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Are Nigerian-market Amlodipine 10 mg tablets interchangeable? Evidence from in-vitro quality tests

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Abstract

Amlodipine is a widely used antihypertensive medication in Nigeria, with multiple generic brands available in the market. Ensuring the quality and therapeutic equivalence of these generics is crucial for patient safety and treatment efficacy. This study evaluated the physicochemical properties and dissolution profiles of thirteen brands of amlodipine besylate 10 mg tablets marketed in Nigeria. The brands were assessed for compliance with British Pharmacopoeia standards, and their dissolution profiles were compared using model-independent parameters (f_1 and f_2). Most brands met the required specifications for weight variation, friability, assay, and dissolution. However, notable variability was observed in dissolution behavior, with some brands exhibiting borderline or non-similar profiles compared to the innovator brand. The f_1 and f_2 values indicated that seven brands were similar to the innovator, while three brands failed to show similarity. The study highlights the need for rigorous regulatory oversight to ensure that only consistently compliant products remain in circulation.

Keywords: Amlodipine; Similarity factor; Dissolution efficiency; Mean dissolution time.

1. Introduction

Hypertension is a leading cause of morbidity and mortality worldwide, affecting more than one billion people [1]. Its prevalence has risen rapidly, particularly in low- and middle-income countries. Estimates from the World Health Organization indicate that the number of adults with hypertension increased from approximately 594 million in 1975 to 1.13 billion in 2015, with the highest prevalence reported in sub-Saharan Africa [2]. In Nigeria, the continent's most populous nation, rapid urbanization and changing lifestyle patterns contribute to a disproportionate burden. Recent estimates suggest that between 22% and 44% of Nigerian adults are affected, corresponding to more than 20 million individuals [3, 4]. Across sub-Saharan Africa, adult prevalence is similarly high, averaging about 46% [5].

The standard of care for hypertension combines lifestyle modification with antihypertensive pharmacotherapy [6]. Calcium-channel blockers, particularly amlodipine, are recommended globally as first-line therapy for uncomplicated hypertension and are endorsed in Nigeria's national treatment guidelines [7]. Amlodipine is well tolerated, has a long half-life, and effectively lowers both systolic and diastolic blood pressure. Studies conducted in Nigeria further demonstrate that once-daily amlodipine may reduce blood pressure more effectively than hydrochlorothiazide monotherapy [8]. Accordingly, amlodipine remains a cornerstone antihypertensive agent both worldwide and nationally.

Following the expiry of its patent, amlodipine is now marketed in Nigeria by numerous generic manufacturers alongside the innovator brand [9]. By definition, generic medicines must be pharmaceutically equivalent, containing the same active ingredient, dosage form, and strength, and must demonstrate bioequivalence to the innovator product to be considered therapeutically interchangeable [10]. Regulatory authorities, including Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), require bioequivalence studies to support claims of substitution [11]. However, differences in excipients, particle size, tablet hardness, or coating can affect dissolution and consequently influence drug bioavailability [12]. Some studies have reported that certain generic products dissolve more slowly than branded formulations [13], underscoring the importance of rigorous in-vitro quality testing to confirm therapeutic equivalence.

Dissolution testing is a key in-vitro indicator of bioavailability and an essential component of pharmaceutical quality control. According to the United States Pharmacopoeia and the British Pharmacopoeia, amlodipine tablets must release at least 75% of their active content within 30 minutes [5, 16]. Additional pharmacopoeial requirements include uniformity of weight, friability, and assay of potency, while hardness and crushing-strength testing are used to assess mechanical integrity. Compliance with these standards provides evidence of adequate bioavailability, ensures batch-to-batch consistency, and enables the detection of substandard products, thereby safeguarding therapeutic effectiveness.

In Nigeria, both imported and locally manufactured brands of amlodipine are widely available. However, this broad availability has raised concerns, as surveys have documented variability in product quality. Some marketed formulations have failed to consistently meet pharmacopoeial specifications for assay and dissolution [14]. Importantly, most published evaluations have focused on the 5 mg strength [4, 8, 5, 14]. To address this gap, the present

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study evaluates the 10 mg strength of amlodipine tablets marketed in Nigeria. It examines compliance with pharmacopoeial quality criteria and benchmarks generic formulations against the innovator product to determine therapeutic equivalence and confirm that available products meet established standards.

2. Materials and methods

2.1. Sample collection

Thirteen brands of amlodipine besylate 10 mg tablets, coded A1–A13, were procured from licensed community pharmacies and registered distributors in Abuja, Nigeria. Both locally manufactured and imported products were included to capture the diversity of products available to patients. For each brand, information such as batch number, NAFDAC registration number, manufacturing date, expiry date, and country of origin was recorded (Table 1). The samples were stored in their original packaging under controlled ambient laboratory conditions until analysis, in accordance with the British Pharmacopoeia (BP, 2023) guidance on sample handling. Brand A1, the innovator product, was designated as the reference for comparative analyses.

Table 1: Sample information.

Brand	Batch No.	NAFDAC No.	Mfg.	Exp.	Country
A1		04-5354	06/2020	07/2023	Spain
A2	229AG		08/2023	09/2026	Hungary
A3	AM5005H	A4-1338	05/2021	06/2024	Nigeria
A4		A4-0333	03/2021	04/2024	Nigeria
A5	CB04537	A4-5263	02/2021	03/2024	Malaysia
A6	22002	A4-5475	01/2022	02/2025	Nigeria
A7	KP2204	B4-6324	04/2022	05/2025	Nigeria
A8	210465	B4-7956	03/2021	04/2024	China
A9	ED092	C4-1770	03/2022	04/2025	India
A10	22T-0804	C4-1306	06/2023	07/2025	India
A11	G010652	B4-6758	12/2021	01/2024	India
A12	S006353	B4-3303	01/2023	02/2025	Nigeria
A13	ALS-246	B4-9217	09/2020	10/2023	India

2.2. Standards and reagents

Amlodipine besylate reference standard, certified in accordance with BP specifications, was obtained from a reputable supplier. Analytical grade reagents were used throughout. The 0.01 N hydrochloric acid (HCl) was prepared freshly and employed for spectrophotometric determinations. Distilled water was used in all tests. All equipment and glassware were calibrated and prepared in accordance with pharmacopoeial procedures.

2.3. Physicochemical evaluation

Physicochemical analyses were performed following procedures outlined in the British Pharmacopoeia [16].

Tablet dimensions (thickness and diameter) were determined for ten tablets from each brand using a digital Vernier caliper, and results were expressed as mean ± standard deviation (SD) [13].

Tablet hardness (crushing strength) was measured on ten tablets using a Monsanto hardness tester, with results expressed in kilogram-force (KgF) [12].

Friability was assessed using a friabilator. Ten tablets from each brand were weighed collectively, placed in the drum, and rotated at 25 revolutions per minute for four minutes (100 revolutions). The tablets were then dedusted and reweighed, and friability was calculated as the percentage weight loss relative to the initial weight. Tablets with friability values not exceeding 1.0% were considered acceptable [13].

Weight variation was determined on twenty randomly selected tablets per brand, each weighed individually on a calibrated analytical balance. The mean tablet weight and percentage deviation from the mean were calculated. Compliance was assessed against BP acceptance criteria, which allow not more than two tablets to deviate by more than 5% from the mean and none by more than 10% [13].

Disintegration testing was conducted on six tablets per brand using a BP disintegration apparatus. Each tablet was placed in a basket-rack assembly immersed in distilled water maintained at $37 \pm 0.5\,^{\circ}\mathrm{C}$. The time taken for complete disintegration, without any visible core remaining, was recorded, and results were expressed as mean ± SD [18].

For the assay of active pharmaceutical ingredient (API) content, ten tablets from each brand were powdered, and an accurately weighed portion equivalent to 10 mg of amlodipine besylate was transferred into a volumetric flask. The powder was dissolved in methanol and made up to volume with 0.01 N HCl to obtain a suitable concentration within the linear range of the calibration curve. The solution was filtered and analyzed using an ultraviolet (UV)-visible spectrophotometer at 360 nm, the $\lambda_{\max}$ of amlodipine besylate in this solvent system. The percentage content of amlodipine was determined relative to the reference standard. Compliance was evaluated against the BP specification of 90.0–110.0% of label claim [16].

Prior to analysis using the UV-visible spectrophotometer, a method validation study was conducted to ensure accuracy and consistency:

Linearity: Standard solutions (0.4–2 mL) were diluted to 10 mL with 0.01 N HCl, yielding concentrations of 4–20 μg/mL. Absorbance was measured and a calibration curve was plotted. The correlation coefficient (r^2) was calculated using least squares linear regression.

Range: The method's range (4–20 μg/mL) was determined from the linear interval of the calibration curve.

Precision: To assess precision, absorbance of a 12 μg/mL amlodipine solution was measured six times.

Accuracy: Method accuracy was determined by calculating the percentage recovery from tablet solutions spiked with known concentrations of the amlodipine reference standard.

Robustness: The method's robustness was evaluated by checking assay performance when wavelength varied slightly (± 2 nm).

2.4. Dissolution testing

In vitro dissolution was performed in accordance with the British Pharmacopoeia (2023). Analytical precision was maintained at a Relative Standard Deviation (RSD) of less than 2% across all replicate determinations, in alignment with ICH validation guidelines. Using USP Apparatus II (paddle method) in 900 mL of 0.01 N HCl at $37 \pm 0.5\,^{\circ}\mathrm{C}$, with paddles rotating at 75 rpm, aliquots of 5 mL were withdrawn at 5, 10, 15, 20, and 30 minutes, filtered, and replaced with fresh medium. Samples were analyzed at 360 nm using a UV spectrophotometer [16]. The cumulative percentage drug release was calculated for each time point.

In addition to comparing profiles against BP specifications (≥75% release at 30 minutes), two model-independent parameters were determined: Dissolution Efficiency (DE) and Mean Dissolution Time (MDT).

Dissolution Efficiency was defined as the area under the dissolution curve (AUC) up to 30 minutes, expressed as a percentage of the area of the rectangle representing 100% dissolution over the same period:

$$DE = \frac{\int_0^t y\,dt}{y_{100} \times t} \times 100 \tag{1}$$

where y is the percentage of drug dissolved at time t, and y_{100} is 100%.

Mean Dissolution Time was calculated as:

$$MDT = \frac{\sum \tilde{t}_i \, \Delta M_i}{\sum \Delta M_i} \tag{2}$$

where $\tilde{t}_i$ is the midpoint of the time interval, and ΔM_i is the incremental percentage of drug dissolved in that interval. MDT represents the average time for drug particles to dissolve and provides an indicator of the rate of dissolution [5].

2.5. Similarity analysis

Dissolution profiles of the test brands (A2–A13) were compared with the innovator brand (A1) using the difference factor (f_1) and the similarity factor (f_2), both of which are model-independent mathematical approaches recommended by the FDA and WHO for assessing bioequivalence of dissolution profiles [5].

The difference factor (f_1) was calculated as:

$$f_1 = \frac{\sum_{t=1}^{n} |R_t - T_t|}{\sum_{t=1}^{n} R_t} \times 100 \tag{3}$$

where R_t and T_t represent the percentage of drug dissolved from the reference (A1) and the test product, respectively, at each of the n sampling time points. An f_1 value between 0 and 15 was considered to indicate a negligible difference between two dissolution profiles.

The similarity factor (f_2) was calculated as:

$$f_2 = 50 \times \log\left\{\left[1 + \frac{1}{n}\sum_{t=1}^{n}(R_t - T_t)^2\right]^{-0.5} \times 100\right\} \tag{4}$$

An f_2 value between 50 and 100 was interpreted as evidence that the two profiles were similar [5].

Both f_1 and f_2 were computed using dissolution data obtained at 5, 10, 15, 20, and 30 minutes.

3. Results and discussion

All thirteen brands of amlodipine besylate 10 mg tablets (A1–A13) were subjected to standard physicochemical evaluation, and the results are presented in Table 2. Tablet thickness and diameter varied modestly across brands but remained within acceptable ranges for compressed tablets. Hardness values ranged from 1.60 to 8.73 KgF, reflecting inter-brand differences in compaction strength. Friability values for all brands were below the BP limit of 1.0%, indicating satisfactory mechanical resistance. Weight variation across brands was minimal, with percentage deviations within BP acceptance criteria.

Figure 1 shows a calibration plot for pure amlodipine drug. A correlation coefficient value of 0.9999 indicates that the drug obeys Beer's law in the concentration range of 4–20 μg/mL. A % RSD value of 0.7994 after six sampling occasions confirms the precision of the analytical procedure. With a recovery value of 99.70% at a concentration level of 120%, the analytical method demonstrated a high level of accuracy, while a % RSD of 2.4459 showed robustness under minimally altered conditions. Overall, the analytical method was found suitable for determining amlodipine in dosage form without interference from excipients (Table 3).

Assay results revealed that most brands contained amlodipine within the BP specification of 90.0–110.0% of the labelled claim. However, brand A4 demonstrated a relatively low content of 89.22%, falling marginally below the pharmacopoeial threshold. Disintegration times varied, with most brands disintegrating in less than 5 minutes, except A8 and A13, which required 6.45 and 5.13 minutes, respectively, though still within BP limits.

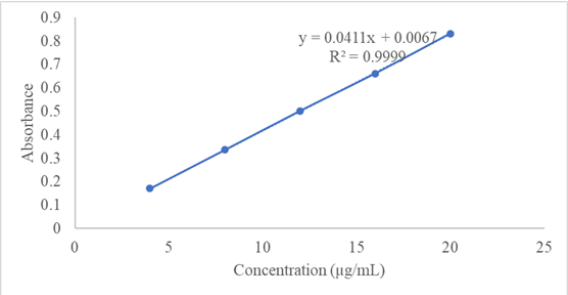

Figure 1: Calibration plot for amlodipine reference sample.

Figure 2 shows dissolution profiles for samples A1–A7, while Figure 3 presents profiles for samples A8–A13. All brands released more than 75% of the labelled drug content within 30 minutes, satisfying the BP requirement. The mean release at 30 minutes across brands was $94.37\% \pm 8.58\%$, ranging from 80.66% (A13) to 111.01% (A3). The innovator (A1) released 90.90% at 30 minutes.

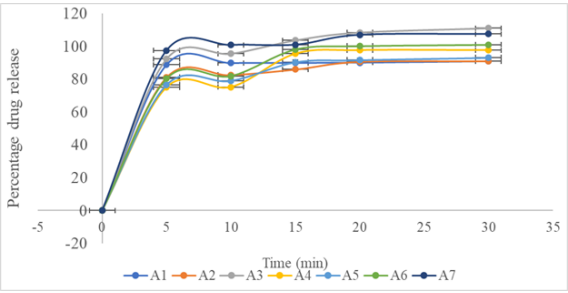

Figure 2: Dissolution profiles for samples A1–A7.

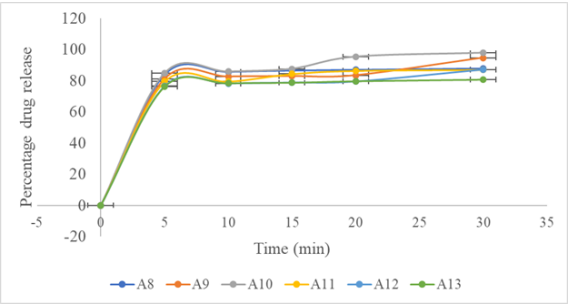

Figure 3: Dissolution profiles for samples A8–A13.

The calculated Dissolution Efficiency (DE) and Mean Dissolution Time (MDT) values are presented in Table 4. DE ranged from 72.17% (A13) to 94.57% (A7), indicating variable efficiency of drug release across brands. The innovator brand (A1) had a DE of 82.42%, which was exceeded by several generics, including A3 (94.16%), A6 (85.30%), and A7 (94.57%). MDT values varied between 2.80 minutes (A1) and 5.36 minutes (A9). Lower MDT values (e.g., A1, A8, A13) suggest faster dissolution, whereas higher MDTs (e.g., A4, A6, A9, A12) reflect slower release dynamics.

These findings highlight inter-brand variability in dissolution behaviour, with some generics (e.g., A3, A6, A7) demonstrating faster or more efficient release than the innovator, while others (e.g., A9, A12, A13) displayed slower release patterns despite meeting pharmacopoeial specifications.

To further evaluate equivalence between the innovator (A1) and generic products, model-independent parameters f_1 and f_2 were calculated. The results are shown in Table 5. Brands A2, A5, A6, A8, A9, A10, and A11 demonstrated dissolution profiles similar to the innovator, with f_1 values less than 15 and f_2 values greater than

Table 2: Physicochemical data for amlodipine besylate 10 mg tablets analysed. T = thickness (mm), D = diameter (mm), H = hardness (KgF), F = friability (%), A = assay (%), WV = weight variation (g, %SD), Dist = disintegration time (min). Values expressed as mean (SD) where applicable.

Brand	T mm (SD)	D mm (SD)	H KgF (SD)	F (%)	A (%)	WV g (%SD)	Dist (min)
A1	3.64 (0.01)	8.36 (0.07)	8.73 (2.00)	0.10	99.10	0.48 (1.21)	0.27 (2.11)
A2	3.89 (0.03)	11.20 (0.09)	5.27 (0.99)	0.95	95.51	0.41 (1.03)	0.27 (1.01)
A3	3.93 (0.05)	12.47 (0.11)	1.77 (0.25)	0.53	95.35	0.55 (1.38)	1.53 (0.52)
A4	4.30 (0.02)	9.25 (0.21)	8.13 (3.44)	0.86	89.22	0.40 (0.99)	0.59 (3.72)
A5	4.71 (0.03)	7.33 (0.02)	6.27 (0.46)	0.12	97.39	0.41 (1.03)	0.27 (1.11)
A6	3.97 (0.25)	6.29 (0.03)	5.93 (2.16)	0.20	95.60	0.25 (0.62)	3.17 (0.88)
A7	4.04 (0.05)	6.10 (0.06)	1.60 (0.72)	0.21	96.01	0.24 (0.60)	3.17 (1.59)
A8	4.32 (0.09)	10.10 (0.03)	3.73 (1.14)	0.20	95.33	0.32 (0.81)	6.45 (0.59)
A9	4.11 (0.05)	6.18 (0.05)	1.80 (0.20)	0.25	98.06	0.22 (0.56)	3.54 (2.11)
A10	3.31 (0.06)	8.16 (0.01)	1.67 (0.40)	0.37	101.6	0.21 (0.53)	3.36 (1.90)
A11	4.55 (0.04)	11.44 (0.07)	4.33 (0.30)	0.14	103.1	0.46 (1.14)	3.41 (1.99)
A12	3.28 (0.07)	7.11 (0.04)	2.33 (1.72)	0.28	97.22	0.14 (0.42)	4.11 (0.12)
A13	4.07 (0.02)	11.29 (0.02)	4.47 (1.29)	0.20	96.40	0.44 (1.11)	5.13 (0.60)

Table 3: Method validation data for amlodipine using UV-visible spectrophotometer. L = linearity (r^2), P = precision (% RSD), R = robustness (% RSD), A = accuracy (% recovery at 12 μg/mL).

L (r^2)	P (% RSD)	R (% RSD)	A (% recovery)
0.9999	0.7994	2.4459	99.70

Table 4: Dissolution efficiency (DE), mean dissolution time (MDT), and percentage drug release at 30 minutes for innovator (A1) and generic brands (A2–A13) of amlodipine tablets.

Brand	DE (%)	MDT (min)	Release % (30 min)
A1 (innovator)	82.42	2.80	90.90
A2	79.44	3.82	91.02
A3	94.16	4.55	111.01
A4	81.64	4.92	97.65
A5	79.47	4.40	93.13
A6	85.30	4.67	101.04
A7	94.57	3.61	107.53
A8	78.98	3.00	87.75
A9	77.64	5.36	94.53
A10	83.07	4.50	97.71
A11	76.52	3.58	86.90
A12	73.15	4.76	86.96
A13	72.17	3.16	80.66

Table 5: Difference factor (f_1) and similarity factor (f_2) values comparing dissolution profiles of generic brands (A2–A13) with the innovator brand (A1).

Brand	f_1	f_2	Interpretation
A2	4.36	64.42	Similar ($f_1 < 15, f_2 > 50$)
A3	13.63	42.73	Not similar ($f_2 < 50$)
A4	10.72	49.16	Borderline ($f_2 < 50$)
A5	6.06	56.49	Similar
A6	9.95	52.15	Similar
A7	14.34	43.74	Not similar
A8	4.23	69.93	Similar
A9	7.25	58.52	Similar
A10	5.02	65.73	Similar
A11	7.45	56.77	Similar
A12	11.18	48.81	Borderline ($f_2 < 50$)
A13	12.51	47.29	Not similar

50. In contrast, A3, A7, and A13 failed to show similarity, with f_2 values below 50 despite acceptable f_1 scores. Brands A4 and A12 produced borderline profiles, with f_2 values marginally below 50 (49.16 and 48.81, respectively).

This study evaluated the physicochemical properties and dissolution profiles of thirteen brands of amlodipine besylate tablets marketed in Nigeria. Most of the brands complied with British Pharmacopoeia requirements for weight variation, friability, assay, and dissolution, indicating that they met minimum quality standards. However, notable variability was observed in assay values, disintegration times, dissolution efficiency, and similarity factors. While several generic products showed dissolution behavior comparable to the innovator, some exhibited borderline or non-similar profiles, raising concerns about their pharmaceutical equivalence. Although UV spectrophotometry at 360 nm is an established and selective wavelength for amlodipine, the observed dissolution values exceeding 100% in some brands likely represent actual batch-specific manufacturing variations rather than excipient interference. Future studies using High-Performance Liquid Chromatography (HPLC) could further explore the presence of specific degradants. However, these findings suggest that while the majority of amlodipine generics in Nigeria are of acceptable quality, variability in performance poses questions about their therapeutic interchangeability.

The results are generally consistent with recent Nigerian studies, although some important variations were noted. While assessing ten brands of 10 mg amlodipine, it was reported that all passed disintegration testing, while nine met official dissolution criteria [17]. In a similar evaluation, five brands sampled in Bayelsa, Nigeria complied with British Pharmacopoeia requirements for weight variation and friability and also passed dissolution testing [18]. These findings suggest that many multi-sourced amlodipine generics achieve the expected standards and could be considered therapeutically interchangeable with the innovator. In contrast, one study reported that ten brands matched the innovator's dissolution profile at pH 6.8, and only four did so under acidic conditions (pH 1.2) [9]. Likewise, only ten brands out of fifteen passed the drug content test despite all demonstrating adequate dissolution in a study carried out in Southern Nigeria [19].

The circulation of substandard or borderline-quality generics has important clinical and regulatory implications. Poor-quality amlodipine may contribute to poorly controlled hypertension and increased cardiovascular risk [8]. The recall of a 10 mg batch by NAFDAC in 2020 due to failed weight and hardness specifications demonstrates the importance of continuous regulatory vigilance [20]. Beyond clinical consequences, the presence of inadequate generics undermines patient trust and may encourage unsafe practices such as dose doubling or brand switching without supervision. Conversely, evidence of equivalence supports safe substitution of generic products, which is critical for improving access and reduc-

ing treatment costs.

The findings of this study emphasize the need for stronger quality assurance and post-market surveillance in Nigeria [21]. NAFDAC should conduct routine sampling of antihypertensive medicines across diverse regions and employ rigorous analytical methods, including high-performance liquid chromatography, to verify compliance. Pharmacovigilance systems also need to be strengthened to capture therapeutic failures or adverse outcomes associated with substandard products. Regulators should incentivize manufacturers who maintain high-quality production and penalize illegal distribution of unregistered products. Furthermore, public health campaigns could improve awareness, encouraging patients and pharmacists to verify NAFDAC registration numbers and preferentially use products with demonstrated compliance. Such strategies are consistent with NAFDAC's current framework, which prioritizes ongoing monitoring of medicines in circulation [22].

Limitations

This study has some limitations. The number of brands sampled and the geographic scope were restricted, meaning the findings may not be fully representative of all Nigerian markets. The analytical method employed, UV spectrophotometry, is less selective than high-performance techniques such as HPLC, which may detect impurities or subtle variations more accurately. Additionally, the study did not investigate the influence of formulation differences such as excipients, manufacturing processes, or tablet coatings, which may contribute to the variability observed between brands. Future research should include larger, nationwide sampling, incorporate multiple analytical methods, and investigate formulation-related factors. Despite these limitations, the findings, when viewed alongside recent Nigerian studies, show that while most generic amlodipine products are of acceptable quality, vigilant regulatory oversight is essential to ensure full therapeutic interchangeability and protect patient safety.

4. Conclusion

This study evaluated the quality of amlodipine besylate 10 mg tablets marketed in Nigeria, focusing on compliance with pharmacopoeial standards and therapeutic interchangeability. Most brands met the required specifications, although variability in dissolution behavior indicated differences in pharmaceutical performance. The results highlight the need for rigorous regulatory oversight to ensure that only consistently compliant products remain in circulation.

Conflict of Interest

None.

Funding

None.

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