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Research Article

Evaluation of the Quality of Artemether-Lumefantrine-based Antimalarials from the Illicit Ivorian Market in West Africa

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Abstract

Background: Counterfeit and substandard medicines represent a severe public health issue, particularly in developing nations where their prevalence exacerbates disease resistance and economic challenges. In addition, many deaths in Côte d'Ivoire could be avoided each year if the drugs prescribed against malaria were compliant with regulations and able to effectively treat the disease. *Objective:* This study aimed to evaluate the quality of artemether-lumefantrine antimalarial combination on the Ivorian illicit market using the GPHF-Minilab® kit. *Methods:* A total of 15 samples were analyzed through visual inspection, disintegration testing, and TLC for qualitative and semi-quantitative assessments. *Results:* The findings reveal significant non-conformities, including 20% of samples lacking manufacturer information, 7% without accompanying instructions, and 20% with physical degradation. 93% of samples disintegrated within 30 minutes, meeting pharmacopoeial standards. One sample exceeded the recommended time, indicating substandard manufacturing. Most samples (67%) met active ingredient quantity requirements, but 26% were underdosed, and 7% were overdosed, highlighting manufacturing and storage deficiencies. In view of these results, it appears that the Artemether-lumefantrine drugs seized on the illegal market in Côte d'Ivoire are not of good quality. *Conclusion:* The GPHF-Minilab® proves a reliable tool for identifying substandard and counterfeit drugs in resource-limited settings, though further validation is required for broader applications. These results underscore the need for stringent regulatory frameworks, public education, and expanded quality control initiatives.

Keywords

Antimalarials, Artemether, Counterfeit Drugs, Lumefantrine, Minilab, Quality Control

1. Introduction

Counterfeit and substandard medicines are a pervasive issue, particularly in developing countries where weak regulatory systems and limited oversight exacerbate the problem. According to the World Health Organization (WHO) research, one in 10 medical products circulating in developing nations is either substandard or falsified [1]. In low-income settings, this figure rises to one in eight, with antimalarials frequently identified among the falsified drugs [2]. These medicines

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jeopardize patient safety, hinder disease control efforts, and contribute to the growing global crisis of antimicrobial resistance [3].

Quality medicines are essential for human health and form the foundation of robust health systems [4]. However, falsified and substandard drugs infiltrate supply chains, particularly in regions like West Africa. These counterfeit drugs not only fail to treat illnesses effectively but can cause toxic effects and exacerbate resistance phenomena [3, 5]. In poor countries where people believe that quality medicines are expensive, the presence of these cheaper "street medicines" often encourages harmful practices such as self-diagnosis and self-medication [6].

In Côte d'Ivoire, the trafficking of counterfeit medicines presents a significant challenge. Less than 10% of the population has health insurance, and like some low- and middle-income countries, 90% of the population would pay for their medicines out of pocket, increasing household poverty [7, 8]. Antimalarials remain a crucial line of defense against malaria—a disease responsible for high morbidity and mortality rates [9]. Artemether, a semi-synthetic derivative of artemisinin, plays a central role in managing uncomplicated malaria in West Africa for three main reasons. First, following WHO recommendations, artemisinin-based combination therapies (ACTs) are the first-line treatment for uncomplicated malaria in countries such as Côte d'Ivoire [10]. Artemether is often combined with lumefantrine (artemether-lumefantrine or AL), which is widely used in this region [10]. Second, artemether-based combinations effectively reduce parasite load, limiting complications and transmission, while demonstrating good tolerance with fewer side effects compared to other antimalarial treatments [11]. Third, although artemisinin resistance has been reported in Southeast Asia, justifying the need to introduce triple therapies in these countries, it remains limited in West Africa [12, 13]. Nevertheless [14], the sale of counterfeit antimalarials on the illicit market undermines public health initiatives and poses significant challenges.

It is estimated that up to 200,000 infant deaths could be prevented each year if prescribed antimalarial drugs were compliant with regulations and effectively treated the disease during pregnancy [15]. To combat the spread of substandard and falsified medicines, slow the emergence of antimalarial resistance, and promote safe medication use, it is essential to develop tools for quality control and counterfeit detection [5]. In response, the Global Pharma Health Fund (GPHF) introduced the GPHF-Minilab® kit, a mini-laboratory designed for rapid quality verification and counterfeit detection [16, 17]. This portable kit provides all necessary equipment for studies such as this one. This study evaluates the quality of artemether-lumefantrine antimalarial combinations seized on the Ivorian illicit market by the Directorate of Narcotics and Drug Stupors (DPSD). Using the GPHF-Minilab® kit, it aims to identify non-conformities and provide insights into the extent of the counterfeit drug problem in Côte d'Ivoire.

2. Materials and Methods

2.1. Materials

The analyses were conducted using the GPHF-Minilab®, a compact, self-contained kit designed for drug quality control. The kit includes reference substances, glassware, and all necessary laboratory equipment for conducting physical and visual inspections, disintegration tests, and thin-layer chromatography (TLC) analyses. It also contains detailed manuals outlining protocols, eluent compositions, and migration times for each test.

Medicines for Analysis

The materials used for this study included reference substances and medicines collected from the Directorate of Narcotics and Drug Stupors (DPSD):

1. *Reference Substance* The reference substance consisted of combination tablets containing 20 mg of Artemether and 120 mg of Lumefantrine with a purity of 100%. This reference was supplied with the GPHF-Minilab® kit under batch number X0129.
2. *Collected Medicines* The medicines collected from the DPSD for analysis were in two pharmaceutical forms: tablets and dry powder for oral suspension. Table 1 lists the commercial names, dosages, and pharmaceutical forms of the samples.

Table 1. *Commercial Name, Dosage, and Pharmaceutical Forms of Samples.*

Commercial Name	Dose	Pharmaceutical Form
Arfan®	20 mg /120 mg	Tablets
Artefan DT®	40 mg /240 mg	Tablets
Artrine®	40 mg /240 mg	Tablets
Bimalaril®	80 mg /480 mg	Tablets
Cartef®	20 mg /120 mg	Tablets

Commercial Name	Dose	Pharmaceutical Form
Combiart®	20 mg /120 mg	Tablets
Gen-M®	80 mg /480 mg	Tablets
Komefan®	20 mg /120 mg	Tablets
Acure®	60 mg /360 mg	Powder for oral suspension
Artefan®	20 mg /120 mg	Powder for oral suspension
Artemether+Lumefantrine®	180 mg /1080 mg	Powder for oral suspension
Combitrine®	15 mg /90 mg /5ml	Powder for oral suspension
Lumizap®	180 mg /1080 mg	Powder for oral suspension
Telufan Forte®	180 mg /1080 mg	Powder for oral suspension
R-Lume®	180 mg /1080 mg	Powder for oral suspension

2.2. Methods

2.2.1. Study Design and Location

This descriptive and analytical study was carried out between July and December 2023.at two locations: the Directorate of Narcotics and Drug Stupors (DPSD) in Abidjan, Côte d'Ivoire, and the Laboratory of Therapeutic Chemistry, Félix Houphouët-Boigny University.

2.2.2. Sampling

Fifteen antimalarial drug samples were collected over one month, starting july 3, 2023, from the DPSD's stock of seized medicines. Sampling was performed randomly based on the stock available at the time. The samples included eight (8) tablets and seven (7) dry powders for oral suspension. Figure 1 provides an overview of the collected samples.

Figure 1. *Products collected from the Directorate of Narcotics and Drug Stupors (DPSD).*

2.2.3. Analytical Procedures

The GPHF-Minilab® was used for the following tests:

1. *Visual and Physical Inspection* Each sample was evaluated comprehensively, including assessments of primary and secondary packaging, dosage forms, manufacturer information, and production and expiration dates. Any discrepancies or signs of degradation were noted.
2. *Disintegration Testing* Tablets or capsules were placed in a 150 ml bottle containing 100 ±2 ml of water at 37 ℃. The bottle was stirred intermittently to observe disintegration, which should occur within 30 minutes.
3. *Thin-Layer Chromatography (TLC)*
   a) *Qualitative Identification:* Active ingredients in the samples were identified by comparing the frontal ratios (Rf values) of the sample spots to those of the reference substances provided in the kit. Matching Rf values confirmed the identity of the active ingredient.
   b) *Semi-Quantitative Assay:* The intensity of the sample's TLC spot was compared to that of reference spots containing 80% and 100% active ingredient. Samples with an active ingredient content below 80% or above 100%, as well as those containing impurities (multiple spots per deposition), were considered non-compliant.

2.2.4. Compliance Assessment

Samples failing to meet any of the following criteria were deemed non-compliant:

1. Presence of active ingredients matching reference standards.
2. Absence of impurities (e.g., more than one spot per deposition).
3. Active ingredient content within the acceptable range of 80% to 100%.

This multi-faceted evaluation provided a comprehensive assessment of the quality of Artemether-lumefantrine antimalarials on the Ivorian illicit market.

3. Results

3.1. Physical and Visual Inspection

In this study, we analyzed 15 samples of antimalarial drugs. These include a mix of formulations with varied countries of origin and physical characteristics. The physical and visual inspection of the samples revealed several non-conformities (Table 2). While all samples had manufacturing and expiry dates present, 20% lacked the manufacturer's address, and 7% of samples did not include a French leaflet. Physically, 80% of the samples were intact, whereas 20% exhibited degradation such as crumbling or discoloration (Figure 2).

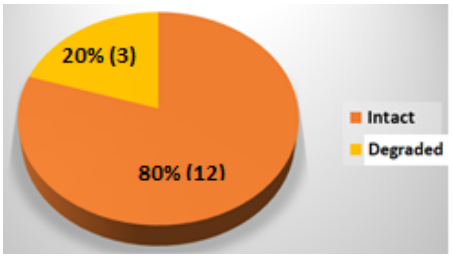

Figure 2. *Physical Integrity of Samples.*

Table 2. *Characteristics and Information on Samples Analyzed.*

Trade Name	Batch number	Drug Manufacturer	Manufacturer Address	Manufacturing Date	Expiry Date	French Leaflet	Physical Aspect
Arfan®	nn	Letap Pharmaceuticals. GHANA	Present	Present	Present	Present	Degraded
Artefan DT®	nn	Ajanta Pharma Ltd. INDIA	Present	Present	Present	Present	Intact
Artefan®	nn	Ajanta Pharma Ltd. INDIA	Present	Present	Present	Present	Intact
Artrine®	nn	Afforis Health Technologies Pvt. Ltd. INDIA	Absent	Present	Present	Present	Intact
A+L®	20190419	ZCM Hamburg gmbh, GER-MANY	Absent	Present 04/ 2019	Present 04/ 2022	Present	Intact
Acure®	nn	nn	Present	Present	Present	Present	Intact
Bimalaril®	181113	Bengbu Tushan Pharmaceutical Co. Ltd. CHINA	Absent	Present 11/2018	Present 11/2021	Present	Intact
Cartef®	AR8005	GB Pharma limited, UNITED KINGDOM	Present	Present 01/ 2018	Present 12/ 2019	Present	Intact
Combiart®	7225119	Strides Arcolab Limited, INDIA	Present	Present 09/2019	Present 10/2022	Absent	Degraded
Combitrine®	nn	Novartis pharma ag, unknown	Present	Present	Present	Present	Intact
Komefan®	nn	Mylan Laboratories Limited. INDIA	Present	Present	Present	Present	Degraded
Gen-M®	nn	Genix pharma private limited, PAKISTAN	Present	Present	Present	Present	Intact
Lumizap®	nn	nd	Present	Present	Present	Present	Intact
R-Lume®	ARL 9003	Impact Healthcare pvt. Ltd, INDIA	Present	Present 07/2018	Present 06/2021	Present	Intact
Telufan®	140906	Jiangsu Ruinian Qianjin Pharmaceutical Co. Ltd. CHINA	Present	Present 09/2014	Present 09/2017	Present	Intact

*nn = not noted

More over, 67% of the samples originated exclusively from India and China. The country of origin distribution showed a majority of samples from India (47%), followed by China (20%) and others (33%) (Figure 3).

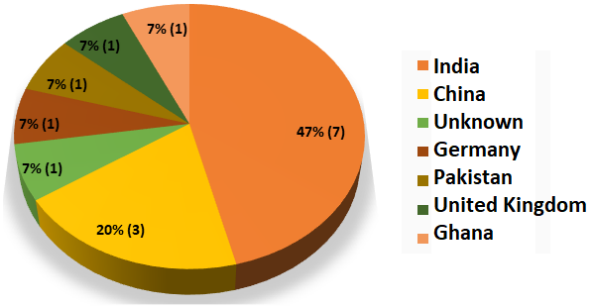

Figure 3. Distribution of samples according to country of origin.

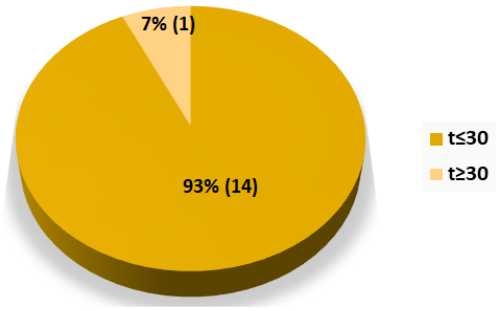

Figure 4. Distribution of samples based on disintegration time.

3.2. Disintegration Test Results

The disintegration test evaluates the ability of drug samples to dissolve within a defined time frame in the stomach. Samples were categorized based on whether they disintegrated within the 30-minute threshold specified in the standard protocol. The results are summarized in Figure 4.

All analyzed samples disintegrated within the prescribed 30 minutes, except for one sample, which required 37 minutes to fully disintegrate. This deviation suggests potential formulation issues or differences in excipient composition.

3.3. Thin-Layer Chromatography (TLC) Results

3.3.1. Qualitative Identification Results

To identify the active pharmaceutical ingredient (API), retention factor (Rf) values were calculated for each sample. An API was deemed identical to the reference if its Rf value matched or was very close to that of the reference substance. The Rf values obtained are shown in Table 3.

Table 3. Retention Factor (Rf) Values of Samples.

Sample	Rf Value	Sample	Rf Value
Reference (1 & 2)	0.50	Reference (6)	0.41
Acure 60/360 mg	0.51	Artrine 40/240 mg	0.41
Lumizap 180/1080 mg	0.48	Combiart 20/120 mg	0.41
A+L 15/90/5ml	0.51	Reference (7)	0.44
Reference (3)	0.53	Bimalaril 80/480 mg	0.46
R-Lume 180/1080 mg	0.51	Gen-M 80/480 mg	0.46
Artefan 20/120 mg	0.52	Reference (8)	0.41
Reference (4)	0.53	Cartef 20/120 mg	0.41
Combitrine 15/90/5ml	0.53	Artefan DT 40/240 mg	0.41
Telufan 180/1080 mg	0.53		
Reference (5)	0.41		
Komefan 20/120 mg	0.41		
Arfan 20/120 mg	0.41		

All samples tested contained Artemether as confirmed by their matching Rf values with the reference. Variations in Rf values across plaques were attributed to differences in migration conditions, such as solvent polarity or migration time. However, Rf values remained consistent within each plaque, ensuring accurate identification.

3.3.2. Quantitative Results of Active Ingredient by TLC

The quantity of Active Pharmaceutical Ingredient (API) in each sample was estimated by comparing the intensity of sample

spots to those of reference spots containing 80% and 100% of the API. Samples were classified as conforming, underdosed, or overdosed based on these comparisons. The results are summarized in Table 4.

Table 4. *Quantification of API in Samples.*

Sample	API Quantification	Sample	API Quantification
Reference (1 & 2)	Compliant	Reference (6)	Compliant
Acure 60/360 mg	Underdosed	Artrine 40/240 mg	Compliant
Lumizap 180/1080 mg	Overdosed	Combiart 20/120 mg	Underdosed
A+L 15/90/5ml	Underdosed	Reference (7)	Compliant
Reference (3)	Compliant	Bimalaril 80/480 mg	Compliant
R-Lume 180/1080 mg	Compliant	Gen-M 80/480 mg	Compliant
Artefan 20/120 mg	Compliant	Reference (8)	Compliant
Reference (4)	Compliant	Cartef 20/120 mg	Underdosed
Combitrine 15/90/5ml	Compliant	Artefan DT 40/240 mg	Compliant
Telufan 180/1080 mg	Compliant		
Reference (5)	Compliant		
Komefan 20/120 mg	Compliant		

1. 67% of the samples analyzed contained the appropriate quantity of active ingredient and were deemed compliant.
2. 26% of the samples were underdosed, posing a risk of treatment failure and increased resistance.
3. 7% of the samples were overdosed, raising concerns about potential toxicity (Figure 5).

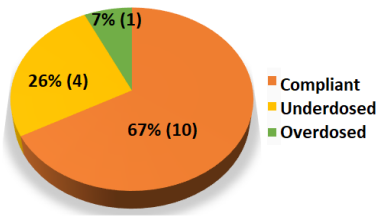

Figure 5. *Distribution of samples based on API quantity.*

These findings highlight significant variability in the quality and compliance of antimalarial drugs, underscoring the need for stricter regulatory controls and quality assurance measures.

4. Discussion

The results highlighted the variability in the quality of Artemether-Lumefantrine antimalarials on the Ivorian illicit market. While most samples complied with disintegration and API content standards, the presence of underdosed and overdosed products underscores the ongoing challenge of ensuring medicine quality. Underdosed formulations may fail to effectively treat malaria, contributing to the development of drug resistance. Conversely, overdosed formulations pose risks of adverse effects, particularly in vulnerable populations.

The GPHF-Minilab® proved effective in identifying non-compliant samples, offering a reliable and accessible tool for rapid quality control. However, further studies incorporating more sophisticated analytical methods, such as high-performance liquid chromatography (HPLC), are recommended to validate these findings and ensure comprehensive quality assessments. Addressing the prevalence of substandard and falsified medicines requires strengthened regulatory frameworks, enhanced market surveillance, and public awareness campaigns to promote the safe use of medications.

The results of this study showed that the majority of the tested artemether-lumefantrine tablet brands passed the disintegration test (30 minutes) as in the study by K. S. Salako et al [18]. In addition, the findings of this study are consistent with WHO reports stating that at least 10% of medicines in low-income countries are of substandard or falsified quality [1]. Likewise, the findings of a study by Wilson J. found that 44% of samples from Senegal and 30% from Madagascar were classified as low quality [17]. The

high prevalence of counterfeit drugs from India and China highlights the global challenge of regulating pharmaceutical exports [19].

The absence of manufacturer information (20%) and missing instructions (7%) increase the risk of misuse and resistance. Substandard drugs, particularly underdosed antimalarials (26%), contribute to prolonged infections and exacerbate the resistance crisis. Robert J Commons et al. demonstrated that the dose of lumefantrine in the combination was not significantly associated with recurrence rate [20].

4.1. Strengths and Limitations

1. *Strengths:* The GPHF-Minilab® provided a rapid and cost-effective method for quality assessment in resource-limited settings.
2. *Limitations:* Semi-quantitative results necessitate complementary confirmatory analyses using high-performance liquid chromatography (HPLC).

4.2. Recommendations

1. Strengthen regulatory frameworks to eliminate counterfeit drugs from the market.
2. Increase public awareness about the dangers of illicit medicines.
3. Invest in robust quality control infrastructures.

5. Conclusions

This study highlights the critical problem of counterfeit antimalarials in Côte d'Ivoire, with 33% of samples either underdosed or overdosed. Indeed, the qualitative analysis shows that all samples contained Artemether and Lumefantrine, confirmed by retention factor (Rf) values consistent with the reference. On the other hand, the semi-quantitative analysis highlighted the following 2 facts: 67% met the active ingredient requirements, 26% were underdosed and 7% were overdosed. These results constitute additional evidence, making it possible to raise awareness among the population on the dangers of consuming drugs from the illicit circuit. The GPHF-Minilab® kit has proven to be an effective tool to identify these non-conformities. In addition, the results highlight the urgent need for comprehensive measures to combat counterfeit drugs, including expanded surveillance, stricter regulation and public education. Future studies should extend this analysis to other therapeutic classes to ensure the safety and efficacy of drugs in low-income settings.

Abbreviations

AL	Artemether-Lumefantrine
API	Active Pharmaceutical Ingredient
DPSD	Directorate of Narcotics and Drug Stupors
GPHF	Global Pharma Health Fund
HPLC	High-Performance Liquid Chromatography
Rf	Retention Factor
TLC	Thin Layer Chromatography
WHO	World Health Organization

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Author Contributions

Déto Ursul Jean-Paul N'guessan: Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing

Songuigama Coulibaly: Conceptualization, Data curation, Methodology, Supervision

Alain Kacou: Investigation, Writing – review & editing

Avi Tanguy Kouaho: Data curation, Investigation, Writing – review & editing

Amelanh Sica Diakité: Investigation, Writing – review & editing

Jean-Fabrice Konan Koffi: Data curation, Investigation, Writing – original draft

Melissa Eunice Apleheni Adouko: Data curation, Investigation, Methodology, Writing – review & editing

Mahama Ouattara: Conceptualization, Methodology, Validation

Conflicts of Interest

The authors declare no conflicts of interest.

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Research Field

Dáto Ursul Jean-Paul N'guessan: Organic and Medicinal Chemistry and Drug Screening, Quality control of medicines, Docking, ADMET and QSAR of Anti-infectious compound, Heterocyclic Compounds Synthesis and Anti-infectious activities, Evaluation of the performance of the health system, Management and governance of universities

Songuigama Coulibaly: Organic and Medicinal Chemistry and Drug Screening, Heterocyclic Compounds Synthesis and Anti-infectious activities, Quality control of medicines, Docking, ADMET and QSAR of Anti-infectious compound

Alain Kacou: Organic and Medicinal Chemistry and Drug Screening, Heterocyclic Compounds Synthesis and Anti-infectious

activities, Quality control of medicines, Antibiofilm activity assessment

Avi Tanguy Kouaho: Organic and Medicinal Chemistry and Drug Screening, Heterocyclic Compounds Synthesis and Anti-infectious activities, Quality control of medicines

Amelanh Sica Diakité: Organic and Medicinal Chemistry and Drug Screening, Heterocyclic Compounds Synthesis and Anti-infectious activities, Quality control of medicines

Jean-Fabrice Konan Koffi: Organic and Medicinal Chemistry and Drug Screening, Heterocyclic Compounds Synthesis and Anti-infectious activities, Quality control of medicines

Melissa Eunice Apleheni Adouko: Organic and Medicinal Chemistry and Drug Screening, Quality control of medicines, Docking, ADMET and QSAR of Anti-infectious compound

Mahama Ouattara: Organic and Medicinal Chemistry and Drug Screening, Heterocyclic Compounds Synthesis and Anti-infectious activities, Quality control of medicines, Docking, ADMET and QSAR of Anti-infectious compound