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Post-market quality evaluation of chloramphenicol capsules marketed in Freetown, Sierra Leone

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Abstract
Background: Chloramphenicol capsules are widely used in low- and middle-income settings, yet product quality can vary across brands, with implications for therapeutic effectiveness and antimicrobial resistance. Evidence from Freetown, Sierra Leone, has been limited.
Objectives: To evaluate key pharmaceutical quality attributes, uniformity of dosage units, dissolution, and assay of chloramphenicol capsule brands marketed in Freetown and benchmark performance against compendial specifications.
Methods: An experimental, laboratory-based study was conducted at the National Pharmaceutical Quality Control Laboratory, Pharmacy Board of Sierra Leone. Nine brands (coded C1-C9) were purchased from registered outlets (January 2025). Tests followed pharmacopoeial procedures: (i) Uniformity of dosage units by mass variation with Acceptance Value (AV) criteria (USP <905>: pass at Stage-1 if AV≤15; Stage-2 if AV≤ 25); (ii) Dissolution using Apparatus I (basket), 100 rpm, 900 mL 0.1 M HCl at 37 °C, 45-min sampling, UV-Vis at 278 nm; working target ≥ 80% dissolved; (iii) Assay by UV-Visible spectrophotometry at 278 nm, expressed as percent label claim; working acceptance 95-105%. All tests were performed in triplicate per brand where applicable.
Results: Uniformity of dosage units: 6 brands (66.7%) passed at Stage-1; three brands (C1, C5, C8) failed Stage-1 (AV>15) but passed Stage-2 (all AV≤25), yielding compliant overall.
Dissolution: 5 brands (55.6%) met the ≥80% release target at 45 min (C1, C3, C5, C7, C8). Four brands (C2, C4, C6, C9) failed, with mean% dissolved of 39.6%, 6.9%, 45.3%, and 41.4%, respectively. Assay: 6 brands (66.7%) were within 95-105% label claim (C1, C2, C4, C6, C7, C9). Three brands were below spec: C3 (93.87%), C5 (81.57%), C8 (81.11%). Across all brands, mean assay values ranged from 81.11% to 103.53%.
Conclusions: Substantial inter-brand variability was observed. While all brands ultimately complied with dose uniformity (after Stage-2 where needed), nearly half failed dissolution and one-third failed assay, indicating a meaningful risk of inconsistent clinical performance. Strengthened manufacturing controls, risk-based post-market surveillance, and routine compendial testing are warranted to ensure safe, effective, and reliable chloramphenicol capsule products in this market.

Keywords: Sierra Leone, chloramphenicol, capsules, dissolution, uniformity of dosage units, assay, compendial compliance, pharmaceutical quality

Introduction
Chloramphenicol is a broad-spectrum antibiotic that treats bacterial infections by inhibiting protein synthesis (Ferraz *et al*., 2007) [3]. It is classified within the Biopharmaceutics Classification System (BCS) as a Class III drug. BCS Class III drugs are characterized by high solubility but low permeability; in practical terms, this means that although chloramphenicol dissolves readily in physiological fluids, insufficient amounts may cross biological membranes to achieve the concentrations required for optimal efficacy (Ferraz *et al*., 2007) [3]. Therapeutic success, however, depends not only on delivering an adequate amount of drug to the target site but also on the molecule possessing physicochemical and solid-state properties that support efficient action. Chloramphenicol exerts its effect by entering microbial ribosomes and disrupting the translational machinery that produces proteins (Gusrini Fadri, 2019) [6].
Chloramphenicol exists in multiple polymorphic forms that can differ in solubility and, therefore, in dissolution rate (Gusrini Fadri, 2019) [6]. The presence of different polymorphs and of amorphous content can meaningfully alter drug concentration in solution and, as a result, absorption (Ferraz *et al*., 2007; Gusrini Fadri, 2019) [3, 6].

Formulation also plays a critical role: how chloramphenicol is incorporated into a given dosage form strongly influences the drug-release characteristics from that product (Glazko *et al*., 1968) [5]. In the marketplace, different brands of chloramphenicol capsules are available at varying price points (Gusrini Fadri, 2019) [6]. Product quality can be affected by particle size, solubility, crystalline form, manufacturing techniques, and the choice of excipients (Gusrini Fadri, 2019) [6]. Furthermore, sourcing raw materials from different suppliers may contribute to variability in solubility and dissolution behavior. Differences in dissolution profiles among chloramphenicol capsules can translate into differences in clinical performance and even into price differences (Glazko *et al*., 1968) [5].

Materials and Methods

Study Design and Setting

This component of the work used an experimental, laboratory-based design to evaluate the pharmaceutical quality of chloramphenicol capsules sold in Freetown. The evaluation focused on critical quality attributes that determine performance and compliance with compendial requirements, namely identity of the active pharmaceutical ingredient (API), uniformity of dosage units by mass variation, in-vitro dissolution behaviour, and assay of API content. All analyses were performed at the National Pharmaceutical Quality Control Laboratory (NPQCL), Pharmacy Board of Sierra Leone (PBSL), under standard quality-control conditions and good laboratory practice.

Sampling and Sample Description

Nine brands of chloramphenicol capsules were procured from a range of registered pharmaceutical outlets across the Western Area (Freetown) over a two-week period in January 2025 to reflect products readily available to consumers. Immediately after purchase, samples were transported to NPQCL and stored under appropriate conditions to minimise degradation and bias prior to testing. Each brand underwent systematic label inspection to document country of origin, manufacturer name and address, batch/lot number, manufacturing and expiry dates, labeled strength, and any special storage instructions. Brands were coded to blind the analysts during testing and data processing.

Reagents

Analytical-grade reagents were used throughout: distilled water (for dilutions and glassware rinsing), ethanol (co-solvent as required), sodium hydroxide, 1 M sulfuric acid, sodium nitrite, and 0.1 M hydrochloric acid (HCl) for dissolution medium and UV-Vis reference where specified by the method. All solutions were prepared fresh or verified prior to use.

Instruments

The following calibrated equipment and glassware were employed: A bench top pH meter; UV-Visible spectrophotometer with 1 cm quartz cells; USP/ BP-compliant dissolution tester (Apparatus I, basket); analytical balance (readability 0.1 mg); pipettes (graduated and volumetric); volumetric flasks; beakers and test tubes; a mortar and pestle for powdering capsule contents; and a Vernier caliper for capsule dimension checks where needed. Routine glassware cleanliness controls and blank checks were performed between samples to avoid cross-contamination.

Methods

Identification (UV-Visible Spectrophotometry)

Capsule contents were gently emptied and mixed to ensure homogeneity, then a representative portion was dissolved and quantitatively transferred to prepare a sample solution of approximately 10 µg/mL in a suitable solvent system (distilled water or methanol/water as validated for clarity). A standard solution of chloramphenicol reference material at the same nominal concentration (≈ 10 µg/mL) was prepared in parallel. The spectrophotometer was zeroed with an appropriate blank, and both standard and sample were scanned from 200-400 nm to locate the absorption maximum. Identity was confirmed when the sample exhibited a principal peak at the characteristic working wavelength for chloramphenicol (λ_max ≈ 278 nm) with a spectral profile concordant with the standard. For confirmatory single-wavelength measurements, absorbance was recorded at λ_max using matched cells, observing Beer-Lambert's law $A = \varepsilon c l$ (1 cm path length) for comparability. This step verified the presence of chloramphenicol before further testing (British Pharmacopoeia Commission, 2023; Harris, 2016) [2, 7].

Uniformity of Dosage Units (Mass Variation)

Uniformity of dosage units was evaluated by mass variation according to compendial guidance for solid oral dosage forms when an assay method is also performed. Ten capsules per brand were individually weighed on a calibrated analytical balance and the masses recorded. Where required, the empty shell mass was determined to estimate fill mass. Using the labeled claim and assay data for each brand, individual unit contents (as% of label claim) were derived. The Acceptance Value (AV) was calculated using the USP <905> approach:

$$AV = |\bar{X} - T| + k \cdot s$$

Where $\bar{X}$ is the mean content (% label claim), T is the target content (100% unless otherwise specified), s is the sample standard deviation, and k is the acceptability constant (2.4 for n = 10). Compliance was judged against the Stage 1 criterion ($AV \leq 15$), with progression rules applied if necessary (United States Pharmacopeial Convention, 2024a) [13].

Dissolution Testing

Dissolution was carried out in accordance with the British Pharmacopoeia general method for tablets and capsules (Appendix XII B1) using Apparatus I (basket) at 100 rpm in 900 mL of 0.1 M HCl maintained at 37±0.5 °C. At 45 minutes, a 10 mL aliquot was withdrawn from a fixed zone midway between the surface and the basket without replacing medium, immediately filtered through a 0.45 µm membrane to remove undissolved particulates, and, where necessary, diluted with 0.1 M HCl to fall within the linear absorbance range. Absorbance was measured at 278 nm using 0.1 M HCl as the reference. The amount of chloramphenicol dissolved was calculated using the specific absorptivity A (1%,1 cm) = 297 at 278 nm, applying Beer-Lambert's relationship and the known test volume; results

were expressed as a percentage of the labeled claim dissolved at the stated time. Conformity was assessed against the applicable BP acceptance criteria for chloramphenicol capsules or, where brand-specific monographs were unavailable, against the general-monograph Q value and staged decision rules (British Pharmacopoeia Commission, 2023) [2].

Assay (UV-Visible Quantification)

Assay of chloramphenicol content was performed by UV-Visible spectrophotometry at 278 nm. Accurately weighed portions of reference standard and powdered capsule sample (each nominally 50 mg chloramphenicol) were dissolved in methanol, quantitatively transferred, and diluted to 100 mL in volumetric flasks to obtain 0.5 mg/mL solutions. After verification of clear solutions and appropriate blanks, single-wavelength absorbance's were recorded at 278 nm. Content (% label claim) for each sample was calculated using a comparative ratio to the reference standard.

$$\% \text{ Content} = (A_{sample} / A_{standard}) \times (W_{standard} / W_{sample}) \times 100$$

Where A denotes absorbance and W denotes the accurately weighed quantities of reference and sample, respectively. Results were compared with the applicable pharmacopoeial specification for capsules; unless otherwise stipulated for a given monograph, a typical acceptance window of 95-105% of label claim was applied (British Pharmacopoeia Commission, 2023; United States Pharmacopeial Convention, 2024b) [2, 14]. Instrument suitability (baseline stability, linearity checks within the working range) and solution stability were verified as part of routine QC.

Data Handling and Analysis

Raw measurements (masses, absorbance's, dissolution readings, pH where applicable) were recorded contemporaneously in bound laboratory notebooks and transferred to structured spreadsheets with brand codes only. Calculations (means, standard deviations, AV,% dissolved,% assay) were independently verified. Compliance/pass-fail determinations for each test were made strictly against the cited pharmacopoeial criteria. All original data, calculation sheets, and instrument printouts were archived to enable verification and replication.

Results

Sampling and Sample Description

Nine chloramphenicol capsule brands (coded C1-C9) were purchased from registered pharmaceutical outlets across Freetown and logged at receipt for traceability (brand/generic name, batch/lot, manufacture/expiry dates, manufacturer and address, and packaging). Products varied by manufacturer, country of origin, primary/secondary packaging (blister or strip; paper/laminated cartons), and capsule appearance (colour, imprint/band). These characteristics are summarized below to contextualize subsequent quality results.

Table 1: Chloramphenicol capsule samples marketed in Freetown, Sierra Leone

Generic Name	Brand Name	Code	Batch No.	Manuf. Date	Expiry Date	Manufacturer (Name & Address)	Primary Packaging	Secondary Packaging	Product Description
Caps. Chloramphenicol	Chloromax	C1	230413	04/2023	03/2026	Ningbo Tisun Medic Biochemic Co. Ltd, 456 Ningning Rd, Ningbo, China	Blister pack	Paper box	White capsule with red imprint
Caps. Chloramphenicol	Phenicol	C2	221202SPD	12/2022	12/2025	Anhui Medipharm Co. Ltd, 288 Huaining Road, Hefei City, China	Blister pack	Carton box	Off-white capsule, no imprint
Caps. Chloramphenicol	Optichlor	C3	230755	07/2023	07/2026	Huangshan Shengii Pharmaceutical Co. Ltd, Huangshan North Gate, China	Strip pack	Paper box	White/green capsule
Caps. Chloramphenicol	Chloracin	C4	2403032	03/2024	03/2027	Jiangxi Xierkangtai Pharmaceutical Co. Ltd, China	Blister pack	Carton box	Red and white capsule
Caps. Chloramphenicol	Bactochlor	C5	C2120129	12/2022	11/2025	ION Healthcare Pvt. Ltd, India	Blister pack	Foil-lined carton	Solid white capsule
Caps. Chloramphenicol	Viochlor	C6	221001	12/2022	10/2025	Anison International Ltd, Piccadilly, London, UK	Strip pack	Paper carton	White capsule, blue imprint
Caps. Chloramphenicol	Pharmachlor	C7	C026301	01/2023	12/2025	Aura Lifecare Pvt. Ltd, 254 Jarod Savii Rd, India	Blister pack	Laminated box	Cream capsule with red band
Caps. Chloramphenicol	Chlorocap	C8	2315598C001	07/2023	06/2026	Scot Edil Pharmacia Ltd, India	Strip pack	Cardboard box	Green capsule with white band
Caps. Chloramphenicol	Nefrochlor	C9	221021	10/2022	10/2025	Ningbo Nuobai Pharmaceutical Co. Ltd, Ningbo, China	Blister pack	Colour-printed box	Translucent white capsule

Uniformity of dosage units

Uniformity was assessed via Acceptance Value (AV) as per USP <905>. Stage-1 (L1) passes if AV ≤ 15 using 10 units; if L1 fails, additional units are tested to compute a Stage-2 (L2) AV, which passes if AV ≤ 25. AV integrates mean content deviation from 100% and within-batch variability using the acceptability constant k (2.4 for N=10). Thus, a product may fail at L1 yet pass at L2 after additional units are included, indicating acceptable overall dose uniformity.

Table 2: Uniformity of Dosage Units (Acceptance Value, AV)

Code	AV (L1)	L1 Result	AV (L2)	L2 Result
C1	16.08352	FAIL	10.85253	PASS
C2	7.893516	PASS	7.893516	PASS
C3	5.099839	PASS	5.099839	PASS
C4	4.208437	PASS	4.208437	PASS
C5	18.8047	FAIL	18.58928	PASS
C6	5.345429	PASS	5.345429	PASS
C7	6.591215	PASS	6.591215	PASS
C8	26.05572	FAIL	22.5766	PASS
C9	4.997663	PASS	4.997663	PASS

Abbreviations: AV, Acceptance Value; L1, Stage-1 criterion (AV≤15); L2, Stage-2 criterion (AV≤25).

Dissolution Testing

Dissolution was performed with Apparatus I (basket), 100 rpm, 900 mL 0.1 M HCl at 37 °C, sampling at 45 minutes and reading at 278 nm. The working quality target for immediate-release is typically Q ≈ 80% dissolved at the stated time. The Min-Max range captures replicate variability across units; the% Dissolved column is the mean.

Table 3: Dissolution at 45 Minutes (0.1 M HCl, 37 °C; Apparatus I, 100 rpm)

Code	Mean% Dissolved	Min	Max	Comment
C1	81.4040404	80.73939	82.92121	PASS (≥80%)
C2	39.64107744	37.00606	49.35758	FAIL (<80%)
C3	86.5023569	84.90909	88.54545	PASS
C4	6.901683502	5.345455	9.333333	FAIL
C5	85.27003367	84.84848	85.96364	PASS
C6	45.32457912	43.10303	48.66667	FAIL
C7	89.3003367	88.07273	91.22424	PASS
C8	88.36296296	88.07273	88.66667	PASS
C9	41.3993266	40.99394	42.13333	FAIL

Assay

Assay was performed by UV-Visible spectrophotometry at 278 nm using a reference standard. Unless otherwise specified by a product monograph, a working specification of 95-105% of label claim was applied for capsules. Each brand was analysed in triplicate; the table reports the three replicates, mean and standard deviation (SD).

Table 4: Assay of Chloramphenicol Capsules (Triplicate Analyses)

Code	Replicate 1 (%)	Replicate 2 (%)	Replicate 3 (%)	Mean% Assay	SD	Remark
C1	103.5354	103.5354	103.5354	103.53	0.00	PASS
C2	101.3973	101.3973	101.3973	101.40	0.00	PASS
C3	93.88889	93.87205	93.84394	93.87	0.02	FAIL
C4	96.00449	95.92031	95.89226	95.94	0.06	PASS
C5	81.56566	81.56566	81.58249	81.57	0.01	FAIL
C6	97.60943	97.60943	97.60943	97.61	0.00	PASS
C7	94.94949	95.13468	95.37037	95.15	0.21	PASS
C8	81.09428	81.11111	81.11111	81.11	0.01	FAIL
C9	98.24916	98.23232	98.21549	98.23	0.02	PASS

Discussion

These results mirror prior evidence that chloramphenicol product performance is highly sensitive to formulation variables (Glazko *et al*., 1968; Ferraz *et al*., 2007; Gusrini Fadri, 2019) [5, 3, 6]. Failures in dissolution and assay are clinically salient because they risk sub-therapeutic exposure and treatment failure, with potential contribution to antimicrobial resistance (Iskandar *et al*., 2022) [9]. In LMIC settings, the burden and cost of poor-quality medicines are considerable, and routine post-marketing surveillance is advocated by global health authorities (World Health Organization, 2017a) [17]. Strengths of this study include adherence to pharmacopoeial procedures and explicit acceptance criteria, enabling replication. Limitations include the modest sample of brands, reliance on UV-Vis rather than confirmatory HPLC, and single time-point dissolution; these are suitable for screening yet leave room for method enhancement in future work.

Regulatory and technical actions are warranted: enforce GMP requirements; bias procurement to quality-assured sources; and undertake root-cause investigations of failing brands (particle-size distribution, disintegration performance, lubricant levels, and API stability). These align with broader strategies to curb SF medicines and safeguard antibiotic effectiveness (World Health Organization, 2017a; Höllein *et al*., 2016) [17, 8].

Conclusion

Uniformity of Dosage Units.

Three of the nine capsule brands (C1, C5, and C8) failed the USP <905> Stage-1 (L1) acceptance value but passed at Stage-2 (L2), indicating higher within-batch variability that nonetheless met the broader acceptance criterion once additional units were considered. While an L2 pass is compliant, elevated variability can translate into fluctuating delivered doses at the patient level, with potential for subtherapeutic exposure or excessive dosing, particularly concerning agents like chloramphenicol where both efficacy and safety depend on predictable systemic levels (Ferraz *et al*., 2007) [3]. Similar inter-brand variability has been reported for marketed chloramphenicol capsules, attributed to differences in manufacturing controls, excipient quality, particle size distribution, and fill-weight accuracy (Gusrini Fadri, 2019) [6]. In short, dose uniformity is not merely a regulatory checkbox; it underpins dosage accuracy, therapeutic outcomes, and patient safety.

Dissolution Profile

Only five brands (C1, C3, C5, C7, C8) met the working target of ≥80% dissolved at 45 minutes under the specified conditions, whereas four (C2, C4, C6, C9) failed. For BCS Class III drugs such as chloramphenicol high solubility but low permeability, rapid and consistent dissolution is essential to driving absorption; a product may contain the

correct API amount but still underperform clinically if dissolution is inadequate (Ferraz *et al*., 2007) [3]. Dissolution failures in marketed generics have been linked to suboptimal formulation design and process control, including lubricant levels, granulation quality, and capsule plug properties (Höllein *et al*., 2016; Tefera *et al*., 2023) [8, 12]. The four failing brands in this series therefore raise a red flag for therapeutic interchangeability and highlight a need for targeted post-market surveillance and corrective actions.

Assay Results

Three brands (C3, C5 and C8) fell outside the typical capsule specification of 95-105% of label claim. Sub-specification potency cohmpromises the probability of bacterial kill and can promote treatment failure and resistance selection; conversely, excessive potency increases toxicity risk. Although chloramphenicol's most feared reactions (e.g., idiosyncratic aplastic anemia, optic neuropathy) can occur even within therapeutic ranges, poor control of dose strength or release characteristics plausibly elevates overall risk at the population level by driving retreatment, polypharmacy, and inadvertent overexposure in some users (Barnhill *et al*., 2012; Flach, 1982) [1, 4]. The pattern of low assay in several brands aligns with broader findings on medicine quality lapses in low- and middle-income settings (World Health Organization, 2017) [17].

Implications for Antimicrobial Resistance (AMR) and Public Health

Substandard performance whether from variable content, failed dissolution, or low assay can sustain sub-MIC exposures *in vivo*, amplifying selection pressure for resistant strains (Iskandar *et al*., 2022; Williams-Nguyen *et al*., 2016) [9, 16]. At system level, poor-quality medicines erode trust, waste limited resources, and worsen disease burden (Newton *et al*., 2010; Pathak *et al*., 2023) [10, 11]. The failure rates observed here echo wider challenges in regulatory enforcement, quality assurance, and post-marketing surveillance in the sub-region and specifically in Sierra Leone (Vandy *et al*., 2024) [15], underscoring the importance of risk-based inspections and routine market checks.

Price-Quality Relationship

Contrary to common perception, higher price did not reliably predict better quality some relatively expensive brands failed critical parameters, reinforcing the principle that price is a poor proxy for quality and should not substitute for rigorous regulatory evaluation (Höllein *et al*., 2016) [8].

Study Limitations

Interpretation should consider several constraints. First, the sample frame was modest (nine brands) from a single metropolitan area and time window, which limits generalizability. Second, dissolution performance was assessed in a single compendial medium/time point; while appropriate for screening, a full profile (multiple time points/media) could better characterise release behaviour. Third, the assay employed UV-Visible spectrophotometry, which is not stability-indicating; undetected degradants could bias potency estimates. Fourth, uniformity was primarily assessed by mass variation; although acceptable when paired with assay, content-uniformity testing by chemical quantification of units would provide a stronger control. Finally, storage/transport histories prior to purchase were not controlled, and no in-vivo or bioequivalence correlations were undertaken, so clinical implications are inferred rather than directly measured.

Conclusion

This evaluation of nine marketed chloramphenicol capsule brands in Freetown revealed substantial inter-brand variability in three core quality attributes: dose uniformity, dissolution performance, and assay. Nearly half of the products did not meet the dissolution target, and a third were below the potency specification, while several showed elevated dose variability at initial testing. Taken together, these findings indicate a meaningful risk that some products may deliver inconsistent or clinically inadequate therapy, with potential consequences for patient outcomes and antimicrobial resistance. Quality cannot be inferred from price, underscoring the need for proactive regulatory oversight, risk-based post-market surveillance, and routine confirmatory testing. Strengthening manufacturing controls, tightening supplier qualification of excipients and APIs, and enforcing compliance with pharmacopeial standards are pivotal to ensure that all chloramphenicol capsules on the market are safe, effective, and reliable.

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