

Securing the ofloxacin–ornidazole combination in the Democratic Republic of the Congo

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ABSTRACT

Introduction

Pharmaceutical stability in tropical regions is a critical public health concern, as extreme heat and humidity can compromise drug integrity before the expiry date.

Purpose

This cross-sectional analytical study, incorporating experimental stability testing, aimed to evaluate the effects of architectural microclimates and hygrothermal conditions on the stability of the ofloxacin–ornidazole combination in the Democratic Republic of the Congo (DRC).

Methods

Observational field sampling (N = 30), combined with laboratory stability testing, was conducted in Kinshasa, Kisangani, and Bukavu. Laboratory stability was assessed using a validated spectrophotometric method.

Results

Drug content levels in Kinshasa pharmacies, characterized by uninsulated iron roofs, showed statistically significant underdosing ($87.27\% \pm 1.45$; $p < .001$; 95% CI [85.8, 88.7]) compared with the $98.40\% \pm 0.55$ observed in temperate Bukavu ($p < .001$).

Conclusion

Building architecture and physical integrity (e.g., tablet crushing) are major determinants of drug quality in Climatic Zone IVb. The observed underdosing may compromise therapeutic efficacy and represents a recognized risk factor for accelerating antimicrobial resistance, as supported by global climatic models.

INTRODUCTION

The internationalization of the pharmaceutical supply chain has the potential to rapidly spread poor-quality medicines worldwide (Ive et al., 2025). In Sub-Saharan Africa, it is estimated that more than 30% of marketed medicines are substandard or degraded (Busha et al., 2022; Ive et al., 2025). In the Democratic Republic of the Congo (DRC), this challenge is amplified by Climatic Zone IVb conditions (temperature > 30°C; relative humidity [RH] > 75%), where the mean kinetic temperature (MKT) frequently exceeds international stability standards.

Structural weaknesses, such as intermittent electricity and the lack of refrigeration in more than 70% of households, create hostile storage environments (Khuluza et al., 2023; Suleman et al., 2025). However, limited evidence exists regarding how real-world architectural microclimates—such as uninsulated pharmacies with low ceiling heights—affect antibiotic stability in tropical regions. Exposure to high temperatures triggers specific degradation mechanisms, including thermal decarboxylation and oxidative side-chain cleavage, in which ambient heat provides the activation energy necessary for chemical instability (Yasmin et al., 2026). Therefore, this study aimed to evaluate the effects of architectural microclimates and hygrothermal conditions on the stability of ofloxacin–ornidazole tablets in the DRC.

METHODS

This study used an observational field sampling design combined with laboratory stability testing.

Sampling and Climatic Characteristics

A total of 30 samples (N = 30), within their expiry dates, were collected across three distinct zones. In Kinshasa (savanna climate), temperatures fluctuate between 22°C and 34°C. In Kisangani (equatorial climate), medicines are exposed to sustained heat (30–31°C) and extreme humidity (80%–90% RH). Bukavu (1,500 m altitude) served as a temperate reference site. Environmental monitoring in uninsulated pharmacies estimated internal microclimates reaching 30°C to 42°C due to solar radiation on corrugated iron roofs.

Analytical Performance and Validation

The analytical method was validated according to ICH Q2(R2) and SFSTP guidelines using the accuracy profile

approach. Metrological robustness ensured that 95% of future measurements would fall within the ±10% pharmacopoeial acceptance limits.

Table 1:
Method Validation Profile and Metrological Robustness

Performance Parameter	Ofloxacin (OFL)	Ornidazole (ORN)	Regulatory Threshold
Linearity range (µg/mL)	3.19–4.79	7.96–11.94	80%–120%
Coefficient of determination (R ²)	0.9913	0.9923	Min. 0.990
Accuracy (recovery, %)	99.04–99.99	99.13–100.13	98%–102%
Intermediate precision (CV, %)	1.14–2.32	0.98–2.45	< 5.0%
Expanded uncertainty (U)	±3.50%	±3.68%	k = 2 (95% CI)

Note: OFL = ofloxacin; ORN = ornidazole; CV = coefficient of variation; CI = confidence interval.

Statistical Analysis

Data distribution was assessed using the Shapiro–Wilk test. Decisional reliability was evaluated using 95% confidence intervals (CI), calculated as:

$$CI = x \pm t(SD/\sqrt{n})$$

where $t = 4.303$ for $n = 3$. Statistical analyses were performed using GraphPad Prism (Version 9.0).

Ethical Approval and Study Scope

This research followed a two-phase approach integrated into a broader project aimed at detecting substandard and falsified medicines in the Democratic Republic of the Congo (DRC).

Phase 1 involved the development and validation of a simultaneous assay method for ofloxacin and ornidazole tablets using UV–visible spectrophotometry. *Phase 2* focused on the routine application of this validated method to assess the effects of tropical climates and physical integrity on drug stability and to support pharmaceutical supply chain security.

All procedures, including multi-laboratory testing, were conducted under ethical clearance granted by the Research Ethics Committee of the University of Kisangani (UNIKIS/CER/042/2023). This approval ensured compliance with national standards for pharmaceutical quality surveillance.

RESULTS

Qualitative Spectral Analysis and Identification

Qualitative UV analysis (200–400 nm) revealed close agreement between the spectral profiles of all field samples and the reference standard. As shown in **Figure 1**, the shapes of the absorption curves remained consistent across all collection sites, confirming preservation of chemical identity under Climatic Zone IVb conditions.

Chemical identity was further confirmed by preservation of the two characteristic absorption maxima (λ_{max}) at

320 nm (ornidazole) and 330 nm (ofloxacin). **Figure 2** illustrates substantial spectral overlap between the two active pharmaceutical ingredients (APIs), supporting the use of Vierordt’s simultaneous equations for accurate quantification. No baseline distortion or emergence of additional peaks was observed.

To meet precision requirements, λ_{max} values were compared across sites (**Table 2**). No deviation from the reference standard was detected ($\sigma = 0.00$ nm; $p > .99$), indicating qualitative homogeneity across all samples.

Figure 1:

Individual UV spectral profiles of the ofloxacin–ornidazole combination: (a) Kisangani (poorly ventilated storage); (b) Kisangani (ventilated pharmacy, equatorial climate); (c) Kisangani (household storage); (d) Kinshasa (pharmacy, tropical climate); (e) reference standard; (f) Bukavu (pharmacy, mountain climate)

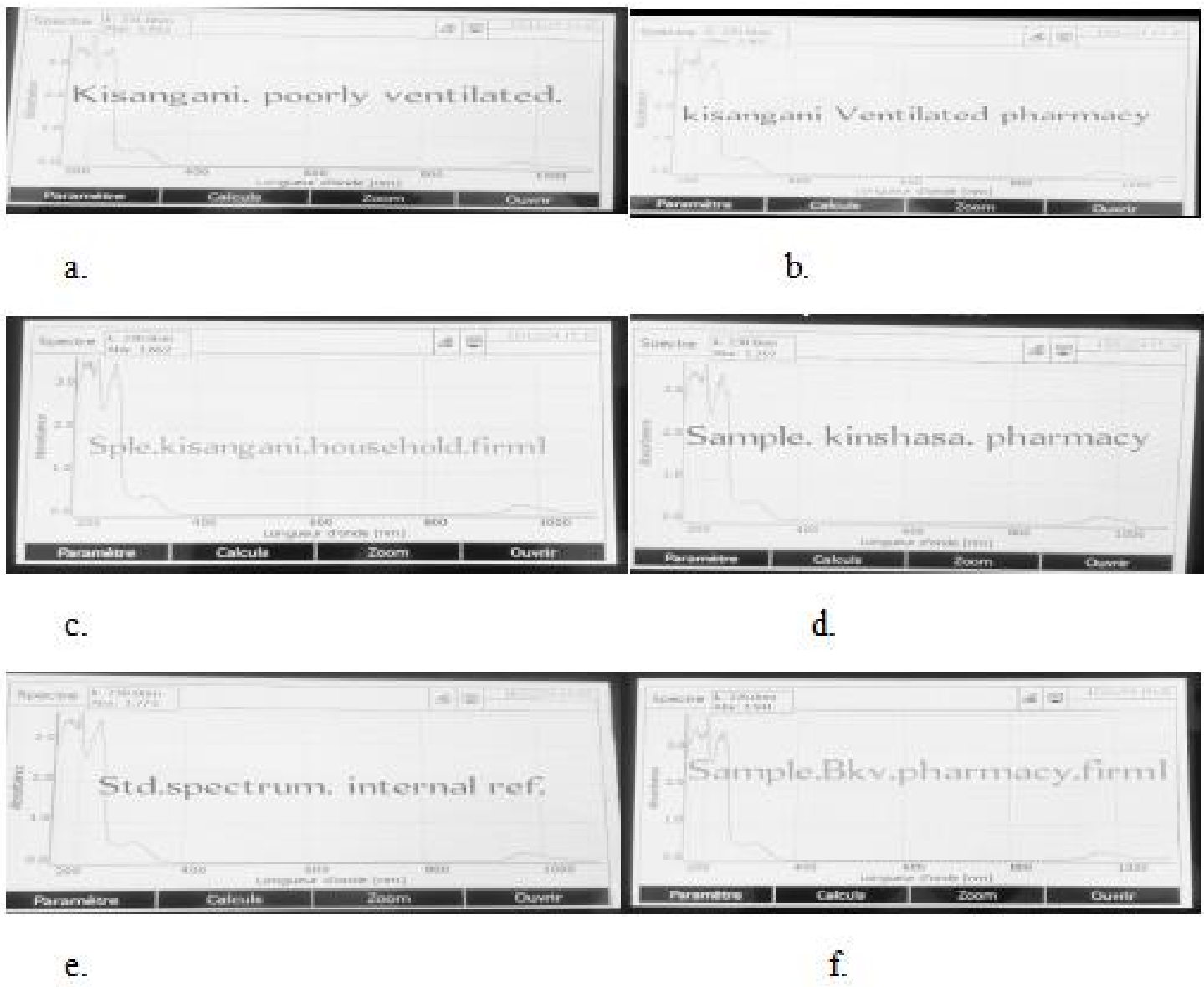


Figure 2:

Spectral overlay illustrating intrinsic overlap between ornidazole ($\lambda_{\text{max}} = 320 \text{ nm}$) and ofloxacin ($\lambda_{\text{max}} = 330 \text{ nm}$). The overlap supports the necessity of Vierordt's simultaneous equations for accurate quantification of each API

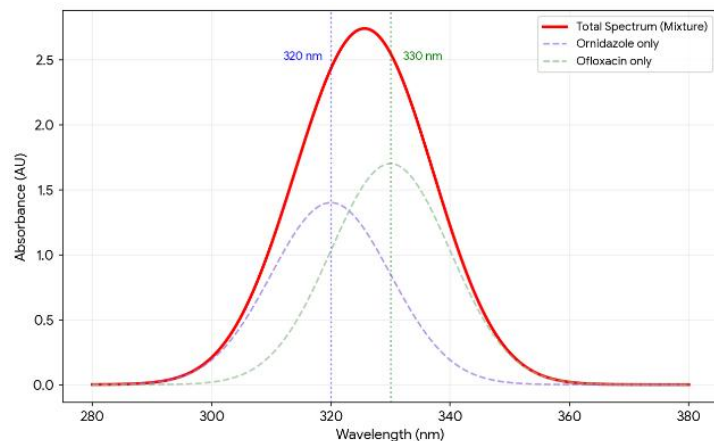


Table 2:
Statistical Comparison of Absorption Maxima (λ_{max}) by Collection Site

Site (Origin)	λ_{max} (nm)	Ornidazole λ_{max} (nm)	Ofloxacin λ_{max} (nm)	Deviation Standard (nm)	From
Reference standard	320.0	330.0	–		
Kinshasa	320.0	330.0	0.0		
Kisangani	320.0	330.0	0.0		

Table 3:
Quantitative Analysis, Compliance, and Statistical Significance of the Ofloxacin–Ornidazole Combination

Site / Storage Condition	Ofloxacin (%; Mean \pm SD)	Ornidazole (%; Mean \pm SD)	Ofloxacin 95% CI	Ornidazole 95% CI	<i>p</i> (vs. Bukavu)	Status
Reference standard	99.15 \pm 0.12	103.35 \pm 0.15	[98.8, 99.5]	[102.9, 103.7]	–	Compliant
Bukavu (pharmacy)	98.40 \pm 0.55	101.20 \pm 0.40	[97.8, 99.0]	[100.2, 102.2]	Reference	Compliant
Kisangani (pharmacy)	94.59 \pm 0.80	100.25 \pm 0.65	[93.7, 95.5]	[98.6, 101.9]	<i>p</i> < .05	Compliant
Kisangani (household)	88.93 \pm 1.20	93.21 \pm 0.95	[87.6, 90.3]	[91.1, 95.3]	<i>p</i> < .001	Substandard
Kinshasa (pharmacy)	87.27 \pm 1.45	91.55 \pm 1.10	[85.8, 88.7]	[89.5, 93.6]	<i>p</i> < .001	Critical
Oven (50°C)	119.45 \pm 0.50	108.20 \pm 0.45	[118.6, 120.3]	[107.5, 108.9]	<i>p</i> < .001	Biased

Note: CI = confidence interval; SD = standard deviation.

DISCUSSION

Chemical Identity and Resolution of Spectral Overlap

The spectral stability observed despite divergent microclimates across the DRC highlights the molecular robustness of the ofloxacin–ornidazole combination. The absence of bathochromic or hypsochromic shifts suggests that chromophores underwent no detectable structural modifications. These findings align with Busha et al. (2022) and underscore the need for continued surveillance given

the environmental stressors described by Suleman et al. (2025).

The overlap between 320 and 330 nm represents a major analytical challenge. As noted by Patil et al. (2021), closely spaced absorption maxima prevent direct quantification without mutual interference. This supports the use of Vierordt's simultaneous equations, a recognized method for resolving binary mixtures with overlapping spectra.

In the DRC, where substandard and falsified products remain prevalent (Lunsevila et al., 2023), qualitative

Site (Origin)	λ_{max} (nm)	Ornidazole λ_{max} (nm)	Ofloxacin λ_{max} (nm)	Deviation Standard (nm)	From
Bukavu	320.0	330.0	0.0		
Standard deviation (σ)	0.00	0.00	<i>p</i> > .99		

Note: λ_{max} = absorption maximum.

Quantitative Stability Assessment and Geographic Disparity

Quantitative analysis (Table 3) revealed significant disparities in potency associated with storage microclimates. Samples from Bukavu remained compliant (ofloxacin: 98.40% \pm 0.55), whereas substantial potency loss was observed in Kinshasa, where ofloxacin content declined to 87.27% \pm 1.45 (95% CI [85.8, 88.7]), failing the 90% regulatory threshold.

Overall, a significant geographic disparity in potency was observed for both APIs. In Kinshasa, the 95% CI for ofloxacin ([85.8, 88.7]) was entirely below the 90% threshold, while ornidazole ([89.5, 93.6]) remained near the compliance boundary. These findings indicate that the ofloxacin–ornidazole combination is sensitive to uninsulated architectural microclimates under Climatic Zone IVb conditions (*p* < .001).

confirmation of identity is essential to ensure reliable quantification and avoid analytical misinterpretation that could contribute to antimicrobial resistance (Garé et al., 2025).

Microclimatic Determinants and Degradation Mechanisms

The statistically significant degradation observed in Kinshasa and in informal household storage in Kisangani ($p < .001$) demonstrates the impact of architectural microclimates on pharmaceutical stability. In tropical settings, uninsulated structures with corrugated iron roofs often lack sufficient thermal inertia, generating an “overnight oven” effect in which indoor temperatures exceed stability limits under Climatic Zone IVb conditions (Khuluza et al., 2023).

Accelerated degradation in crushed (pulverized) tablets may be explained by the Noyes–Whitney principle: disruption of the protective film coating increases surface area and accelerates moisture exposure and drug–excipient interactions. These findings suggest that physical integrity is a critical barrier against chemical instability in humid tropical environments (Suleman et al., 2025).

Comparative Stability and the Hyperchromicity Paradox

Differential vulnerability was observed between the two APIs: ofloxacin exhibited greater potency loss (87.27%) than ornidazole (91.55%). This may be explained by fluoroquinolone degradation pathways, including thermal decarboxylation and oxidative side-chain cleavage, which are exacerbated under high humidity conditions typical of Climatic Zone IVb (Yasmin et al., 2026).

The apparent overestimation observed during 50°C stress testing (119.45%) reflects a hyperchromicity paradox. As reported by Dahoumane et al. (2021), non-separative UV methods may yield inflated absorbance when degradation products contain auxochromes. This creates a “Vierordt bias,” leading to artificially elevated potency estimates and masking degradation of the parent compound.

Public Health Implications and Selective Pressure

Subtherapeutic concentrations (<90%) observed in Kinshasa and household storage represent a significant public health concern. Although clinical causality requires further microbiological data, failure to achieve the

minimum inhibitory concentration (MIC) is widely recognized as a driver of selective pressure. Chronic underdosing may therefore contribute to the antimicrobial resistance burden in the DRC (Ive et al., 2025).

These findings support the recommendation that ofloxacin–ornidazole tablets should be stored in climate-controlled environments and should not be crushed prior to administration in tropical regions.

Study Limitations

This study has several limitations. First, the sample size ($N = 30$) limits generalizability. Second, the absence of continuous digital hygrothermal logging prevented direct quantification of indoor temperature fluctuations and heat flux; exposure conditions were therefore estimated based on architectural characteristics. Finally, although UV spectrophotometry is accessible for surveillance, it cannot separate degradation products with the precision achievable using high-performance liquid chromatography (HPLC).

CONCLUSION

This study confirms that although the ofloxacin–ornidazole combination maintained qualitative spectral identity across diverse regions of the DRC, its quantitative stability was critically compromised by architectural microclimates under Climatic Zone IVb conditions. Significant degradation observed in Kinshasa (87.27%) and informal household storage in Kisangani (88.93%) represents a major public health concern, as these subtherapeutic concentrations fail to meet regulatory standards (<90%). The observed hyperchromicity paradox under stress testing further cautions against the potential overestimation of potency when non-separative UV methods are used in the presence of degradation products. To mitigate these risks, regulatory authorities in the DRC should enforce stricter climate-controlled storage requirements for pharmacies, particularly in low-ceiling or uninsulated buildings. In addition, healthcare providers should be sensitized to the implications of the Noyes–Whitney principle: crushing tablets in tropical climates may accelerate chemical degradation and should be avoided.

Future studies should incorporate larger longitudinal sampling across multiple provinces and employ HPLC to

characterize degradation kinetics and identify specific degradation products.

Data Availability: The raw data and spectrophotometric datasets generated during this study are available from the corresponding author upon reasonable request.

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Conflicts of Interest: None declared.

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