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Quality control of injectable artesunate marketed in Kisangani in the Democratic Republic of the Congo

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ABSTRACT

Introduction

Malaria remains a major public health problem in the Democratic Republic of Congo (DRC), where injectable artesunate is the standard treatment for severe forms. Effective treatment relies on the availability of high-quality medicines, including injectable artesunate. However, the circulation of falsified or substandard products poses a serious threat to patient care.

Purpose

This study aimed to evaluate the physicochemical quality of injectable artesunates marketed in Kisangani, based on the standards of the *International Pharmacopoeia* (2022) and the *British Pharmacopoeia* (2024).

Methods

A prospective qualitative and quantitative study was conducted from February to May 2024, involving 30 batches of injectable artesunate collected from pharmacies across the six municipalities of Kisangani. Analyses were carried out at the LACOMEDA laboratory in Kinshasa using the following analytical techniques: mass uniformity, pH determination, and High-Performance Liquid Chromatography (HPLC) for identification and assay of the active ingredient and impurities, in line with the pharmacopoeial standards.

Results

All 30 samples met the visual inspection and labelling requirements. The pH ranged from 3.62 to 4.23, while mass uniformity was within ±10%, consistent with the *British Pharmacopoeia* (2024). Artesunate content ranged from 95.9% to 108.1%, within the specified limits (90–110%). Impurities A, B, and C were detected in low amounts; impurity A ranged from 0.2% to 0.7%. All impurity levels remained below the acceptance thresholds defined by the *International Pharmacopoeia* (2022).

Conclusion

All analysed samples complied with pharmacopoeial specifications during the study period. These results underscore the importance of systematic post-marketing surveillance to prevent the distribution of substandard drugs in pharmacies in Kisangani, DRC.

INTRODUCTION

Malaria remains a major cause of morbidity and mortality in the Democratic Republic of Congo (DRC), particularly among children under five years of age. In 2023, the World Health Organization (WHO) estimated that there were 263 million malaria cases worldwide, with 597,000 deaths; 94% of cases and 95% of deaths occurred in sub-Saharan Africa. The DRC accounted for 11.3% of global malaria deaths, the second-highest global burden after Nigeria (WHO, 2024).

Plasmodium falciparum is responsible for the majority of severe cases in Africa. Transmission occurs primarily through the bites of infected female *Anopheles* mosquitoes, but can also occur through transfusion or exposure to contaminated needles (WHO, 2024).

The city of Kisangani, the capital of Tshopo province, is particularly vulnerable. Its geographical position at the confluence of the Congo and Tshopo rivers, combined with its high humidity (around 80%), makes it an important transit point for goods and medicines, which may encourage the circulation of falsified or substandard pharmaceutical products.

The National Strategic Plan for Malaria Control 2024–2028 aims to reduce malaria morbidity by 70% and mortality by 50% by 2030 (PNLP, 2023). In this perspective, injectable artesunate is recommended as first-line treatment for severe cases, in accordance with WHO guidelines (WHO, 2022a).

However, studies conducted in Ghana, Malawi, and Mali have revealed high proportions of falsified or substandard medicines, with prevalence reaching up to 88.4% of samples tested (Chikowe et al., 2015; Osei-Safo et al., 2014; Sidibé, 2011; Tivura et al., 2016). According to the United Nations Office on Drugs and Crime (UNODC, 2023), an estimated 270,000 deaths per year in sub-Saharan Africa are attributable to the use of falsified antimalarial medicines.

In this context, the present study aims to evaluate the physicochemical quality of injectable artesunate marketed in pharmacies in Kisangani, based on the specifications of the *International Pharmacopoeia* (2022) and the *British Pharmacopoeia* (2024), thereby contributing to post-marketing surveillance efforts.

METHODS

Study design and sampling

This was a prospective experimental study focused on the identification and quantification of artesunate as the active ingredient, as well as the measurement of any detectable impurities. Thirty (30) batches of injectable artesunate were sampled from pharmacies in the six communes of Kisangani city using a mystery shopper approach (Collins et al., 2020; IOM, 2019), with five batches per commune. Each batch was obtained from a registered local pharmacy. The sampling aimed to ensure representativeness of the products marketed in this endemic area.

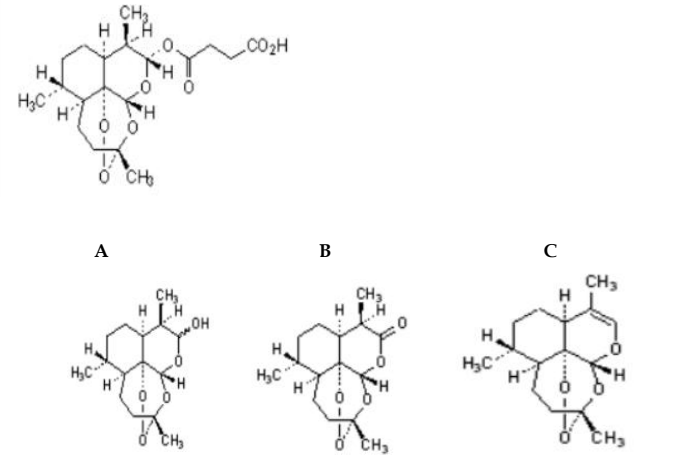
Environment and period of study

The collected samples were analysed at the "Laboratory for the Analysis and Control of Medicines and Foodstuffs" (LACOMEDA), located within the Faculty of Pharmaceutical Sciences of the University of Kinshasa, DRC. The study was conducted between February and May 2024.

Drugs tested

Artesunate is a semi-synthetic derivative of artemisinin, the active compound extracted from *Artemisia annua*, a plant with recognised antimalarial properties (WHO, 2022b). Three major impurities are monitored in this drug: dihydroartemisinic acid (impurity A), artesunate delta-lactone (impurity B), and dihydroartemisinin (impurity C), all listed in the *International Pharmacopoeia* (2022) (see **Figure 1**).

Figure 1:
Chemical structures of artesunate and its impurities: A (dihydroartemisinic acid), B (artesunate delta-lactone), and C (dihydroartemisinin) (International Pharmacopoeia, 2022).



The reference standards used (purity >99%) were obtained from Tokyo Chemical Industry Co., Ltd (Tokyo, Japan). Impurity standards A, B, and C from the same company were used for impurity identification.

Chemicals and reagents

Analytical grade (LC-grade) solvents and reagents were supplied by Merck (Germany), including acetonitrile and monopotassium phosphate. Ultrapure water was obtained using a Milli-Q Plus 185 system (Millipore, USA). All products were handled under recommended conditions.

Analytical methods

Pharmacotechnical testing

Each vial was visually inspected for conformity of powder appearance, clarity of the reconstituted solution, integrity of the primary packaging (vial, cap, seal), and completeness of labelling information. Mass uniformity was assessed according to the *British Pharmacopoeia* (2024) specifications for powders for injection (<300 mg: tolerance of ±10%).

Physicochemical analysis

The pH of the reconstituted solution was measured with a calibrated pH meter. Each measurement was performed in triplicate (n = 3), and results were expressed as mean ± standard deviation.

HPLC method

The identification and quantification of artesunate and impurities were performed by High-Performance Liquid Chromatography (HPLC), following the *International Pharmacopoeia* (2022). Analyses were conducted using Hitachi HPLC equipment controlled by Chromaster Software (Antwerp, Belgium) and equipped with a diode array detector.

Chromatographic separation was achieved using a Luna® C18 column (250 × 4.6 mm, 5 µm). The mobile phase consisted of a saline phosphate buffer (pH 3.0) and acetonitrile (56:44, v/v), pumped at 1.0 mL/min. The injection volume was 20 µL, and detection was performed at 216 nm.

For mass uniformity, a GRAM FV-220C electronic balance (IPESAGE SAS, France) was used.

Colorimetric test

- To a quantity of powder equivalent to 0.1 g of artesunate, add 40 mL of absolute alcohol R, shake and filter. Add 0.5 mL of hydroxylamine chloride to half of the filtrate and 0.25 mL of sodium hydroxide (~80 g/L). Heat in a boiling water bath, allow to cool, then add 2 drops of hydrochloric acid (~70 g/L) and 2 drops of ferric chloride (~50 g/L); a light purple colour is obtained.
- Evaporate the remaining filtrate from test "A" to a volume of approximately 5 mL. Place a few drops in a white porcelain container. Add a drop of vanillin/sulphuric acid and allow to stand for 30 minutes; a red colouration develops (International Pharmacopoeia, 2022).

Statistical methods

Data were entered and analysed using GraphPad Prism software (version 9.0). Each measurement was performed in triplicate (n = 3). Results were expressed as mean ± standard deviation. Compliance with standards was assessed as the percentage of batches meeting the *International Pharmacopoeia* (2022) and *British Pharmacopoeia* (2024) specifications.

Preparation of solutions

- **Buffer solution at pH 3.0:** Dissolve 1.36 g of potassium dihydrogen phosphate R in 900 mL of water R, adjust to pH 3.0 with phosphoric acid (1440 g/L), make up to 1000 mL with water R, then filter.
- **Standard solution:** Accurately weigh 40 mg of artesunate, dissolve in 10 mL of acetonitrile, then filter.
- **Sample solution:** Prepared under the same analytical conditions as the standard (*International Pharmacopoeia, 2022*).

RESULTS

Origin and characteristics of the samples

Thirty (30) batches of injectable artesunate were collected from the six communes of Kisangani between February and May 2024. The samples originated from four countries: India (17 batches), DRC (9 batches), China (2 batches), and Indonesia (2 batches). Dosages ranged from 30 mg to 240 mg. All samples included a descriptive sheet containing the

batch number, manufacturing date, expiry date, manufacturer, and place of purchase.

Visual inspection

All vials contained a white, amorphous powder. The reconstituted solutions were clear and transparent, with no precipitate or visible particles. The vials were tightly sealed with a rubber stopper and an aluminum cap. Compliance rate: 100% (30/30 batches).

Pharmacotechnical test

The mass deviations of the samples ranged from −1.9% to +1.9%, within the ±10% limit specified by the *British Pharmacopoeia* (2024) for injectable powders below 300 mg. Only mass uniformity was assessed and achieved (see **Table 1**).

Table 1:
Mass uniformity test results compared to BP 2024 limits

Code	*Batch number*	*Average weight (mg)*	*Gap (%)*	*Code*	*Batch number*	*Average weight (mg)*	*Gap (%)*
A01	JFQ012064	60.1	-0.9 to +1.4	A16	D-2308002	120.4	-1.2 to +1.1
A02	JFQ012060	60.5	-0.7 to +0.9	A17	D-2307023	120.2	-1.4 to +1.0
A03	LA211136	60.2	-1.2 to +1.1	A18	D-2307023	150.3	-0.7 to +0.9
A04	LA211138	60.1	-0.8 to +1.9	A19	D-2306019	180.3	-0.7 to +1.1
A05	IP22282	60.7	-1.6 to +1.2	A20	D-2307020	180.2	-0.8 to +0.9
A06	IP22282	60.5	-1.1 to +1.8	A21	D-2306018	240.2	-1.8 to +0.7
A07	GLAR25A	120.7	-0.8 to +0.6	A22	22E44	30.7	-0.7 to +1.2
A08	GLAR26A	60.4	-1.9 to +1.7	A23	22E16	30.2	-0.9 to +1.1
A09	GLAR15A	60.5	-0.7 to +1.0	A24	22E42	30.6	-1.9 to +1.5
A10	GLAR23A	60.8	-1.4 to +1.1	A25	22I46	60.7	-1.5 to +1.2
A11	GLAR12S	60.7	-1.4 to +1.0	A26	22L49	60.5	-0.9 to +0.4
A12	GLAR15S	60.2	-1.8 to +0.7	A27	22L41	120.5	-0.8 to +0.9
A13	GLAR20A	60.5	-1.2 to +1.5	A28	22L40	120.8	-1.2 to +1.0
A14	D-2304002	31.0	-0.6 to +1.1	A29	22I18	150.8	-1.9 to +1.6
A15	D-2308019	60.4	-1.4 to +1.0	A30	22E32	150.9	-1.5 to +1.8

Physicochemical tests

All pH values of the reconstituted solutions were within the acceptable limits of the European Pharmacopoeia (2002), with an overall mean of 4.02 ± 0.19 and a compliance rate of 100% (see **Table 2**).

Table 2:
pH-related results

Code	**pH** ***(3.5 to 4.5)***	**Code**	**pH** ***(3.5 to 4.5)***
A01	3.81	A16	4.16
A02	3.89	A17	4.09
A03	3.62	A18	4.11
A04	3.69	A19	4.23
A05	4.01	A20	4.08
A06	3.98	A21	4.01
A07	3.82	A22	3.92
A08	4.21	A23	3.81
A09	4.18	A24	3.98
A10	4.19	A25	3.79
A11	4.22	A26	3.82
A12	4.08	A27	4.08
A13	4.23	A28	4.23
A14	4.15	A29	3.69
A15	4.24	A30	3.74

Identification of the active ingredient and impurities

As shown in **Figures 2A** and **2B**, artesunate was clearly separated from other substances, allowing identification based on retention time. Impurities were detected in some samples, but their distribution was random.

Figure 2A:
Typical chromatogram of a reference solution containing artesunate (RT = 8.8 min) and its main impurities (impurity A at RT = 0.9 min, impurity B at RT = 5.2 min, and impurity C at RT = 11.2 min)

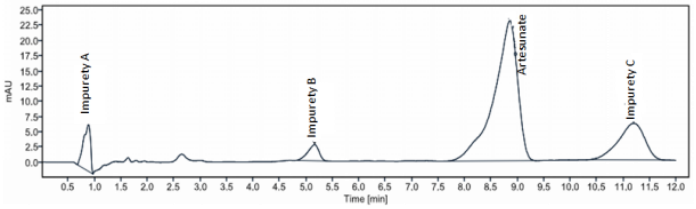
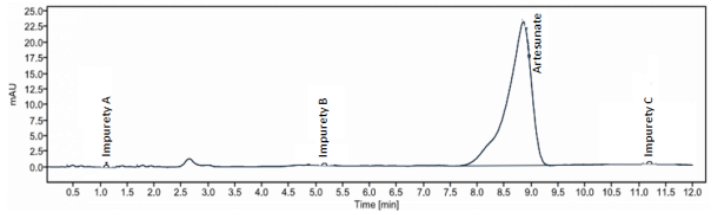


Figure 2B:
Typical chromatogram of a sample solution showing artesunate and impurities A, B, and C



Additional colorimetric tests confirmed the presence of artesunate

Determination of artesunate by HPLC

HPLC-measured concentrations ranged from 95.9% to 108.1%, with an overall mean ± standard deviation of 101.4% ± 2.1%, in accordance with *International Pharmacopoeia* specifications (2022) (see **Table 3**).

Table 3:
Artesunate content in the 30 samples tested

Code	Average ± σ (in %,) Specifications: 90-110%	**Code**	Average ± σ (in %,) Specifications: 90-110%
A01	106.1% ± 1.17%	**A16**	96.0% ± 0.96%
A02	100.6% ± 1.61%	**A17**	107.4% ± 1.29%
A03	103.2% ± 1.75%	**A18**	108.1% ± 2.38%
A04	99.5% ± 0.99%	**A19**	100.9% ± 1.72%
A05	107.0% ± 0.75%	**A20**	97.4% ± 2.14%
A06	103.2% ± 1.03%	**A21**	96.5% ± 0.87%
A07	96.5% ± 2.03%	**A22**	95.9% ± 1.05%
A08	99.1% ± 1.39%	**A23**	96.7% ± 2.22%
A09	98.7% ± 1.28%	**A24**	103.4% ± 0.41%
A10	100.9% ± 0.81%	**A25**	98.4% ± 0.79%
A11	98.0% ± 0.88%	**A26**	102.3% ± 0.61%

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A12	105.3% ± 1.58%	**A27**	107.5% ± 1.07%
A13	102.4% ± 2.15%	**A28**	103.1% ± 0.72%
A14	103.2% ± 1.34%	**A29**	105.5% ± 1.27%
A15	96.4% ± 1.54%	**A30**	101.1% ± 1.01%

Impurities were also assessed using the same chromatograms **(Table 4)**, with a 100% compliance rate according to *International Pharmacopoeia* standards (2022).

Table 4:
Impurity content in the 30 samples tested

Code	Impurity A < 1%	Impurity B < 0.5%	Impurity C < 0.3%	Code	Impurity A < 1%	Impurity B < 0.5%	Impurity C < 0.3%
A01	0.6	0.0	0.0	A16	0.4	0.0	0.0
A02	0.4	0.0	0.1	A17	0.5	0.0	0.0
A03	0.5	0.2	0.0	A18	0.6	0.0	0.0
A04	0.6	0.0	0.0	A19	0.7	0.0	0.0
A05	0.3	0.0	0.0	A20	0.5	0.0	0.1
A06	0.6	0.0	0.0	A21	0.5	0.0	0.0
A07	0.4	0.0	0.1	A22	0.6	0.0	0.0
A08	0.2	0.0	0.0	A23	0.4	0.1	0.0
A09	0.6	0.0	0.0	A24	0.3	0.0	0.0
A10	0.5	0.0	0.0	A25	0.5	0.0	0.0
A11	0.5	0.1	0.0	A26	0.5	0.0	0.0
A12	0.6	0.0	0.0	A27	0.6	0.0	0.0
A13	0.5	0.0	0.1	A28	0.4	0.1	0.0
A14	0.7	0.0	0.0	A29	0.5	0.0	0.1
A15	0.4	0.1	0.0	A30	0.6	0.0	0.0

DISCUSSION

Summary of main results

This study evaluated 30 batches of injectable artesunate marketed in the six municipalities of Kisangani. All samples met compliance criteria for labelling and physicochemical properties. Mass uniformity and pH values were within acceptable limits, while the content of the active ingredient and impurities A, B, and C were within authorized thresholds.

Comparison with other studies

These findings contrast with previous studies in sub-Saharan Africa. For example, Sidibé (2011) reported a 7.04% non-compliance rate in Mali, including cases with absent active ingredient and pH non-compliance. Post-marketing surveys in Ghana and Malawi reported falsified or substandard medicine proportions ranging from 35% to 88.4% (Chikowe et al., 2015; Osei-Safo et al., 2014; Tivura et al., 2016). No such irregularities were observed in this study, suggesting effective pharmaceutical supply chain control in Kisangani during the sampling period.

Implications

The complete conformity of the analysed samples is reassuring for local clinical practice, particularly in managing severe malaria cases. It indicates acceptable quality of available products in the short term. Slight variations in pH and less homogeneous dissolution observed in some local batches may relate to differences in manufacturing, excipient quality, or storage conditions, which are often precarious in urban–rural municipalities lacking stable electricity.

Boundaries and limitations

This study has certain limitations. Sterility testing was not performed, although it is critical for injectable drugs. Long-term stability of products was not assessed, despite Kisangani's high humidity potentially affecting active ingredient degradation. Additionally, although the sample size is locally representative, it is insufficient to generalize results nationwide.

Recommendations

To ensure sustainable access to quality medicines, regular post-marketing surveillance should be implemented in public and private pharmacies, including capacity building for national control laboratories. Expansion of analyses to microbiological criteria, including sterility testing, is recommended. Regulatory authorities should also enforce good manufacturing practices and improve transport and storage conditions, especially for locally produced products.

CONCLUSION

This study rigorously assessed the quality of 30 batches of injectable artesunate marketed in Kisangani. Results demonstrated full compliance with *International Pharmacopoeia* (2022) and *British Pharmacopoeia* (2024) standards across visual, physicochemical, and chromatographic analyses. No adulteration or significant deviations were observed. These findings indicate satisfactory product quality during the study period. However, drug stability in humid tropical conditions and the absence of sterility testing underscore the need for strengthened monitoring. Systematic post-marketing surveillance is strongly recommended to ensure safe and effective malaria treatments.

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Research Authorization: Approval was obtained from the Faculty of Medicine and Pharmacy, University of Kisangani, and the Provincial Pharmacy Inspection of Tshopo.

Ethical Approval: Ethical approval was granted by the University of Kisangani Ethical Committee, Ministry of Higher and University Education, DRC (N°UNIKIS/CER/014/2024).

Conflicts of Interest: None declared.

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Mwanga, M. JJ.[2]: Nil identified
Shabani, M. L.[3]: Nil identified
Ntokamunda, K. J.[4]: Nil identified
Marini, D. R.[1,5]: Nil identified

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