlicensed Vendors in Kisumu County

Sample code	Active pharmaceutical ingredient(s)	Dosage form	Dosage strength (mg)	Batch Number	Expiry Date
Pen V 1	Phenoxymethylpenicillin	Tablet	250	230678	26-Mar
Pen V 1	Phenoxymethylpenicillin	Tablet	250	200344	24-Dec
AMO1	Amoxicillin	Capsule	500	706230345	26-Mar
AMO2	Amoxicillin	Capsule	500	MX463M06	25-Aug
AMO3	Amoxicillin	Capsule	500	223131609	25-Jun
AMO4	Amoxicillin	Capsule	500	84636	26-Aug
AMO5	Amoxicillin	Capsule	500	220652	25-Nov
AMO6	Amoxicillin	Capsule	250	2209286	26-Mar
AMO7	Amoxicillin	Capsule	250	220601	26-Jan
D1	Doxycycline	Capsule	100	220110	26-Mar
D2	Doxycycline	Capsule	100	230609	25-Jan
D3	Doxycycline	Capsule	100	B5812109E	26-Jun
S1	Cotrimoxazole	Tablet	800/160	B230086	26-May
S2	Cotrimoxazole	Tablet	800/160	BN83380	25-Feb
S3	Cotrimoxazole	Tablet	800/160	B80772	24-Dec
S4	Cotrimoxazole	Tablet	800/160	B5809924	25-Jan
S5	Cotrimoxazole	Tablet	800/160	B5812109	26-Apr
S6	Cotrimoxazole	Tablet	800/160	B5809539	25-Jan
S7	Cotrimoxazole	Tablet	800/160	B5810051	24-Dec
S8	Cotrimoxazole	Tablet	800/160	B58099224	25-Feb
S9	Cotrimoxazole	Tablet	800/160	B5809947	25-Feb
S10	Cotrimoxazole	Tablet	800/160	B5709946	24-Oct
AMP1	Ampicillin/cloxacillin	Capsule	250/250	2308250	26-Jul
AMP2	Ampicillin/cloxacillin	Capsule	250/250	260509	26-Mar
AMP3	Ampicillin/cloxacillin	Capsule	250/250	2305005	26-Apr

Specifications

All quality control tests were performed according to the methods described in the official monograph for each respective drug product in the United States Pharmacopeia (USP, 2024). System suitability tests (SST) were conducted prior to each chromatographic run for verification of the analytical system.

Identification: All drug product samples were identified by comparing the retention time of the major peak in the sample chromatogram with that of the corresponding CRS. Additionally, for amoxicillin, doxycycline, and phenoxymethylpenicillin, identification was complementarily confirmed by comparing the UV absorption spectrum of the sample with that of the corresponding CRS.

Weight variation: The weight variation test was performed by individually weighing 20 randomly selected tablets or capsules from each sample. The average weight was calculated, and the percentage deviation of each individual unit from the average determined.

Assay: The content of the API in each sample was determined using the validated HPLC method specified in the USP (2024). Standard and sample solutions were prepared as prescribed in the USP (2024), chromatographed and the API content was calculated as a percentage of the label claim. Triplicate determinations were carried out and subjected to statistical analysis for precision.

Dissolution: The release of API from the dosage form was assessed using the specified dissolution apparatus, medium and rotation speed in accordance with the USP (2024). Samples were withdrawn at the designated time points, and the amount of dissolved drug was quantified by UV spectrophotometry or HPLC using validated and verified analytical methods.

Microbial Load Test: A prepared dilution of each sample was plated on TSA (for bacteria) and SDA (for fungi) and incubated at 30-35°C for 3-5 days and 20-25°C for 5-7 days, respectively. The number of colony-forming units (CFU) was determined as total aerobic microbial count (TAMC) and total yeast and mold count (TYMC).

RESULTS AND DISCUSSION

Sample Profiles

A total of 25 antimicrobial samples were collected and analyzed. The most frequently encountered antimicrobials were cotrimoxazole (n=10, 40%) and amoxicillin (n=7, 28%). Notably, 4 of the 10 cotrimoxazole samples (40%) were labeled as property of the Kenya Medical Supplies Authority (KEMSA), indicating potential diversion from the public health supply chain. Such diversion of government procured medicines raises concerns about the integrity of the public health supply chain.

Easy access to medicines in open-air markets promotes self-medication within communities. Furthermore, it highlights the inadequacies of regulatory systems intended to ensure that antimicrobial medications are dispensed solely by authorized personnel in approved locations, following prescriptions from licensed prescribers. In this ecosystem, patients may sell their own prescribed medicines or to other hawkers due to economic pressures. This denotes medication non-compliance, which may result in treatment failure and exacerbate antimicrobial resistance due to sub-therapeutic dosing. This situation underscores the critical need for stringent regulatory measures to prevent the diversion of antimicrobials and ensure adherence to proper dispensing practices. Implementing educational initiatives for both dispensers and the public can significantly enhance awareness of appropriate antimicrobial use and the dangers of self-medication. Moreover, the challenge of drug diversion and self-medication is compounded by a lack of public awareness regarding the implications of inappropriate antimicrobials use. Previous studies have demonstrated that a significant portion of the population remains uninformed about the risks of AMR and the proper use of antimicrobials.[10,11] Such ignorance not only perpetuates the cycle of self-medication but also contributes to the alarming rise of resistant strains of bacteria, as individuals often resort to leftover antibiotics or illicit purchase without prescriptions. Consequently, enhancing

community education on the dangers of self-medication and the importance of adhering to prescribed treatments is imperative. Such initiatives could be integrated into public health campaigns, focusing on the role of antibiotics in treating bacterial infections and the consequences of misuse, thereby fostering a more informed public capable of making better health decisions.

Quality control results

The results of the quality control tests performed on the samples are summarized in Table 2. Overall, 23 of the 25 samples (92%) complied with all USP (2024) specifications for the tests conducted. All 25 samples were positively identified as containing the correct API. The retention times and/or UV spectra of the samples matched those of their respective CRS (Figure 1).

Twenty-four of the 25 samples complied with the USP requirements for weight variation, with one ampicillin/cloxacillin sample (AMP1) failing this test. This manufacturing defect can lead to inconsistent dosing, exposing patients to either sub-therapeutic or potentially toxic drug levels. Additionally, all the 25 drug product samples passed the tests for dissolution and microbial load, thus meeting the required pharmacopeial specifications.

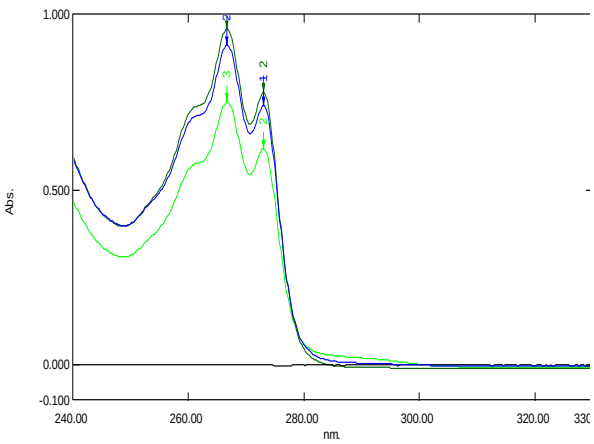
On the other hand, twenty-four samples complied with the USP specifications for API content (90.0-110.0% of label claim). One ampicillin/cloxacillin sample (AMP3) failed the assay of ampicillin, which was found to be 86.4% of the stated amount. The presence of one non-compliant sample raises concerns about the consistency of pharmaceutical manufacturing practices or as a result of product degradation in the market consequent to excursion from recommended storage conditions. This not only jeopardizes patient safety but also contributes to the broader issue of antimicrobial resistance, which is exacerbated by the misuse of antimicrobials in self-medication scenarios.

The presence of substandard products in open-air markets can lead to inadequate treatment outcomes, encouraging the development of resistant strains of bacteria that complicate infections and increase healthcare costs.[12] Moreover, the regulatory challenges faced by national medicine regulatory authorities (NMRAs), such as those highlighted in studies from other regions, suggest a pressing need for enhanced training and resources for inspectors and quality assurance personnel to ensure compliance with good manufacturing practices.[13] As evidenced by the low compliance rates for some GMP parameters in Afghanistan, a similar approach could be beneficial in Kenya, where systematic quality control measures are essential to safeguard public health and restore trust in the pharmaceutical supply chain. [14] This also calls for improved regulatory frameworks and consistent enforcement to enhance the quality of pharmaceuticals available to the public.

All the samples analyzed complied with microbial load specifications, despite exposure to open market and often unsanitary conditions in the sampling sites. This could be attributed to the inherent antimicrobial nature of the products themselves or the protective effect of blister packing. Moreover, the use of packaging of the antibiotics further provided additional microbial stability even in the unsanitary sale conditions in open air markets. However, this does not negate the risks associated with chemical and physical degradation from improper storage.

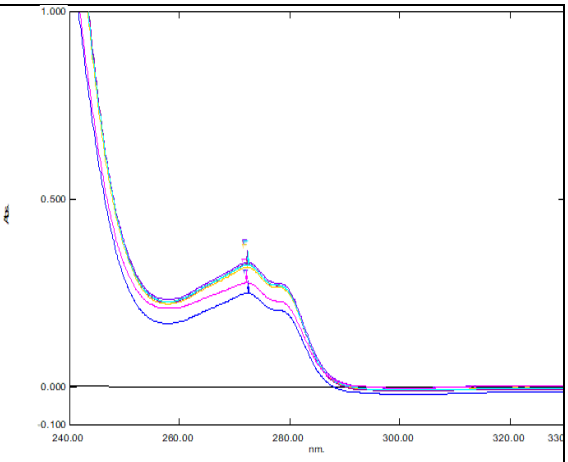
The prevalence of amoxicillin and cotrimoxazole in the samples collected reflects their common use (and hence misuse) for treating respiratory, urinary tract, and opportunistic infections in the Kenyan context. Easy accessibility of these drugs from unlicensed vendors encourages self-medication and irrational use, further fueling the AMR crisis.

The present study employed convenience sampling, hence the results obtained may not accurately reflect the situation in Kisumu County or other regions in Kenya. The scope was limited to five antimicrobial agents presented in solid dosage forms. A more extensive, nationwide post-market surveillance study employing a randomized sampling strategy is warranted to understand the full extent of this problem. Additionally, separate studies to elucidate the root causes of drug ‘hawking’ in Kisumu County should be conducted and appropriate regulatory, policy and practice changes instituted to remedy this menace.



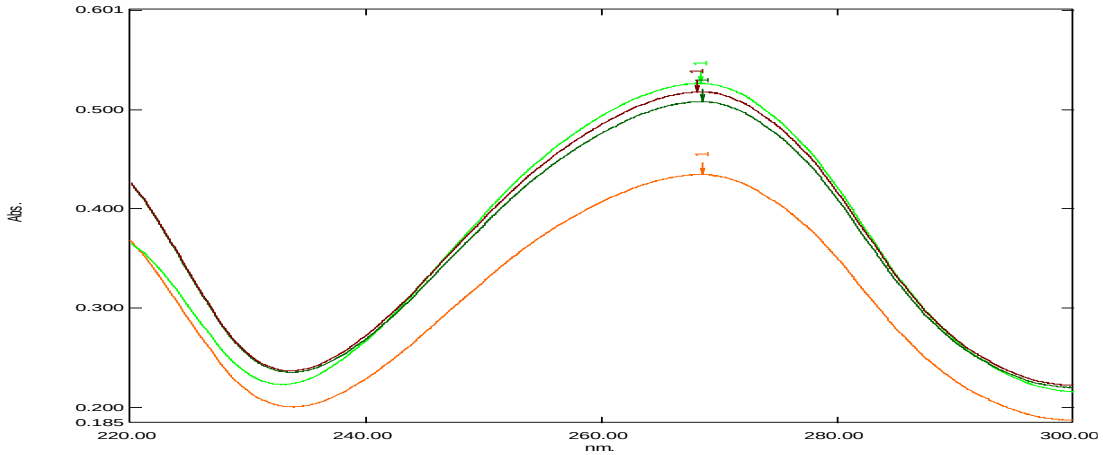
Phenoxymethyl penicillin CRS and tablet samples

Green = Standard Blue = Pen V1 sample
Black = Pen V 2



Amoxicillin CRS and samples

Blue - Standard, Grey -AMO1, Green- AMO2, Purple-AMO3, Orange-AMO4, Pink-AMO5, Violet – AMO6, light blue -AMO7



Doxycycline CRS and samples. Standard= green, D1= maroon, D2= red, D3= Grey

Figure 1: Representative Overlaid UV-Vis Spectra for Identification of Samples against their Chemical Reference Standards (CRS).

Table 2: Summary of Quality Control Test Results for Antimicrobial Samples

Brand code		Uniformity of weight	Dissolution (% LC)	Assay (% LC)
Pen V 1		Complies	103 (Complies)	104.9 (Complies)
Pen V 2		Complies	101 (Complies)	101.2 (Complies)
Amo 1		Complies	86 (Complies)	97.8 (Complies)
Amo 2		Complies	102 (Complies)	98.5 (Complies)
Amo 3		Complies	100 (Complies)	97.2 (Complies)
Amo 4		Complies	100 (Complies)	99.5 (Complies)
Amo 5		Complies	99 (Complies)	96.6 (Complies)
Amo 6		Complies	103 (Complies)	100.6 (Complies)
Amo 7		Complies	101 (Complies)	95.8 (Complies)
Doxy1		Complies	95 (Complies)	100.9 (Complies)
Doxy2		Complies	101 (Complies)	100.8 (Complies)
Doxy3		Complies	94 (Complies)	102.7 (Complies)
S1	T	Complies	100 (Complies)	97.8 (Complies)
	S	Complies	99 (Complies)	94.3 (Complies)
S2	T	Complies	100 (Complies)	97.4 (Complies)
	S	Complies	99 (Complies)	93.0 (Complies)
S3	T	Complies	95 (Complies)	98.0 (Complies)
	S	Complies	97 (Complies)	93.0 (Complies)
S4	T	Complies	98 (Complies)	97.8 (Complies)
	S	Complies	95 (Complies)	94.3 (Complies)
S5	T	Complies	100 (Complies)	96.1 (Complies)
	S	Complies	101 (Complies)	93.7 (Complies)
S6	T	Complies	97 (Complies)	95.7 (Complies)
	S	Complies	99 (Complies)	103.5 (Complies)
S7	T	Complies	101 (Complies)	102.0 (Complies)
	S	Complies	100 (Complies)	96.2 (Complies)
S8	T	Complies	101 (Complies)	102.0 (Complies)
	S	Complies	100 (Complies)	96.2 (Complies)
S9	T	Complies	103 (Complies)	104.7 (Complies)
	S	Complies	100 (Complies)	97.4 (Complies)
S10	T	Complies	98 (Complies)	96.8 (Complies)

Brand code		Uniformity of weight	Dissolution (% LC)	Assay (% LC)
	S	Complies	93 (Complies)	93.1 (Complies)
AMP1	A	**Does not comply**	103 (Complies)	98.0 (Complies)
	C	**Does not comply**	100 (Complies)	100.7 (Complies)
AMP2	A	Complies	88V (Complies)	97.2 (Complies)
	C	Complies	99 (Complies)	96.8 (Complies)
AMP3	A	Complies	81 (Complies)	86.4 (**Does not comply**)
	C	Complies	96 (Complies)	99.6 (Complies)

A = Ampicillin, C = cloxacillin, LC – label claim, S – sulphamethoxazole, T - trimethoprim. Acceptance criteria: Uniformity of weight - USP <905>; Dissolution - ≥80% (varies by monograph); Assay - 90.0–110.0% (varies by monograph).

CONCLUSION

This study provides evidence on the quality of antimicrobials circulating in the informal market in Kisumu County, Kenya. While the majority (92%) of the analyzed samples met USP specifications, the two substandard products (8%) found raise alarm of attendant public health threats. Poor-quality antibiotics poses a direct hazard to patient safety and global efforts to contain AMR. The diversion of public-sector medicines into this unregulated market further complicates the issue.

Based on this study's findings, a multi-faceted approach is recommended to improve medicine accessibility and safety. This approach includes strengthening regulatory enforcement at national and county levels to curb illegal medicine sales through enhanced surveillance and stricter penalties. Simultaneously, comprehensive public awareness campaigns are crucial to educate citizens about the dangers of unauthorized medicine sources and the importance of professional healthcare consultation. Furthermore, enhancing supply chain integrity is vital in preventing diversion of medicines from both public and private channels through advanced tracking technologies. Finally, continuous, risk-based post-marketing surveillance in all markets is essential for the early detection and removal of substandard and falsified products, thereby safeguarding public health.

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