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Investigating the quality of marketed Azithromycin in the Democratic Republic of the Congo: A case of tablets in the city of Kisangani

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ABSTRACT

Introduction

Azithromycin is an antibiotic belonging to the macrolide family. It is widely used in the management of infectious diseases caused by both Gram-positive and Gram-negative bacteria, as well as certain aerobic infections. During the COVID-19 outbreak, its use increased in many countries as part of disease management protocols. Unfortunately, this surge was associated with the introduction of counterfeit products on the market. This drug remains widely circulated, particularly in the far north of Kisangani Province in the Democratic Republic of the Congo.

Purpose

This study aimed to evaluate the quality of marketed Azithromycin tablets available in the region of Kisangani, Democratic Republic of the Congo.

Methods

To achieve this goal, appropriate physicochemical analyses were conducted to verify product quality through organoleptic, pharmaco-technical, qualitative, and quantitative assessments. A total of 14 samples from seven different laboratories (two batches from each) were collected. The study adopted a cross-sectional laboratory-based design using UV-Vis spectrophotometry and HPLC techniques. Data were statistically analysed using the Student's *t*-test method.

Results

Analyses yielded satisfactory results for 100% of the samples, which were consistent with survey findings and confirmed the effectiveness and reliability of Azithromycin-based treatment, except for one sample (Zithromcin, batches 1 and 2) that failed the friability test. This non-conforming result represented less than 20% of the total sample size.

Conclusion

The study results align with those obtained from the survey. We recommend that regulatory authorities use similar analytical tests and trials for drug approval processes and the classification of high-monitoring drugs. The analytical methods implemented in this research can serve as reference procedures for routine quality control of this macrolide antibiotic.

INTRODUCTION

During the COVID-19 outbreak, azithromycin was one of the main antibiotics used in patient management protocols worldwide, including in the Democratic Republic of the Congo (DRC) in general, and in the city of Kisangani in particular (Ministry of Health [MoH]-DRC, 2020).

In this context, the quality of azithromycin has remained a major concern among healthcare professionals. The quality of medical drugs is defined by the overall control of parameters and properties that ensure patient safety through improved product integrity. Quality evaluation is primarily conducted by analysing the risks associated with substandard and/or falsified medicines, which could contribute to bacterial resistance to this antibiotic given its increased demand over the past three years (Poupaert et al., 2020).

According to World Health Organization (WHO) research conducted in 2017, one out of every ten medicines circulating in low- and middle-income countries is either substandard or falsified. This implies that many patients consume medications that cannot effectively prevent or treat infections. Poor-quality medical products can also cause serious health and socio-economic problems, and in some cases, lead to death (WHO, 2017).

This pandemic altered the pattern of antibiotic consumption in Brazil, showing a decrease in the use of amoxicillin and cephalexin and an increase in azithromycin consumption (OFSP, 2020). During this period, many treatment protocols in the DRC placed azithromycin at the centre of therapeutic management.

In the management of infectious diseases, azithromycin is commonly used to treat infections caused by *Neisseria gonorrhoeae*, *Streptococcus*, and *Staphylococcus* species. It is frequently prescribed for otolaryngological infections and is often used as an alternative antibiotic for patients allergic or sensitive to penicillin (Amani et al., 2021). Due to its increasing demand across several provinces and cities in the DRC—particularly in Kisangani—substandard or falsified products may circulate on the market, potentially compromising treatment quality and patient outcomes.

This situation highlights the need for quality control studies to verify the integrity of marketed azithromycin and the quality of treatments provided to the population. Furthermore, azithromycin is available in Kisangani in two pharmaceutical forms: tablets and oral suspension. This study focuses on the tablet form, which was more commonly used during the COVID-19 outbreak for managing various influenza-like illnesses.

The relevance of this research lies in addressing the public health threat posed by substandard and falsified medicines, establishing the link between antibiotic overconsumption and compromised drug quality, and reflecting on strategies for effective control. Therefore, this study emphasises the technical aspects of combating substandard and falsified medicines by applying simple and practical analytical techniques to assess the quality of azithromycin-based formulations.

METHODS

Solvents and Reagents

All reagents were of analytical grade, and solvents were of HPLC grade, including acetonitrile, sodium hydroxide, dipotassium phosphate, orthophosphoric acid, and methanol, which were used for both mobile-phase and sample preparation. These solvents and reagents were supplied by MERCK (Germany) and obtained from the LAPHAKI laboratory stock. They were provided free of charge as part of the research collaboration. Azithromycin Standard UPS 2024 was also purchased from Merck, Germany.

Sample Size and Sampling Method

The sample size was calculated using the general formula proposed by Daniel Schwartz (Monar et al., n.d.):

$$n \geq p(1-p)\frac{z^2}{E^2}$$

Where:

- p = prevalence
- z = constant corresponding to a 95% confidence level
- E = margin of error at 95% confidence level

Since precise data on the prevalence of misuse and overconsumption in the DRC were unavailable, a global prevalence of 10% was considered (WHO, 2017; Nnanga et

al., 2015). Using p = 0.1, E = 5%, and z = 1.96, the calculated sample size was 140 units per batch.

However, due to logistical challenges in purchasing and collecting samples, only seven firms were identified in Kisangani. Two batches were obtained from each firm, resulting in 14 samples analysed randomly, representing 10% of the calculated sample size.

Stratified sampling was conducted based on the usual pharmaceutical supply chain levels in Kisangani:

1. Products obtained from wholesale establishments;
2. Medications from viable and non-viable pharmacies;
3. Medications found in healthcare units handling COVID-19 cases (2020–2022).

Physicochemical Analysis

Physicochemical tests included organoleptic tests (visual inspection), pharmaco-technical tests (mass uniformity, disintegration, hardness, friability, or dissolution), qualitative and quantitative analysis by UV-Vis spectrophotometry, and chemical analysis by HPLC.

Visual Inspection

This assessment focused on the labelling and appearance of primary and secondary packaging, as well as the pharmaceutical form. Information collected included brand name, International Nonproprietary Name (INN), active ingredient content, dosage form, batch number, expiry and manufacturing dates, package insert presence, manufacturer details, marketing authorisation holder, country of origin, storage precautions, composition, spelling accuracy, indelibility of information, legibility, official language, and registration details. The visual inspection also evaluated the physical state of the tablets and packaging (Mwamba et al., 2021; Mbinze, 2023; Tavernier et al., 2020; Koissi et al., 2008).

The simplified visual inspection checklist contained 26 binary (Yes/No) questions across four themes: packaging, identification, traceability, and physical appearance (Ousmane, 2011; Awono et al., 2021).

The existence of marketing authorisation was verified using the official website of the national regulatory authority (ACOREP; Mbinze et al., 2017; Ngwato, 2023).

Pharmaco-Technical Tests

The various pharmaco-technical tests were carried out with the aim of controlling, correcting, or optimising the manufacturing parameters of pharmaceutical forms. Since this study primarily focused on the tablet form, the tests considered included mass uniformity, mass variation, friability, hardness, disintegration or dissolution, and dissolution.

Uniformity of Mass

A total of 20 randomly selected tablets were individually weighed, and the average mass was determined. The individual mass of two or fewer of the 20 units could deviate from the average mass by a percentage higher than that indicated in the following table; however, no unit could deviate by more than double that percentage (Roquefeuil et al., 2020; Albert et al., 2011; ACOREP, 2024; Pharmacopée Européenne, 2014).

Mass Variation

The test was conducted by individually weighing 10 tablets and calculating the estimated individual content of each tablet using the following equation:

$$X_i = \frac{A}{W} \times W_i$$

Where:
X_i= estimated content of each tablet or capsule, A= result of the active ingredient assay performed on the mixture of 10 tablets, W= average mass of 10 tablets or capsules, W_i= mass of each tablet or capsule.

The acceptance value (AV) was determined as follows:

1. If 98.5% ≤ $\bar{x}$≤ 101.5%, then AV = Ks.
2. If $\bar{x}$≤ 98.5%, then AV = 98.5 − $\bar{x}$+ Ks.
3. If $\bar{x}$≥ 101.5%, then AV = $\bar{x}$− 101.5 + Ks.

Where:
$\bar{x}$= average estimated individual value of 10 tablets expressed as a percentage of the declared content, K = acceptability constant (K = 2.4 for n = 10 or n = 30), s = standard deviation.

Acceptance limit: AV ≤ 15.0% (British Pharmacopoeia, 2009; United States Pharmacopeia [USP], 2013).

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Friability

For this test, 10 whole tablets were taken, carefully dusted before testing, weighed, and placed in the drum. The apparatus was run for 100 rotations (25 rotations per minute for four minutes). The tablets were then removed, dusted, and weighed again precisely.

If at the end of the rotation cycle any tablet was cracked or broken, it failed the test. If the results were inconclusive or the mass loss exceeded the target value, the test was repeated twice and the average of the three results was calculated. For most products, the maximum acceptable mass loss (resulting from a single test or the average of three tests) was 1.0% (Demoré et al., 2018; Temely, 2021).

Hardness

Ten tablets were randomly selected, and the force required to break each was measured in Newtons. For the tablet-breaking strength test, no clear universal specifications exist (Garry, 1998; Julie, 2020). The hardness of a tablet depends on the manufacturer's own specifications, which can vary from one pharmaceutical brand to another (Cacoub et al., 2020; IT, 2020; Becherini, 2020).

Naanga et al. (2016) proposed a formula to interpret the results by calculating the observed average hardness (OAH), the upper control limit (UCL = OAH × 1.1), and the lower control limit (LCL = OAH × 0.9). The tablets were compliant if none of the hardness values exceeded the calculated UCL or fell below the LCL.

Disintegration

This test determines the ability of tablets or capsules to disintegrate within a prescribed time, in a liquid medium, and under controlled experimental conditions (Julie, 2020). Disintegration does not imply complete dissolution of the unit or of its active component.

Disintegration is considered complete when any residue—apart from insoluble coating fragments or capsule shells—consists of a soft mass with no palpable core (Québec, 2020; Adrien et al., 2020).

Procedure: One unit of the preparation was placed in each of six tubes of the rack. The device was operated using the specified medium maintained at 37 ± 2°C. At the indicated time, the tube holder was raised out of the liquid, and the condition of the units was examined (Mylène, 2020; Maria Luzinete, 2021; Biswas, 2001).

For coated or film-coated tablets, the disintegration time must not exceed 60 minutes (Jocelyne, 2013; World Health Organization [WHO], 1992, 2018).

Dissolution

Dissolution is a physicochemical process in which a drug dissolves in a solvent to form a homogeneous solution. Dissolution tests are part of stability and quality control assessments, evaluating mechanisms that directly affect drug absorption and bioavailability.

These tests, regulated by different pharmacopoeias, depend on several factors such as the pH of the dissolution medium and the type of surface material of the drug (Mwamba, 2015; Institut national de santé publique du Québec [INSPQ], 2024; Violaine, 2008).

This study aimed to conduct a comparative analysis of the dissolution kinetics of the original drug and generic versions to prevent therapeutic failures related to the bioequivalence of generics (Gounin et al., 2010; Ekongo Lofalanga, 2008).

Analysis Protocol

We conducted an analysis of azithromycin tablets using UV–visible spectrophotometry after the dissolution test. According to the *British Pharmacopoeia* (BP, 2024) monograph, the standards stipulate the following:

Dissolution requirements:

The dissolution process must meet the requirements for tablets and capsules.

1°. Test conditions:

- Apparatus: Type 2 (paddle method), rotating at 75 revolutions per minute (RPM)
- Medium: 900 mL of 0.1 M sodium dihydrogen phosphate, adjusted to pH 6.0 with sodium hydroxide, maintained at 37°C

2°. Modified dissolution test:

Due to concentration and pH adjustments, the dissolution conditions were modified as follows:

- Apparatus: Type 2 (paddle method), at 75 RPM

- Dissolution volume: Reduced from 900 mL to 500 mL
- Medium: 0.1 M sodium dihydrogen phosphate adjusted to pH 8.0 with 85% orthophosphoric acid
- Temperature: 37°C
- Duration: 45 minutes

Preparation of Buffer, Samples, and Reference Standard (RS)

A stock solution of 0.5 M disodium phosphate ($Na_2HPO_4 \cdot 2H_2O$) was prepared by dissolving 35.5 g of disodium phosphate in water to make a final volume of 500 mL. When stored at 4°C, some crystallisation occurred; these crystals were dissolved by gentle heating and stirring on a hot plate. In this study, an ultrasonic bath at a mild temperature (25–35°C) was used to aid dissolution.

To prepare 5000 mL (5 L) of 0.1 M solution, 70 g of disodium phosphate was dissolved in 1000 mL of water as stock (0.5 M), and this 1000 mL stock was then diluted to 5000 mL. The pH was adjusted to 8.50 using 85% orthophosphoric acid at 25.2°C.

Statistical Analysis

All collected data were statistically analysed using the Student's *t*-test based on mean comparisons. Additional statistical calculations—such as determination of mean, standard deviation, and rate—were performed using Microsoft Excel for critical value estimation (British Pharmacopoeia, 2024; USP, 2024).

Qualitative and Quantitative Analysis

The planned dissolution test was followed by High-Performance Liquid Chromatography (HPLC) analysis, according to the 2024 *United States Pharmacopeia* (USP) standards.

Dissolution testing procedure:

Each of the six vessels of the USP Type 2 dissolution apparatus was filled with 900 mL of 0.1 N HCl. A tablet from each of the six samples and the standard product was randomly distributed into each vessel. The paddles were rotated at 75 RPM. From each vessel, a 2 mL aliquot was withdrawn at 5, 10, 20, 30, 40, 60, 80, and 120 minutes, then filtered (Millipore No. 1). The filtrates were diluted to 100 mL with 0.1 N HCl and analysed for azithromycin dihydrate content. After each withdrawal, 2 mL of fresh medium was added to maintain sink conditions.

Each dissolution cycle was repeated using six units of each sample and the innovator product, all subjected to multi-point dissolution testing.

Quantification by HPLC:

Azithromycin dihydrate was quantified using a Merck Hitachi 24–1 HPLC system (Tokyo, Japan) equipped with a C-18 reverse-phase column (4.6 × 150 mm, 5 µm). The column was maintained at 50°C, and detection was performed at 210 nm. The mobile phase consisted of 0.03 M phosphate buffer and HPLC-grade methanol (20:80 v/v, pH = 7.5; Merck Co.), at a flow rate of 2 mL/min.

Standard solution preparation:

A reference azithromycin dihydrate solution (0.1 mg/mL) was prepared by dissolving the standard in 0.1 N HCl and filtering (Millipore No. 1). Ten milligrams of standard substance were weighed into a 10 mL flask, mixed with the mobile phase, and agitated in an ultrasonic bath.

Sample solution preparation:

Six samples were prepared by weighing 50 mg of azithromycin into 50 mL flasks containing mobile phase, agitating in an ultrasonic bath, and filtering. Concentration correction was made according to the standard label and final dilution factor.

Mobile phase preparation:

Two batches of phosphate buffer were prepared by dissolving 4.6 g of monobasic anhydrous potassium phosphate (KH_2PO_4) in 900 mL of ultrapure water, adjusting pH to 7.5 with 1 N NaOH, and diluting to 1 L. The mobile phase consisted of acetonitrile and buffer (65:35 v/v), yielding 1300 mL acetonitrile and 700 mL buffer for 2 L total volume.

Chromatographic conditions:

- Injection volume: 20 µL
- Mode: Liquid chromatography
- Column: 4.6 mm × 15 cm, 5 µm packing (L1)
- Column temperature: 50°C
- Flow rate: 2 mL/min

The final eluent formed by the system ensured optimal separation without affecting the result accuracy.

Ethical Considerations

This study involved only laboratory-based analyses of commercially available pharmaceutical products and did not include human participants or animals. Therefore, formal ethical approval was not required. All samples were handled according to standard laboratory safety and quality control procedures.

RESULTS

The following tests—uniformity of mass, hardness, and friability of the tablets, as well as disintegration and dissolution results of the different samples—are presented in this subsection.

Uniformity of Mass and Mass Variation Test

The results of these two tests for the six samples are presented in the **Table** below.

Table I:
Mass Uniformity Norms

Dosage form	Mean mass	Limit deviation and percentage of mass mean	Tablets number
Uncoated tablets	80 mg or less	±10	Minimum 18
and coated tablets	80 to 250 mg	±20	Maximum 2
		±7,5	Minimum 18
		±15	Maximum 2
	More than 250 mg	±5	Minimum 18
		±10	Maximum 2

Friability Test Results

Table 2 shows the results obtained from the friability test of the six azithromycin brands examined in this study. Each sample was identified by brand name, and results were based on the friability rate calculated from the mean initial weight (20 tablets) and the final mass after the test.

Table 2:
Friability Test Results

Sample	P_1 (g) Initial mass (mean of 20)	P_2 (g) Mass after test	Friability rate	Conclusion
Azipro	14.01	14.005	0.0357	Conform
Zithroplus	15.164	15.131	0.2176	Conform
Azimyn	14.37	14.366	0.0278	Conform
Cemycine	14.472	14.464	0.0553	Conform
Zadycine	13.97	13.966	0.0286	Conform
Zithromcin	6.98	6.88	1.4527	Not conform

Hardness Test Results

Table 3 presents the results of the hardness test performed under appropriate laboratory conditions.

Table 3:
Hardness Test Results

Sample	Thickness (mm)	Diameter (mm)	Hardness (N)	SD (%)	UCL	LCL	Tablets out of interval	Conclusion
Azipro	5.8	17.7×7.6	87.70	7.77	96.47	78.93	0	Conform
Zithroplus	6.2	17.3×8.2	61.02	3.37	67.12	54.92	0	Conform
Azimyn	6.0	17.2×8.7	70.63	16.43	77.70	63.57	0	Conform
Cemycine	6.6	14.6×8.1	69.95	8.23	76.94	62.94	0	Conform
Zadycine	6.0	18.2×8.2	74.36	11.24	81.80	66.92	0	Conform
Zithromcin	4.8	10.0	45.24	11.85	49.76	40.71	0	Conform

Dissolution Test Results

Several parameters can influence the disintegration of a dosage form, including the nature of the material, the particle size distribution of the powder, the shape of the particles, the nature of the interparticulate bonds, the cohesive forces between the particles, the ambient temperature, and the residual humidity (Diamantis, 2020; Oulahbib, 2023).

The dissolution test results of the active ingredient, which has a considerable impact on absorption and bioavailability, are presented in **Tables 4** and **5**.

Table 4:
Absorbance of Samples in the Dissolution Test

Concentration mean (mg/ml)	Analysis period 04/10/2024 -05/10/2024 Absorbances with mean of 4 tests							
	0.2546	0.2633	0.3302	0.3411				SD (mean)
	Basket 1	Basket 2	Basket 3	Basket 4	Basket 5	Basket 6	Mean of Baskets	
Azipro 500 mg	0.263175	0.27885	0.2841	0.296675	0.29355	0.262055	0.28327	0.2973
Zithroplus 500 mg	0.390575	0.376375	0.392875	0.3975	0.389075	0.38366	0.389280	0.2973
Azimyn 500 mg	0.128975	0.1311	0.137525	0.13375	0.1404	0.131245	0.13435	0.2973
Cemycine 500 mg	0.301375	0.307175	0.3092	0.31065	0.290575	0.296155	0.303795	0.2973
Zadycine 500 mg	0.37465	0.363475	0.38105	0.40755	0.416475	0.397875	0.388640	0.2973

The UV-Vis spectrophotometry technique is based on the property of certain molecules to absorb specific wavelengths of the UV-visible spectrum. It allows for measurements according to Beer–Lambert's law, which demonstrates a proportional relationship between absorbance and concentration and supports structural analysis of complexes through absorption spectra. This method uses a spectrophotometer that determines the absorption of a solution for a specific wavelength or range (Lawrence, 2024; United States Pharmacopeia [USP], 2024; Aly Tembely, 2021; Sambiani, 2025).

Table 5:
Active Ingredient Percentage in Samples

Mean of concentration (mg/ml)	% active ingredients in samples								Specification in %
	Correction factor (Purety) P (µg /mg) 947 et F (mg/µg) 0,001								
	% Test 1	**% Test 2**		**% Test 1**	**% Test 2**		**% Test 1**	**% Test 2**	
Azipro 500 mg	83,8300	88,8231	Azipro 500 mg	83,8300	88,8231	Azipro 500 mg	83,8300	88,8231	Azipro 500 mg
Zithroplus 500 mg	124,4112	119,8880	Zithroplus 500 mg	124,4112	119,8880	Zithroplus 500 mg	124,4112	119,8880	Zithroplus 500 mg
Azimyn 500 mg	41,0829	41,7597	Azimyn 500 mg	41,0829	41,7597	Azimyn 500 mg	41,0829	41,7597	Azimyn 500 mg
Cemycine 500 mg	95,9980	97,8455	Cemycine 500 mg	95,9980	97,8455	Cemycine 500 mg	95,9980	97,8455	Cemycine 500 mg
Zadycine 500 mg	119,3386	115,7790	Zadycine 500 mg	119,3386	115,7790	Zadycine 500 mg	119,3386	115,7790	Zadycine 500 mg

Qualitative and Quantitative Analysis Results

Table 6 presents the identification and quantification results of the investigated products by brand, based on the *United States Pharmacopeia* (USP, 2024) monograph for azithromycin tablets.

Table 6:
Analytical (Qualitative and Quantitative) Results

Monography	Date of analysis (interval of day and week)	№	Product name and dosage	Concentration (mg/ml)		Retention time (mean)			Peak surface (mean)		
				Conc.1 (mg/ml)	Conc.2 (mg/ml)	Test 1	Test 2	Mean	Test 1	Test 2	Mean
Azithromycin tablets USP 2024											
	19/08/2024	Std.	Travail (Initial et final)	1,014	-	10,410	10,533	**10,472**	712,027	711,435	**711,731**
		Std.	Contrôle	1,015	-	10,440	-	**10,440**	705,431	-	**705,431**
		1	Azipro 500 mg	0,990	0,991	10,450	10,458	**10,454**	775,961	782,036	**778,999**
		2	Zithroplus 500 mg	1,007	1,008	10,467	10,474	**10,471**	765,277	765,238	**765,258**
		3	Azimyn 500 mg	0,994	1,002	10,484	10,490	**10,487**	723,960	723,687	**723,824**
		4	Cemycine 500 mg	0,987	0,987	10,498	10,506	**10,502**	707,785	707,868	**707,827**
		5	Zadycine 500 mg	1,008	1,007	10,508	10,514	**10,511**	755,661	761,917	**758,789**
		6	Zithromcin 250 mg	1,003	1,003	10,524	10,527	**10,526**	711,063	710,064	**710,564**

DISCUSSION

Mass Uniformity and Variation

Based on the mass uniformity results **(Table 1)**, Zithroplus weighed more than the other samples, whereas Azipro weighed the least. The standard deviation (SD) ranged between 0.91 and 3.50. All samples complied with the mass uniformity test.

This test verifies that individual unit weights fall within established limits relative to the mean mass, thereby ensuring the uniform distribution of the active ingredient (Camille Niaufre, 2014; Koissi et al., 2008; Schiavetti, 2020; World Health Organization [WHO], 2009). Non-compliance could result in under- or overdosing, leading to therapeutic failure, intoxication, or antimicrobial resistance.

Friability Test

Table 2 shows that five of the six samples had a friability rate below 1%, demonstrating compliance with the *European Pharmacopoeia* specification (<1%). However, Zithromcin (250 mg) failed the friability test, which could result in tablet chipping or breakage and potential underdosing during administration or transport.

Hardness Test

The hardness test **(Table 3)** indicated that all six samples were compliant. The UCL and LCL were determined by multiplying the mean hardness by 1.1 and 0.9, respectively.

These results align with those of Mwamba (2012), who reported that all samples in his study were compliant. In contrast, Nnanga et al. (2015, 2021) and Awono et al. (2021) found varying degrees of non-compliance in similar studies. According to Nnanga et al. (2015), hardness influences disintegration and bioavailability, as tablets that are too hard or too soft may alter drug release and therapeutic effect. In this study, no such issues were observed, suggesting consistent manufacturing standards across brands.

Dissolution Test

All six samples passed the disintegration test. The longest disintegration time was observed for Azimyn (7 min 12 s), and the shortest for Azipro (1 min 14 s). These results are

consistent with those of Awono et al. (2021) and Nnanga et al. (2015), who reported 100% compliance among tested samples.

Table 5 shows that all products passed the UV-Vis spectrophotometry analysis except Azimyn, which displayed low absorbance, indicating potential bioavailability challenges. The oral bioavailability of standard azithromycin is approximately 37%, with peak plasma concentration achieved within 2–3 hours. Further studies combining dissolution and UV-Vis analysis are recommended to deepen the understanding of these results. As dissolution predicts bioavailability—a parameter of therapeutic efficacy—it is sensitive to variations in the manufacturing process. Azimyn's low bioequivalent active ingredient content (42.63%) may affect its therapeutic performance.

Qualitative and Quantitative Analysis

The analysis **(Table 6)** showed that the retention time (RT) for the working standard was 10.472 min and for the control 10.440 min. The samples' RT values ranged between 10.454 and 10.526 min, closely matching those of the standards.

The peak profiles of the samples were consistent with the reference standard, confirming the presence of azithromycin in all six brands. These findings corroborate the survey data indicating user satisfaction with azithromycin treatments in Kisangani.

CONCLUSION

In response to the high demand for azithromycin during the COVID-19 pandemic, this study assessed the quality of azithromycin tablets available in Kisangani and Tshopo Province. A combination of field and laboratory analyses confirmed satisfactory quality across most samples, except for Zithromcin, which failed the friability test.

The physicochemical analyses confirmed both product identity and concentration consistency, with active ingredient content ranging between 98.7% and 100.7%, within the acceptable USP range of 95–105%.

It is therefore recommended that regulatory authorities mandate these quality control tests prior to market approval of azithromycin-based products to ensure patient safety and maintain therapeutic efficacy.

Ethical Approval: Nil required.

Conflicts of Interest: None declared.

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