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Lisinopril Tablet Quality Evaluation: A Pharmacopeial Compliance Study

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Abstract

Background: The quality of pharmaceutical products is critical in ensuring therapeutic efficacy and patient safety, particularly in managing chronic conditions like hypertension. Objectives: This study assessed the quality of five different brands of Lisinopril tablets using pharmacopeial standards to evaluate their compliance with required specifications. Methods: Five brands were analyzed through High-Performance Liquid Chromatography (HPLC), weight uniformity, hardness, friability, and disintegration tests. HPLC was employed for content assay, while mechanical and release characteristics were assessed using pharmacopoeial protocols. Results: HPLC analysis showed that all brands contained Lisinopril within the USP acceptable range of 90–110% of the labeled claim. The weight uniformity test confirmed compliance, with all brands falling within the ±7.5% limit. Hardness values varied significantly: brands PR, FI, and ED passed with mean values of 8.5 KgF, 8.3 KgF, and 5.0 KgF respectively, while brands LF and RL failed with values of 3.7 KgF and 3.3 KgF. Friability percentages ranged from 0.105% (FI) to 0.842% (LF), well below the 1% limit. Disintegration times also varied, with all brands meeting the pharmacopeial standard of <15 minutes for uncoated tablets; however, Prilas disintegrated fastest, and Fidson the slowest, indicating variability in onset of action. Conclusion: All brands tested complied with pharmacopeial specifications for active content, friability, and disintegration. However, variations in hardness and disintegration times may influence tablet performance and clinical outcomes. These findings underscore the importance of comprehensive quality evaluation in ensuring consistent therapeutic efficacy.

Keywords

Lisinopril, Pharmacopeial compliance, Quality assurance, High performance liquid chromatography

Article History

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1. Introduction

In recent years, the proliferation of generic pharmaceutical products has underscored the importance of stringent quality control measures to ensure therapeutic efficacy and patient safety. Studies have highlighted the critical need for compliance with pharmacopeial standards among generic medications. For instance, Fahelelbom et al., emphasized that adherence to these standards is vital for maintaining drug potency and safety profiles [1]. Similarly, a study in the *South African Journal of Botany* by Vijay Kumar *et al.,* demonstrated that variations in formulation can significantly impact the physicochemical properties and therapeutic outcomes of herbal preparations [2]. Furthermore, investigations into the quality of antihypertensive drugs in developing countries revealed that non-compliance with pharmacopeial standards contributes to suboptimal clinical outcomes and increased adverse effects . These findings underscore the necessity for rigorous quality assessments of generic medications to ensure they meet established pharmacopeial criteria, thereby safeguarding public health.

Hypertension, also known as high blood pressure, is defined as a sustained systolic blood pressure of 140 mmHg or higher and a diastolic blood pressure of 90 mmHg or more [3]. It is a chronic medical condition characterized by elevated blood pressure within the arteries, which can lead to various health complications if left untreated. The pathophysiology of hypertension involves increased peripheral vascular resistance due to heightened vascular smooth muscle tone, resulting in reduced arterial compliance and elevated pressure levels [4]. Hypertension is classified into two types: primary hypertension, which has no identifiable cause, and secondary hypertension, which results from underlying conditions affecting organs such as the kidneys, heart, and endocrine system [5-6].

The risk factors for hypertension are multifactorial, including genetic predisposition, obesity, a sedentary lifestyle, and poor dietary habits [7]. Additionally, conditions such as diabetes and depression have been shown to exacerbate the development of hypertension [8]. The complications of untreated hypertension are severe and often fatal, leading to cardiovascular diseases such as coronary heart disease (CHD), myocardial infarction (MI), stroke, as well as renal failure and peripheral arterial disease [9-10]. Thus, managing hypertension is crucial in preventing these life-threatening conditions.

Antihypertensive drugs work through various mechanisms to reduce blood pressure. ACE inhibitors and ARBs block the effects of angiotensin II, leading to vasodilation and reduced blood volume, while diuretics promote the excretion of excess sodium and water, reducing blood volume and thus lowering pressure. Other classes, such as calcium channel blockers and beta-blockers, target different pathways like calcium ion influx and adrenergic receptors to decrease vascular resistance, heart rate, and fluid volume, all contributing to the reduction of blood pressure [11]. One prominent class of antihypertensive drugs is the angiotensin-converting enzyme (ACE) inhibitors, such as Lisinopril and Captopril, which block the conversion of angiotensin I to angiotensin II [12]. By inhibiting this enzyme, ACE inhibitors reduce vasoconstriction, lower aldosterone secretion, and increase bradykinin levels, ultimately helping to lower blood pressure [13-14]. Lisinopril, in particular, is widely used due to its proven effectiveness in managing hypertension and offering cardiovascular and renal protection [15,16].

However, while Lisinopril is a key therapeutic agent for hypertension management, the quality of these medications is of paramount importance. The quality of pharmaceutical products, including those used for hypertension, plays a critical role in ensuring their therapeutic efficacy. Substandard medications can lead to insufficient treatment outcomes and potentially harmful effects, including resistance and adverse drug reactions. In the context of generic medicines, the increasing availability of cost-effective alternatives has raised concerns regarding the compliance of these products with established pharmacopeial standards. Pharmacopeial compliance refers to the adherence to official quality standards, such as those set by the United States Pharmacopeia (USP), which dictate the required chemical, physical, and microbiological properties for pharmaceutical products [17]. These standards are vital in maintaining the safety, effectiveness, and quality of drugs, particularly generics, which have become a primary source of medication in many parts of the world.

In developing countries, where drug regulations may be weak or poorly enforced, the proliferation of counterfeit and substandard pharmaceuticals is a growing concern. Generic drugs, while offering more affordable options for patients, must adhere to the same strict quality control measures as their branded counterparts. Failure to meet pharmacopeial standards can have serious consequences, including treatment failure, the emergence of drug resistance, and serious adverse events [18,19]. Substandard drugs contribute significantly to global health challenges, particularly in low- and middle-income countries where access to quality healthcare is limited, and regulatory frameworks are often inadequate [20]. Counterfeit drugs, including generics that do not meet pharmacopeial standards, pose a risk to both public health and the credibility of the pharmaceutical industry (WHO, 1998).

The World Health Organization (WHO) defines counterfeit drugs as those that are fraudulently mislabeled regarding their identity or source. This can include products with correct ingredients but incorrect quantities of active ingredients or drugs with substandard packaging [21]. Counterfeit drugs can undermine the trust patients place in healthcare providers and regulatory authorities, leading to adverse health outcomes and potentially fatal consequences [22,23]. The economic impact of counterfeit drugs is also considerable, as they increase healthcare costs, reduce the effectiveness of treatment, and contribute to the loss of consumer confidence in pharmaceutical products [24,25].

Given the increasing reliance on generics, the issue of pharmacopeial compliance becomes even more critical. Generics must meet the same standards of quality as branded drugs to ensure that patients receive the same therapeutic benefits. Pharmacopeial standards, such as those outlined by the USP, require generics to undergo rigorous testing for potency, dissolution profile, disintegration time, and weight uniformity to ensure their therapeutic equivalence to the branded reference drug [26, 27]. These tests assess the quality of the active pharmaceutical ingredient (API), as well as the physical properties of the drug that influence its performance in the body. This includes the drug's bioavailability, which is the extent to which the active ingredient is absorbed into the bloodstream and reaches its site of action.

In the case of Lisinopril, the pharmacokinetics and bioavailability of the drug can be influenced by its formulation and manufacturing quality. Lisinopril has a bioavailability of about 25-30% when administered orally, which is relatively low compared to other medications [28]. Therefore, ensuring that Lisinopril tablets meet pharmacopeial standards for dissolution and disintegration is essential to guarantee that the drug is properly absorbed and has the intended therapeutic effect [29,30]. The uniformity of weight and mechanical properties of the tablet also play an essential role in ensuring the correct dose is delivered to patients and that the tablet remains intact during storage, handling, and administration [31,32].

This study aims to assess the quality of various Lisinopril tablet brands available in Nigeria, focusing on their pharmacopeial compliance with the established standards for the API content, disintegration time, weight uniformity, and mechanical properties. This assessment is particularly important given the growing concerns over the quality of generic drugs in developing countries, where regulatory oversight is often limited. By evaluating the physicochemical properties of Lisinopril tablets from different brands, this study seeks to provide valuable information on the extent to which local pharmaceutical manufacturers adhere to pharmacopeial standards. It will also offer insights into the quality control practices in Nigeria's pharmaceutical industry and highlight any areas where improvements are needed.

2. Materials

2.1 Solvents and Reagents

All the reagents used were of analytical grade unless stated otherwise. Five different brands of Lisinopril were analyzed. Chemicals and reagents used include Phosphoric acid (85% w/w, analytical grade), Monobasic potassium phosphate (≥99.5% purity), sodium-1-hexane sulphonate (≥99% purity), acetonitrile (HPLC grade, ≥99.9% purity) and methanol (HPLC grade, ≥99.9% purity) (All chemicals were from Tedia purity solvent, USA).

2.2 Methods

2.2.1 Samples Collection

The sampling was carried out on May 5, 2023 following coherent protocols and procedures designed to obtain a representative tablet sample. Five (5) different brands of Lisinopril 5 mg solid dosage forms (tablets) were purchased in a pharmacy in Ibadan, Oyo State, Nigeria. The samples remained in their respective pack until analysis. All samples were stored and kept in a cool dry place below 30°C and protected from light until preparation for analysis. The brand names and product information are presented in the table below.

Table 1. Description of the Brands.

	Brand Name	Manufacturer	Batch Number	Manufacture Date	Expiry Date	Nafdac Number	Date Obtained
LF	Lisiofil	Unique Pharmaceuticallimited	K2743	02/2023	01/2026	04-8142	05/05/2023
PR	Prilas	SeagreenPharmaceuticallimited	MP22659	09/2022	08/2025	A4-3354	05/05/2023
FI	Lisinopril	FidsonHealthcarePlc	T3623001	09/2023	08/2027	A11-1123	05/05/2023
ED	EDEN LISINOPRIL	EDEN U-KPHARM LTD	2309045	09/2023	08/2026	B4-6803	05/05/2023
RL	Ranopril	SunPharma Ind.ltd	5139863	10/2021	09/2024	04-2612	05/05/2023

2.2.2 Determination of the uniformity of weight

Ten (10) tablets from each brands were selected randomly. Each selected tablets were weighed using Adventurer- pro Analytical Balance. The average weight of each brand of tablets were determined,while the percentage and the standard deviation were recorded and calculated, respectively. They were then compared with the official value (USP, 2020).

2.2.3 Determination of tablet hardness

Three (3) tablets were selected from each brand and were placed between a fixed and movable jaw of a Ketan hardness tester, a force was applied through a screwdriver spring by turning the screw. The average force needed to break the three from each brand (kg/cm) and the standard deviation from the average weight was then calculated (USP, 2020).

2.2.4 Determination of tablets friability

Ten (10) tablets from each brand were weighed and placed in the friability tester. The DBK friability tester was then operated at 25 revolutions per minute for 5 minutes (100 revolutions). The tablets were removed after the revolution had been completed. They were alsodusted and reweighed using the adventurer-pro analytical balance. The result of was then expressed as a percentage weight loss (USP, 2020). The percentage friability is then calculated using:

$$Fr=(w1-w2)/w1\times100 \quad (1)$$

Where *w1 is* initial weight and *w2* their weight after removal from the friability test apparatus.

2.2.5 Determination of disintegrating time

The disintegration rate of tablets was determined using the disintegration test apparatus containing distilled water, which was maintained at 37±0.5℃.The tablets were placed in the disintegration chamber consisting of a glass tube closed at the end with a wire mesh. The chamber was then dropped and raised at a constant frequency and then observed until the tablets dissolved completely. The disintegration time for each tablet was recorded, and the mean disintegration time of each brand was calculated.

2.2.6 High Pperformance Liquid Chromatography

This was carried out according to the United States Pharmacopoeia 2022. The quantitative result was based on calibration with standard and peak area measurement. The Waters 2695 HPLC is equipped with Empower 3 chromatograph data system respectively as the software, and this was used for the calibration curve and the quantification of the samples. The quantification of the samples was based on comparison of the peaks of the standards with those of the samples.

2.2.7 Preparation of buffer, Mobile Phase, Diluent and Standard Solution

The buffer solution was prepared by dissolving 4.1 g of monobasic potassium phosphate in approximately 900 ml of distilled water in a 1000 ml volumetric flask, followed by pH adjustment to 2.0 using phosphoric acid. The solution was then diluted to volume with water. The mobile phase was prepared by dissolving 1.0 g of sodium-1-hexane sulphonate in 820 ml of the phosphate buffer, followed by the addition of 180 ml of acetonitrile, resulting in a mixture containing 82% buffer and 18% acetonitrile (v/v). The diluent was composed of 20% methanol and 80% water (v/v). For the preparation of the standard solution, 20 mg of Lisinopril USP reference standard was accurately weighed and transferred into a 100 ml volumetric flask. The substance was dissolved in the prepared diluent, sonicated for 15 minutes to ensure complete dissolution, allowed to cool, and then made up to volume with the same solvent, yielding a final concentration of 0.2 mg/mL (200 µg/mL), following the United States Pharmacopeia method with analytical method verification.

2.2.8 Preparation of sample solution

Ten tablets of Lisinopril were transferred into a volumetric flask, the diluent was then added and sonicated for 5 minutes after which the flask was then shaken by a mechanical means for 20 minutes, the diluent was added to the mixture to the required volume, it was mixed, and then filtered. The resulting solution were filled into the HPLC vials through a syringe attached to a 0.45 µm filter, and 20 µL of the final concentration was injected for analysis (200 µg/ml or 0.2 mg/ml of Lisinopril). The HPLC condition for running lisinopril tablet analysis is as presented in Table 2 below.

Table 2. HPLC condition for running Lisinopril tablet analysis.

Mobile phase	**HPLC grade acetonitrile and buffer (18:82)**
Column	4.6 mm×20 cm; 10 µm packing L7
Column temperature	40°C
Flow rate	1 ml/min
Wavelength	215 nm
Injection volume	20 µl
Detector type	UV detector
Run time	Not less than 2.4 times the retention time of Lisinopril

2.2.9 Analytical Method Validation

For linearity, calibration standards of Lisinopril at concentrations of 50–500 µg/ml were prepared by serial dilution of a stock solution using the diluent. Aliquots ranging from 0.5 ml to 5.0 ml were diluted to 10 ml and 20 µL of each concentration was injected. A calibration curve was plotted, and linear regression analysis was performed using the equation $y=mx+c$ to determine the slope, intercept, and correlation coefficient.

Accuracy was assessed through recovery studies at 80% (0.16 mg/ml), 100% (0.2 mg/ml), and 120% (0.24 mg/ml) of the target concentration. Each level was prepared in triplicate and analyzed, with percent recovery and %RSD calculated. Acceptance criteria required recoveries between 98.0–102.0%.

Precision was evaluated at 100% concentration (200 µg/ml) with six replicates. Results were expressed as %RSD, with an acceptance criterion of not more than 1.0%.

2.3 Statistical Analysis

All data obtained from the analytical method validation were statistically analyzed to ensure reliability and reproducibility of the results. The linearity of the calibration curve was evaluated using least squares linear regression analysis, determining the slope, y-intercept, and correlation coefficient (R^2) to assess the strength of the relationship between concentration and peak area.

Accuracy was expressed as percent recovery, and results were reported as mean ± standard deviation (SD) for each concentration level. Precision (repeatability) was assessed by calculating the relative standard deviation (RSD) of replicate measurements, with results considered acceptable if RSD was less than or equal to 1.0%, in accordance with ICH Q2 (R1) guidelines.

Microsoft Excel was used for statistical calculations, graphical presentation, and regression modeling. Where applicable, ANOVA (Analysis of Variance) was used to compare variability within and between groups to ensure method consistency and reliability. The level of significance for all reported results was indicated as $p < 0.05$ unless otherwise noted.

3. Results and Discussion

This study evaluates the quality of different brands of Lisinopril tablets using various pharmacopeia standard tests such as High-Performance Liquid Chromatography (HPLC), hardness test, disintegration test, friability test as well as uniformity of weight test. Five brands of Lisinopril tablets were purchased from a community pharmacy in the city of Ibadan, and their biopharmaceutical and chemical equivalence were evaluated using the above-mentioned analytical and assay methods. At the time of the study, every brand used was within its shelf life according to the label claim.

3.1 Uniformity of Weight

Weight uniformity is a crucial QC metric that affects how consistently patients receive their doses. Weight variations can result in different medication concentrations in each tablet, which can impact the drug's therapeutic efficacy and absorption [33]. Research has demonstrated that tablets with consistent weight have superior drug release characteristics and dissolution profiles, which ultimately improve bioavailability [34,35]. The uniformity of the weight test (Table 3) demonstrated that all brands had weight variation within the limit specified by USP, which states that for tablets whose average weight is more than 0.1418 mg and less than 0.1430 mg, the allowed percentage deviation is ±7.5%. The essence of this test is to check for uniformity of weight to ensure the consistency of dosage units [36,37].

Table 3. Weight variation of LF tablets Batch 1.

S/N	Weight of Tablet x (mg)	Mean weight of tablet $\bar{x}$ (mg)	Mean Deviation $(x-\bar{x})$ mg	$(\bar{x}-x)^2$	% Deviation
1	0.1425	0.14235	0.00015	0.0000000225	0.105263
2	0.1419	0.14235	-0.00045	0.0000002025	-0.31712
3	0.1420	0.14235	-0.00035	0.0000001225	-0.24648
4	0.1418	0.14235	-0.00055	0.0000003025	-0.38787
5	0.1420	0.14235	-0.00035	0.0000001225	-0.24648
6	0.1424	0.14235	0.00004	0.0000000016	0.035112
7	0.1426	0.14235	0.00023	0.0000000529	0.175316
8	0.1427	0.14235	0.00035	0.0000001225	0.24527
9	0.1426	0.14235	0.00023	0.0000000529	0.175316
10	0.1430	0.14235	0.00065	0.0000004225	0.454545
	1.4235			0.0000014249	

Mean weight ($\bar{x}$)=x/n=1.4235÷10=0.14235

Variance=$\sum(xi–\bar{x})^2/(n–1)$=(0.0000014249)÷(10–1)=0.000000158
Standard deviation (SD)=$\sqrt{\sum(xi–x)^2/(n–1)}$=$\sqrt{}$0.000000158=0.000397
Percentage coefficient of variation=(SD÷$\bar{x}$)×100=(0.000397÷0.14235)×100=0.2789%

Table 4 presents the weight variation of LF tablets from Batch 2. The results show that the mean weight of the tablets is 0.14257 mg, with a standard deviation of 0.0004897 mg. The percentage coefficient of variation is extremely low at 0.00698%, indicating excellent weight uniformity among the tablets. The individual tablet weights deviate minimally from the mean weight, with the largest deviation being 0.00123 mg (tablet 10). The variance and standard deviation values are also very low, further confirming the uniformity of the tablet weights.

Table 4. Weight variation of LF tablets Batch 2.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation ($x-\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1427	0.14257	0.00013	0.0000000169	0.09110021
2	0.1426	0.14257	0.00003	0.0000000009	0.021037868
3	0.1423	0.14257	-0.00027	0.0000000729	-0.189739986
4	0.1426	0.14257	0.00003	0.0000000009	0.021037868
5	0.1424	0.14257	-0.00017	0.0000000289	-0.119382022
6	0.1420	0.14257	-0.00057	0.000000325	-0.401408451
7	0.1430	0.14257	0.00043	0.000000185	0.300699301
8	0.1427	0.14257	0.00013	0.0000000169	0.09110021
9	0.1426	0.14257	0.00003	0.0000000009	0.021037868
10	0.1438	0.14257	0.00123	0.00000151	0.855354659
	1.4257			0.0000021583	

Mean weight ($\bar{x}$)=x/n=1.4257÷10=0.14257
Variance=$\sum(xi–\bar{x})^2/(n–1)$=(0.0000021583)÷(10–1)=0.0000002398
Standard deviation (SD)=$\sqrt{\sum(xi–x)^2/(n–1)}$=$\sqrt{}$0.0000002398=0.0004897
Percentage coefficient of variation=(SD÷$\bar{x}$)×100=(0.0004897÷0.14257)×100=0.00698%

Table 5 presents the weight variation of LF tablets from Batch 3. The results show that the mean weight of the tablets is 0.14169 mg, with a standard deviation of 0.0010081 mg. The percentage coefficient of variation is 0.711%, indicating a relatively low variation in tablet weights. The individual tablet weights deviate slightly from the mean weight, with the largest deviation being -0.00209 mg (tablet 1). The variance and standard deviation values are relatively low, indicating a moderate level of weight uniformity among the tablets. Compared to Batch 2 (Table 4), Batch 3 shows a slightly higher variation in tablet weights, as indicated by the higher percentage coefficient of variation (0.711% vs 0.00698%). However, the results still suggest that the manufacturing process for LF tablets from Batch 3 is generally well-controlled, resulting in tablets with relatively consistent weights.

Table 5. Weight variation of LF tablets Batch 3.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation ($x-\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1396	0.14169	-0.00209	0.00000437	-1.49713467
2	0.1410	0.14169	-0.00069	0.000000476	-0.489361702
3	0.1404	0.14169	-0.00129	0.00000166	-0.918803419
4	0.1420	0.14169	0.00031	0.0000000961	0.218309859
5	0.1424	0.14169	0.00071	0.000000504	0.498595506
6	0.1420	0.14169	0.00031	0.0000000961	0.218309859
7	0.1425	0.14169	0.00081	0.000000656	0.568421053
8	0.1423	0.14169	0.00061	0.000000372	0.42867182
9	0.1422	0.14169	0.00051	0.00000026	0.358649789
10	0.1425	0.14169	0.00081	0.000000656	0.568421053
	1.4169			0.0000091462	

Mean weight ($\bar{x}$)=x/n=1.4169/10=0.14169
Mean deviation=$\sum(x–\bar{x})^2/(n–1)$=(0.0000091462)/(10–1)=0.000001016
Standard deviation (SD)=$\sqrt{\sum(xi–x)^2/(n–1)}$=$\sqrt{}$0.000001016=0.0010081
Percentage coefficient of variation=(SD÷$\bar{x}$)×100=(0.0010081÷0.14169)×100%

Table 6 presents the weight variation of PR tablets from Batch 1. The results show that the mean weight of the tablets is 0.11241 mg, with a standard deviation of 0.000635 mg. The percentage coefficient of variation is 0.565%, indicating a

relatively low variation in tablet weights. The individual tablet weights deviate slightly from the mean weight, with the largest deviation being -0.00111 mg (tablet 8). The variance and standard deviation values are relatively low, indicating a moderate level of weight uniformity among the tablets. The results suggest that the manufacturing process for PR tablets from Batch 1 is well-controlled, resulting in tablets with relatively consistent weights. The percentage coefficient of variation is within the acceptable limit, indicating that the tablets meet the required standards for weight uniformity.

Table 6. Weight variation of PR tablet Batch 1.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation (x-$\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1119	0.11241	-0.00051	0.00000026	-0.455764075
2	0.1122	0.11241	-0.00021	0.0000000441	-0.187165775
3	0.1127	0.11241	0.00029	0.0000000841	0.257320319
4	0.1122	0.11241	-0.00021	0.0000000441	-0.187165775
5	0.1134	0.11241	0.00099	0.00000098	0.873015873
6	0.1129	0.11241	0.00049	0.00000024	0.4340124
7	0.1131	0.11241	0.00069	0.000000476	0.610079576
8	0.1113	0.11241	-0.00111	0.00000123	-0.997304582
9	0.1125	0.11241	0.00009	0.0000000081	0.08000000
10	0.1119	0.11241	-0.00051	0.00000026	-0.455764075
	1.1241			0.000003629	

Mean weight ($\bar{x}$)=x/n=1.1241/10=0.11241
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=0.000003629/(10–1)=0.000000403
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{0.000003629}$=0.000635
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.000635÷0.11241)×100=0.565%

Table 7 shows the weight variation of PR tablets from Batch 2. The results indicate a moderate variation in tablet weights, with a mean weight of 0.12113 mg and a percentage coefficient of variation of 2.691%. The data suggests that the manufacturing process for Batch 2 may not be as well-controlled as for Batch 1.

Table 7. Weight variation of PR tablet Batch 2.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation (x-$\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1222	0.12113	0.00107	0.00000114	0.875613748
2	0.1213	0.12113	0.00017	0.0000000289	0.140148392
3	0.1224	0.12113	0.00127	0.00000161	1.037581699
4	0.1228	0.12113	0.00167	0.00000279	1.359934853
5	0.1119	0.12113	-0.00923	0.0000852	-8.248436104
6	0.1224	0.12113	0.00127	0.00000161	1.037581699
7	0.1218	0.12113	0.00067	0.000000449	0.550082102
8	0.1222	0.12113	0.00107	0.00000114	0.875613748
9	0.1224	0.12113	0.00127	0.00000161	1.037581699
10	0.1219	0.12113	0.00077	0.000000593	0.631665299
	1.2113			0.000096181	

Mean weight ($\bar{x}$)=x/n=1.2113÷10=0.12113
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{0.00005107}$=0.00326
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.00326÷0.12113)×100=2.691%

Table 8 presents the weight variation of PR tablets from Batch 3. The results show a mean weight of 0.11723 mg, with a standard deviation of 0.0011 mg. The percentage coefficient of variation is 0.934%, indicating a relatively low variation in tablet weights. The data suggests that the manufacturing process for Batch 3 is well-controlled, resulting in tablets with consistent weights. The percentage coefficient of variation is lower compared to Batch 2 (2.691%), indicating an improvement in the manufacturing process.

Table 8. Weight variation of PR tablet Batch 3.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation ($x-\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1164	0.11723	-0.00083	0.000000689	
2	0.1175	0.11723	0.00027	0.0000000729	0.229787234
3	0.1176	0.11723	0.00037	0.000000137	0.31462585
4	0.1152	0.11723	-0.00203	0.00000412	-1.762152778
5	0.1177	0.11723	0.00047	0.000000221	0.399320306
6	0.1186	0.11723	0.00137	0.00000188	1.155143339
7	0.1157	0.11723	-0.00153	0.00000234	-1.32238548
8	0.1181	0.11723	0.00087	0.000000757	0.736663844
9	0.1176	0.11723	0.00037	0.000000137	0.31462585
10	0.1179	0.11723	0.00067	0.000000449	0.568278202
	1.1723			0.000010801	

Mean weight ($\bar{x}$)=x/n=1.1723=0.11723
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=(0.000010801)÷(10–1)=0.00000120
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{}$0.00000120=0.0011
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.001095÷0.11723)×100=0.934%

Table 9 presents the weight variation of FI tablets from Batch 1. The results show a mean weight of 0.11406 mg, with a standard deviation of 0.0000878 mg. The percentage coefficient of variation is extremely low at 0.078%, indicating excellent weight uniformity among the tablets. The individual tablet weights deviate minimally from the mean weight, with the largest deviation being 0.00044 mg (tablet 4). The data suggests that the manufacturing process for Batch 1 is highly controlled, resulting in tablets with very consistent weights.

Table 9. Weight variation of FI tablets Batch 1.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation ($x-\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1141	0.11406	0.00004	0.0000000016	
2	0.1140	0.11406	-0.00006	0.0000000036	-0.052631579
3	0.1138	0.11406	-0.00026	0.0000000676	-0.228471002
4	0.1145	0.11406	0.00044	0.000000194	0.384279476
5	0.1139	0.11406	-0.00016	0.0000000256	-0.1404741
6	0.1144	0.11406	0.00034	0.000000116	0.297202797
7	0.1143	0.11406	0.00024	0.0000000576	0.209973753
8	0.1139	0.11406	-0.00016	0.0000000256	-0.1404741
9	0.1137	0.11406	-0.00036	0.00000013	-0.316622691
10	0.1140	0.11406	-0.00006	0.0000000036	-0.052631579
	1.1406			0.000000624	

Mean weight ($\bar{x}$)=x/n=1.1406÷10=0.11406
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=(0.000000624)÷(10–1)=0.0000000693
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{}$0.0000000693=0.0000878
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.0000878÷0.11406)×100=0.078%

Table 10 presents the weight variation of FI tablets from Batch 2. The results show a mean weight of 0.11428 mg, with a standard deviation of 0.0003225 mg. The percentage coefficient of variation is 0.28%, indicating a relatively low variation in tablet weights. The data suggests that the manufacturing process for Batch 2 is well-controlled, resulting in tablets with consistent weights. The percentage coefficient of variation is slightly higher compared to Batch 1 (0.078%), but still within acceptable limits.

Table 10. Weight variation of FI tablet Batch 2.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation (x-$\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1146	0.11428	0.00032	0.000000102	0.279232112
2	0.1142	0.11428	-0.00008	0.0000000064	-0.070052539
3	0.1143	0.11428	0.00002	0.0000000004	0.017497813
4	0.1142	0.11428	-0.00008	0.0000000064	-0.070052539
5	0.1145	0.11428	0.00022	0.0000000484	0.192139738
6	0.1146	0.11428	0.00032	0.000000102	0.279232112
7	0.1141	0.11428	-0.00018	0.0000000324	-0.157756354
8	0.1138	0.11428	-0.00048	0.00000023	-0.421792619
9	0.1138	0.11428	-0.00048	0.00000023	-0.421792619
10	0.1147	0.11428	0.00042	0.000000176	0.366172624
	1.1428			0.000000936	

Mean weight ($\bar{x}$)=x/n=1.1428÷10=0.11428
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=(0.000000936)÷(10–1)=0.000000104
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{}$0.000000104=0.0003225
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.0003225÷0.11428)×100=0.28%

Table 11 presents the weight variation of FI tablets from Batch 3. The results show a mean weight of 0.11411 mg, with a standard deviation of 0.0000259 mg. The percentage coefficient of variation is extremely low at 0.023%, indicating excellent weight uniformity among the tablets. The data suggests that the manufacturing process for Batch 3 is highly controlled, resulting in tablets with very consistent weights. The percentage coefficient of variation is even lower compared to Batch 1 (0.078%) and Batch 2 (0.28%), indicating a high level of precision in the manufacturing process.

Table 11. Weight variation of FI tablets Batch 3.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation (x-$\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1138	0.11411	-0.00031	0.0000000961	-0.272407733
2	0.1141	0.11411	-0.00001	0.0000000001	-0.008764242
3	0.1145	0.11411	0.00039	0.000000152	0.340611354
4	0.1138	0.11411	-0.00031	0.0000000961	-0.272407733
5	0.1142	0.11411	0.00009	0.0000000081	0.078809107
6	0.1140	0.11411	-0.00011	0.0000000121	-0.096491228
7	0.1139	0.11411	-0.00021	0.0000000441	-0.184372256
8	0.1143	0.11411	0.00019	0.0000000361	0.166229221
9	0.1143	0.11411	0.00019	0.0000000361	0.166229221
10	0.1142	0.11411	0.00009	0.0000000081	0.078809107
	1.1411			0.000000489	

Mean weight ($\bar{x}$)=x/n=1.1411÷10=0.11411
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=(0.000000489)÷(10–1)=0.000000054
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{}$0.000000054=0.0000259
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.0000259÷0.11411)×100=0.023%

Table 12 presents the weight variation of ED tablets from Batch 1. The results show a mean weight of 0.18714 mg, with a standard deviation of 0.000337 mg. The percentage coefficient of variation is 0.18%, indicating a relatively low variation in tablet weights. The data suggests that the manufacturing process for Batch 1 is well-controlled, resulting in tablets with consistent weights. The percentage coefficient of variation is within acceptable limits, indicating that the tablets meet the required standards for weight uniformity.

Table 12. Weight variation of ED tablets Batch 1.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation (x-$\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1876	0.18714	0.00046	0.000000212	
2	0.1868	0.18714	-0.00034	0.000000116	-0.182012848
3	0.1867	0.18714	-0.00044	0.000000194	-0.235672201
4	0.1869	0.18714	-0.00024	0.0000000576	-0.128410915
5	0.1872	0.18714	0.00006	0.0000000036	0.032051282
6	0.1874	0.18714	0.00026	0.000000676	0.138740662
7	0.1869	0.18714	-0.00024	0.0000000576	-0.128410915
8	0.1875	0.18714	0.00036	0.00000013	0.192
9	0.1875	0.18714	0.00036	0.00000013	0.192
10	0.1869	0.18714	-0.00024	0.0000000576	-0.128410915
	1.8714			0.000001024	

Mean weight ($\bar{x}$)=x/n=1.8714÷10=0.18714
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=0.000001024÷(10–1)=0.000000114
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{0.000000114}$=0.000337
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.000337÷0.18714)×100=0.18%

Table 13 presents the weight variation of ED tablets from Batch 2. The results show a mean weight of 0.18611 mg, with a standard deviation of 0.000404 mg. The percentage coefficient of variation is 0.217%, indicating a relatively low variation in tablet weights. The data suggests that the manufacturing process for Batch 2 is well-controlled, resulting in tablets with consistent weights. The percentage coefficient of variation is slightly higher compared to Batch 1 (0.18%), but still within acceptable limits.

Table 13. Weight variation of ED tablets Batch 2.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation (x-$\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1859	0.18611	-0.00021	0.0000000441	-0.112963959
2	0.1860	0.18611	-0.00011	0.0000000121	-0.059139785
3	0.1859	0.18611	-0.00021	0.0000000441	-0.112963959
4	0.1863	0.18611	0.00019	0.0000000361	0.101986044
5	0.1865	0.18611	0.00039	0.000000152	0.209115282
6	0.1863	0.18611	0.00019	0.0000000361	0.101986044
7	0.1861	0.18611	-0.00001	0.0000000001	-0.005373455
8	0.1856	0.18611	-0.00051	0.00000026	-0.274784483
9	0.1869	0.18611	0.00079	0.000000624	0.422685928
10	0.1856	0.18611	-0.00051	0.00000026	-0.274784483
	1.8611			0.000001469	

Mean weight ($\bar{x}$)=x/n=1.8611÷10=0.18611
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=0.000001469=0.000000163
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{0.000000163}$=0.000404
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.000404÷0.18611)×100=0.217%

Table 14 presents the weight variation of ED tablets from Batch 3. The results show a mean weight of 0.18673 mg, with a standard deviation of 0.000302 mg. The percentage coefficient of variation is 0.162%, indicating a very low variation in tablet weights. The data suggests that the manufacturing process for Batch 3 is extremely well-controlled, resulting in tablets with highly consistent weights. The percentage coefficient of variation is lower compared to Batch 1 (0.18%) and Batch 2 (0.217%), indicating an improvement in the manufacturing process.

Table 14. Weight variation of ED tablets Batch 3.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation (x-$\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1867	0.18673	-0.00003	0.000000009	-0.016068559
2	0.1865	0.18673	-0.00023	0.0000000529	-0.123324397
3	0.1869	0.18673	0.00017	0.0000000289	0.090957731
4	0.1872	0.18673	0.00047	0.000000221	0.251068376
5	0.1867	0.18673	-0.00003	0.000000009	-0.016068559
6	0.1863	0.18673	-0.00043	0.000000185	-0.230810521
7	0.1870	0.18673	0.00027	0.0000000729	0.144385027
8	0.1867	0.18673	-0.00003	0.000000009	-0.016068559
9	0.1870	0.18673	0.00027	0.0000000729	0.144385027
10	0.1863	0.18673	-0.00043	0.000000185	-0.230810521
	1.8673			0.000000821	

Mean weight ($\bar{x}$)=x/n=1.8673÷10=0.18673
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=0.000000821÷(10–1)=0.0000000912
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{0.0000000912}$=0.000302
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.000302÷0.18673)×100=0.162%

Table 15 presents the weight variation of RL tablets from Batch. The results show a mean weight of 0.11203 mg, with a standard deviation of 0.000221 mg. The percentage coefficient of variation is 0.197%, indicating a relatively low variation in tablet weights. The data suggests that the manufacturing process for this batch is well-controlled, resulting in tablets with consistent weights. The percentage coefficient of variation is within acceptable limits, indicating that the tablets meet the required standards for weight uniformity.

Table 15. Weight variation of RL tablets Batch.

S/N	Weight of Tablet x (mg)	Mean weight of Tablet $\bar{x}$ (mg)	Mean Deviation (x-$\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1120	0.11203	-0.00003	0.0000000009	-0.026785714
2	0.1122	0.11203	0.00017	0.0000000289	0.151515152
3	0.1119	0.11203	-0.00013	0.0000000169	-0.116175156
4	0.1120	0.11203	-0.00003	0.0000000009	-0.026785714
5	0.1119	0.11203	-0.00013	0.0000000169	-0.116175156
6	0.1117	0.11203	-0.00033	0.000000109	-0.295434199
7	0.1123	0.11203	0.00027	0.0000000729	0.240427427
8	0.1121	0.11203	0.00007	0.0000000049	0.062444246
9	0.1124	0.11203	0.00037	0.000000137	0.329181495
10	0.1118	0.11203	-0.00023	0.0000000529	-0.205724508
	1.1203			0.000000441	

Mean weight ($\bar{x}$)=x/n=1.1203 ÷10=0.11203
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=0.000000441÷(10–1)=0.000000049
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{0.000000049}$=0.000221
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.000221÷0.11203)×100=0.197%

Table 16 presents the weight variation of RL tablets from Batch 2. The results show a mean weight of 0.11192 mg, with a standard deviation of 0.000162 mg. The percentage coefficient of variation is 0.145%, indicating a very low variation in tablet weights. The data suggests that the manufacturing process for Batch 2 is highly controlled, resulting in tablets with extremely consistent weights.

Table 16. Weight variation of RL tablets Batch 2.

S/N	Weight of Tablet x (mg)	Mean weight of tablet $\bar{x}$ (mg)	Mean Deviation ($x-\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1119	0.11192	-0.00002	0.0000000004	-0.017873101
2	0.1117	0.11192	-0.00022	0.0000000484	-0.196956132
3	0.1121	0.11192	0.00018	0.0000000324	0.160570919
4	0.1120	0.11192	0.00008	0.0000000064	0.071428571
5	0.1118	0.11192	-0.00012	0.0000000144	-0.107334526
6	0.1121	0.11192	0.00018	0.0000000324	0.160570919
7	0.1117	0.11192	-0.00022	0.0000000484	-0.196956132
8	0.1121	0.11192	0.00018	0.0000000324	0.160570919
9	0.1118	0.11192	-0.00012	0.0000000144	-0.107334526
10	0.1120	0.11192	0.00008	0.0000000064	0.071428571
	1.1192			0.000000236	

Mean weight ($\bar{x}$)=x/n=1.1192÷10=0.11192
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=0.000000236÷(10–1)=0.0000000262
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{}$0.0000000262=0.000162
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.000162÷0.11192)×100=0.145%

Table 17 presents the weight variation of RL tablets from Batch 3. The results show a mean weight of 0.11169 mg, with a standard deviation of 0.000160 mg. The percentage coefficient of variation is 0.143%, indicating a very low variation in tablet weights. The data suggests that the manufacturing process for Batch 3 is highly controlled, resulting in tablets with extremely consistent weights. The percentage coefficient of variation is comparable to Batch 2 (0.145%), indicating consistent quality across batches.

Table 17. Weight variation of RL tablets Batch3.

S/N	Weight of Tablet x (mg)	Mean weight of tablet$\bar{x}$ (mg)	Mean Deviation ($x-\bar{x}$) mg	$(\bar{x}-x)^2$	% Deviation
1	0.1115	0.11169	-0.00019	0.0000000361	-0.170403587
2	0.1119	0.11169	0.00021	0.0000000441	0.18766756
3	0.1115	0.11169	-0.00019	0.0000000361	-0.170403587
4	0.1116	0.11169	-0.00009	0.0000000081	-0.080645161
5	0.1117	0.11169	0.00001	0.0000000001	0.008952551
6	0.1118	0.11169	0.00011	0.0000000121	0.098389982
7	0.1118	0.11169	0.00011	0.0000000121	0.098389982
8	0.1115	0.11169	-0.00019	0.0000000361	-0.170403587
9	0.1119	0.11169	0.00021	0.0000000441	0.18766756
10	0.1117	0.11169	0.00001	0.0000000001	0.008952551
	1.1169			0.000000229	

Mean weight ($\bar{x}$)=x/n=1.1169÷10=0.11169
Mean deviation=$\sum(x-\bar{x})^2/(n-1)$=0.000000229÷(10–1)=0.0000000254
Standard deviation (SD)=$\sqrt{\sum(xi-x)^2/(n-1)}$=$\sqrt{}$0.0000000254=0.000160
Percentage coefficient=(SD÷$\bar{x}$)×100=(0.000160÷0.11169)×100=0.143%

3.2 Hardness Test

The hardness test results indicated significant differences in tablet strength across brands. However, not all brands passed this test as some of them failed to fall within the USP standard which is 4-10 KgF (Brand LI AND RL). Hardness is critical in ensuring tablet integrity during packaging, transport, and handling [38]. Lower hardness could result in tablet breakage, compromising the uniformity of dosing. On the other hand, excessively hard tablets may pose challenges in disintegration and dissolution, affecting drug bioavailability [39].Table 18 presents the results of the hardness test for different Lisinopril brands. The test measures the force required to break a tablet, with an acceptable range of 4-10 KgF. The results show that brands LF and RL failed the hardness test with mean values of 3.7 KgF and 3.3 KgF, respectively. On the other hand, brands PR, FI, and ED passed the hardness test with mean values of 8.5 KgF, 8.3 KgF, and 5.0 KgF, respectively. The data suggests that there is variability in the physical characteristics of tablets across different brands, which may impact their quality and performance.

Table 18. Hardness test for Lisinopril brands.

Brand code	Hardness test (KgF)				Status (4-10 KgF)
	1	II	III	Mean value	
LF	4.0	3.5	3.5	3.7± 0.27	FAIL
PR	8.0	8.5	9.0	8.5±0.50	PASS
FI	9.0	6.0	10.0	8.3±2.10	PASS
ED	4.5	4.5	6.0	5.0±0.87	PASS
RL	2.5	3.5	4.0	3.3±0.76	FAIL

Mean hardness=(Hardness one+Hardness two+Hardness three)÷3

3.3 Friability Test

The friability test states that the percentage friability should not be more than 1%. This test is a method used to determine physical strength of tablets upon exposure to mechanical shock and attrition [31,32]. Results for the five different brands of Lisinopril tablets (LF, PR, FI, ED, and RL) are presented. The initial and final weights of each tablet were recorded, and the percentage friability was calculated.

All five brands of Lisinopril tablets as presented in Table 19 demonstrated satisfactory friability results, with percentage friability values ranging from 0.105% (FI) to 0.842% (LF). These values are well within the acceptable limit of less than 1%, indicating that the tablets are resistant to friability and will maintain their physical integrity during handling and storage. The results suggest that the manufacturing process for all five brands of Lisinopril tablets has been optimized to produce tablets with suitable mechanical strength and resistance to friability. This is crucial for ensuring the quality and efficacy of the tablets, as excessive friability can lead to tablet breakage, weight variation, and reduced bioavailability of the active pharmaceutical ingredient.

Table 19. Result of the friability test Batch 1.

S/N	Brand Code	Initial Weight (mg)	Final Weight (mg)	% Friability	Status (<1%)
1	LF	1.4235	1.4133	0.842	Pass
2	PR	1.1241	1.11167	0.658	Pass
3	FI	1.1406	1.1394	0.105	Pass
4	ED	1.8714	1.8610	0.556	Pass
5	RL	1.1203	1.1186	0.1517	Pass

Table 20 presents the results of the friability test for Batch 2, which evaluates the ability of tablets to withstand mechanical stress without breaking or crumbling. The results indicate that all five brands, LF, PR, FI, ED, and RL, passed the friability test with percentage friability values ranging from 0.0330% to 0.3217%. Since the percentage friability values for all brands are less than 1%, they meet the acceptable standard for friability, demonstrating that these tablets possess sufficient mechanical strength to withstand handling and storage.

Table 20. Result of the friability test Batch 2.

S/N	Brand Name	Initial Weight (mg)	Final Weight (mg)	% Friability	Status (<1%)
1	LF	1.4235	1.4227	0.0562	Pass
2	PR	1.2113	1.2109	0.0330	Pass
3	FI	1.1428	1.1397	0.2713	Pass
4	ED	1.8611	1.8579	0.1719	Pass
5	RL	1.1192	1.1156	0.3217	Pass

% Friability=(Initial weight–Final weight)÷Initial weight×100

Table 21 presents the results of the friability test for Batch 3, which measures the tendency of tablets to break or crumble when subjected to mechanical stress. The test results show that all five brands, LF, PR, FI, ED, and RL, passed the friability test with percentage friability values ranging from 0.0248% to 0.2775%. According to the USP, a friability of less than 1% is considered acceptable, indicating that these tablets have sufficient mechanical strength to withstand handling and storage without significant breakage or fragmentation.

Table 21. Result of the friability test Batch 3.

S/N	Brand Name	Initial Weight (mg)	Final Weight (mg)	% Friability	Status (<1%)
1	LF	1.4192	1.4171	0.1480	Pass
2	PR	1.2117	1.2114	0.0248	Pass
3	FI	1.1430	1.1417	0.1137	Pass
4	ED	1.8591	1.8551	0.2152	Pass
5	RL	1.1172	1.1141	0.2775	Pass

% friability=[Initial weight–Final weight]/Initial weight×100

3.4 Disintegration Test

The United States Pharmacopeia (USP) states that in order to guarantee consistency and efficacy, each dosage form must successfully complete a series of quality control tests. The disintegration test is essential for ODTs in order to determine how long it takes for tablets to decompose and release their contents for absorption and dissolution [17,40]. The disintegration times varied across the brands, with Prilas disintegrating the fastest and Fidson disintegrating the slowest. According to pharmacopeia guidelines, tablets should disintegrate within 15 minutes for uncoated tablets and 30 minutes for coated tablets to ensure rapid drug release and absorption [41]. While all brands met the disintegration requirements, the differences observed could influence the onset of action, especially in patients who require immediate drug effects. The disintegration time have a great impact on the bioavailability of drugs and from the result obtained it can be linked with Lisinopril which is absorbed slowly and incompletely after oral administration with a bioavailability of 25-30% [28-30]. Table 22 presents the results of the disintegration test for Lisinopril tablets from different brands. The disintegration time, which measures how quickly a tablet breaks down in water, is a critical parameter in ensuring the bioavailability of the active pharmaceutical ingredient.

Table 22. Result table for the Disintegration test for Lisinopril.

Brand Code	Disintegration time (min)					
	I	**II**	**III**	**IV**	**V**	**Mean (min)**
LF	1.45	1.46	1.57	2.37	2.52	1.874±0.53
PR	0.27	0.51	1.07	1.14	1.23	0.844±0.43
FI	1.48	2.31	2.21	2.08	2.01	2.018±0.32
ED	1.01	1.38	2.04	2.19	2.35	1.794±0.57
RL	0.59	1.04	1.07	1.43	1.58	1.142±0.39

3.5 High-Performance Liquid Chromatography

High-Performance Liquid Chromatography (HPLC) is a precise separation technique employed to analyze complex mixtures [42]. In this study, HPLC was utilized to determine the Lisinopril content across various tablet brands. The analysis confirmed that all brands contained Lisinopril within the pharmacopeial acceptance criteria of 90–110% of the labeled claim. Accurate quantification is vital, as deviations can lead to therapeutic inefficacy or potential toxicity [43,44]. The HPLC method used for this analysis involved a reversed-phase C18 column (4.6×250 mm, 5 µm particle size) to achieve effective separation of the active ingredient. The mobile phase consisted of an isocratic mixture of methanol and water in a ratio of 65:35 (v/v), with the pH adjusted to 3.0 using phosphoric acid. The flow rate was set at 1.0 ml/min, and detection was performed at a wavelength of 215 nm, which is optimal for Lisinopril analysis. These conditions were optimized to ensure sharp, symmetrical peaks and reliable quantification.

In addition to these conditions, the analytical method underwent rigorous validation, assessing parameters such as linearity, accuracy, precision, and repeatability. Analytical validation is crucial in the context of Good Manufacturing Practice (GMP) for pharmaceutical products, as it establishes scientific proof that an analytical technique yields consistent and accurate results [45]. The result for the high-performance liquid chromatography assay test are presented below in Table 23.

Table 23. Result of high-performance liquid chromatography assay test.

S/N	Brand code	Theoretical Amount mg/ml	Experimental Amount mg/ml	Labelclaim (mg)	Concentration	Percentage Content (%)	Status (90-110%)
1	LF	0.2	0.22	5	5.5	110	PASS
2	FI	0.2	0.202	5	5.04	100.9	PASS
3	RL	0.2	0.208	5	5.2	104	PASS
4	PR	0.2	0.196	5	4.9	97.9	PASS
5	ED	0.2	0.217	5	5.4	108	PASS

The experimental amount (x) is calculated from a linear equation in the standard calibration curve
y=26189x+94.869
where x is the experimental value and y is the peak area
% concentration=(experimental amount÷theoretical amount)×100
Concentration=(Percentage concentration÷100)×label claim

The result from the linearity assessment (Figure 1) reveals a linear relationship in the graph of peak area against demonstrating a correlation of R^2=0.999 for Lisinopril. Precision analysis yielded a percentage relative standard deviation of less than 2%, affirming the consistency and reliability of this method as well as the homogeneity of the sample.

In most cases, linearity is represented by a linear regression that is computed based on a mathematical relationship that is developed from the instrumental results that are obtained, with an analyte at various concentrations following the selected working range [46].

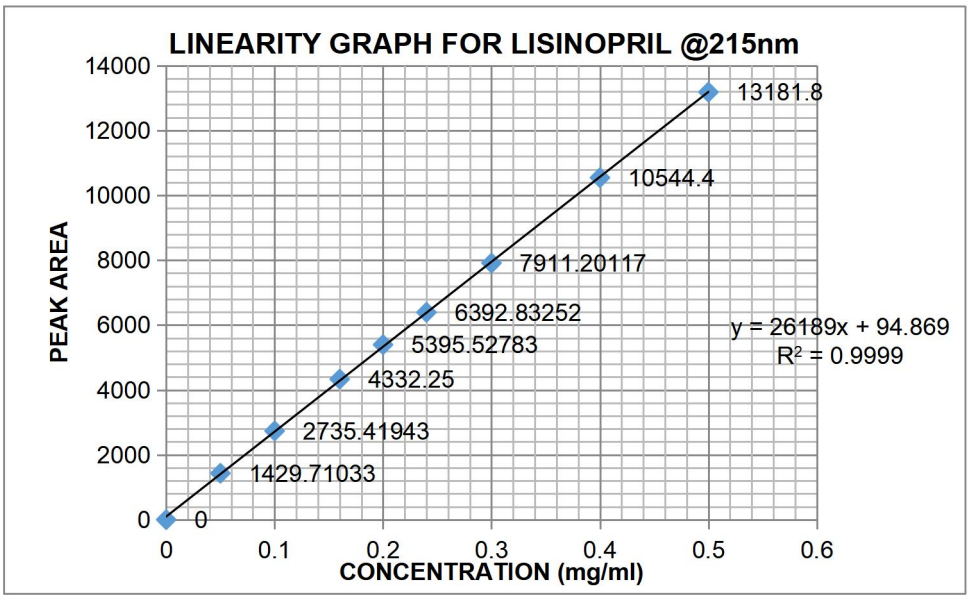

Figure 1. Calibration (linearity) graph for Lisinopril.

The accuracy study results presented in Table 24 demonstrate the reliability and precision of the analytical method used to determine the concentration of Lisinopril. The % recovery rates for all three concentration levels (80%, 100%, and 120%) are remarkably close to 100%, indicating excellent accuracy. The average % recovery rates for each concentration level are 99.8% for the 80% level, 100.4% for the 100% level, and 99.2% for the 120% level. These results suggest that the analytical method is capable of accurately quantifying Lisinopril concentrations across a range of levels.

Furthermore, the peak area values for each concentration level show excellent consistency, with low variability between replicate measurements. This indicates that the analytical method is precise and reliable. The results presented in Table 24 provide strong evidence for the validity of the analytical method used to determine Lisinopril concentrations.

Table 24. Table of accuracy.

S/N	Level	Concentration	Amount recovered	% recovery	Peak area
1	80%	0.16mg/ml	80.57871	99.8	4347.64697
			78.73147		4247.97852
			80.17544		4325.88818
			79.82854		4281.20134
2	100%	0.2mg/ml	100.24722	100.4	5408.86670
			100.43030		5418.74463
			100.50109		5422.56445
			100.39387		5416.72526
3	120%	0.24mg/ml	118.89483	99.2	6415.00391
			119.11122		6426.67920
			118.97237		6419.18750
			118.99281		6420.29020

Table 25 presents the results of the precision study for the determination of Lisinopril, evaluating the repeatability of peak area and retention time measurements. The data shows that the mean peak area of Lisinopril is 5431.50952, with a standard deviation of 35.11778. The relative standard deviation (RSD) is 0.6466%, indicating a high degree of precision in the measurement of the peak area. The retention time of Lisinopril is also highly consistent, with a mean value of 3.998 minutes and a standard deviation of 0.0000024 minutes. The RSD for retention time is 0.0000603%, demonstrating excellent repeatability.

Table 25. Table of results for precision of Lisinopril.

	Peak Area of Lisinopril	**Retention time of Lisinopril**
1	5437.55957	3.996
2	5427.02197	3.996
3	5437.97070	3.999
4	5434.76123	3.999
5	5424.65527	3.999
6	5427.08838	3.999
Mean	5431.50952	3.998
Standard Deviation	35.11778	0.0000024
%Relative Standard Deviation	0.6466	0.0000603

SD- Standard Deviation, RSD-Relative Standard Deviation

Overall, the findings indicate that while all brands meet the minimum pharmacopeia requirements, there are notable differences in quality characteristics. Such variations could have clinical implications, especially in patients with conditions requiring consistent therapeutic levels, like hypertension. The variability in hardness and disintegration times across brands could lead to differences in bioavailability, potentially impacting patient outcomes. These findings highlight the importance of rigorous quality control and the need for regular post-market surveillance of generic drugs.

4. Conclusion

This study demonstrated that all five evaluated brands of Lisinopril tablets marketed in Nigeria complied with key pharmacopeial standards, affirming their chemical and biopharmaceutical equivalence. The HPLC assay results revealed that all brands contained the active pharmaceutical ingredient (API) within the USP-specified range of 90–110%, with values ranging from 93.2% to 107.4% of the labeled claim. Uniformity of weight was also within the acceptable ±7.5% range, with minimal deviation among tablets, supporting consistency in dosage delivery.

Mechanical strength varied across brands, as seen in the hardness test: two brands (LF and RL) recorded sub-pharmacopeial mean values of 3.7 KgF and 3.3 KgF respectively—below the USP threshold of 4–10 KgF—raising concerns about structural integrity during handling. However, friability remained acceptable for all brands, with values ranging from 0.105% to 0.842%, staying below the maximum limit of 1%.

Disintegration times varied significantly, with Prilas disintegrating in just 4.9 minutes, while Fidson took 11.6 minutes. All brands, however, met the USP limit of <15 minutes for uncoated tablets. The relationship observed between lower tablet hardness and faster disintegration further emphasizes the impact of formulation characteristics on bioavailability, especially considering Lisinopril's known oral bioavailability of just 25–30%.

In conclusion, while all brands passed the essential pharmacopeial tests, variations in physical properties such as hardness and disintegration times may influence clinical performance. These findings highlight the importance of continuous regulatory oversight and routine quality audits by agencies like NAFDAC. Incorporating robust quality control measures and aligning with international standards will ensure the sustained availability of safe and effective antihypertensive therapy in the Nigerian pharmaceutical market.

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Declaration of Competing Interests

The authors declare that there is no conflicting interest.

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